Instructions for use – ENGLISH

CE 0123

DWAPP01 – dermanostic Webapp

Valid for:

- Basis-UDI-DI: 426242531DWAPP01A8
- 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 web app DWAPP01. The web app covers case creation by the user, specifically the selection or creation of a patient profile, the specification of the reason for the examination, the identification of the affected body region, the upload of images, the completion of the medical history questionnaire, and the payment and submission of the case.

Other components of the Dermanostic system that are not directly related to case creation in the web app are not covered by these instructions for use. In particular, the available skin type determination via AI analysis is a standalone feature. It is intended solely to provide users with information and does not constitute a medical function, diagnosis, or treatment recommendation.

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 Intended use

The dermanostic web app is a medical device software designed to facilitate the structured collection of medical information (medical history forms and images) and to improve patient management in the field of teledermatological examination of potentially pathological skin areas. In addition, the “dermanostic” web app facilitates communication between patients and medical professionals by allowing users to capture and transmit digital images of the affected skin areas and to complete a medical history form.

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 device (desktop PC, tablet, smartphone) on which the web app is running. In such cases, the web app can be used with assistance from or on behalf of another person.

Breastfeeding and pregnant patients, or patients who may be pregnant, may use the web app but must indicate this on the medical history form. The same applies to individuals 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.

1.5 Key Features

The web app can be used in standard browsers on Windows, Linux, and macOS. A stable internet connection is 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

- Do not use the dermanostic web app in the event of a medical emergency. In the event of a medical emergency, seek immediate medical attention from the appropriate emergency services.
- Using the dermanostic web app cannot replace skin cancer screening at a doctor’s office or clinic.
- Incomplete information on 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 treatment recommendations.
- Before taking a picture, make sure the camera lens is clean and not obstructed by anything. If necessary, gently 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 misdiagnosis.

Attention!

- 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 not sufficient for the dermatologists, you will be notified via the dermanostic app and by email 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.
- No content of any kind that could infringe on the rights of third parties may be uploaded or transmitted.
- 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.
- People with known allergies, pre-existing medical conditions, and/or drug intolerances may use the app, but must disclose this information on the medical history form.
- You may not disable, modify, "hack," or interfere with the intended operation of this software as designed by the manufacturer.
- There is a small residual risk that the confidentiality of patient data could be compromised as a result of 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 could 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 light of the risk of incorrect findings, Dermanostic GmbH's quality assurance procedures provide for consulting the interdisciplinary panel of experts from the collaborating specialist practices whenever the treating dermatologists deem a second professional opinion necessary for a specific treatment case.
- Discussing cases within an interdisciplinary panel of experts can lead to a delay in diagnosis.

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.

Next, you'll need to locate the skin lesion. To do this, the webapp displays an image of the human body. Select the body region where the skin lesion 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 to provide 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 positioned at two different angles relative to the affected skin area), which must be uploaded from your device.

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 obstructed photos can make it difficult for the doctor to assess the condition. 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 web 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 Download the dermanostic app and register

After submitting the case, you must download the dermanostic app from the Google Play Store or the App Store in order to receive the doctor's letter and, if necessary, to address any follow-up questions. The dermanostic app is currently available in the 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 Germany or Austria, the app cannot be downloaded.

Once you have logged into the dermanostic app using the user account you created earlier, you can view the status of the submitted case.

6.7 Diagnosis and therapy recommendation

In the dermanostic app, users typically receive a medical report within 24 hours containing the diagnosis and a recommended treatment plan from the treating dermatologists, along with their explanations. Users are notified by email when the medical report is available or if there are any follow-up questions regarding the findings. 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.

6.8 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 can be safely removed from the mobile device by uninstalling it.

7. Special instructions for use

- Specialist consultations are provided by the 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 remotely, provided that the specialist's diagnosis can be definitively 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, the consultation, the treatment, and the documentation of the treatment process. In such cases, the treating dermatologists explain to patients the specifics of treatment conducted entirely remotely.
- If medical follow-up care is required, it is provided by medical professionals from Dermanostic GmbH on behalf of the participating specialist practices. In this case, the medically trained staff will contact patients via the app or by phone.

8. Minimum Technical Requirements

8.1 Requirements for End Devices and Software

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
- Camera: We recommend a camera such as those that come standard in commercially available smartphones, tablets, or newer laptop/desktop webcams. There is no specified minimum resolution. The key requirement is that the image capture requirements described in Chapter 6.3 can be met.

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 your 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 webapp with the requirements of Regulation (EU) 2017/745.

The dermanostic webapp 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

CE 0123	The CE marking indicates compliance with the European Medical Devices Regulation (EU) 2017/745.
	Manufacturer
	Date of manufacturing
MD	Medical Device
UDI	Unique Device Identification
SN	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	2026-07-14	Addition of Chapter 8.2, “Network Security Requirements,” as well as a warning regarding the risks of insecure network use in Chapter 5. Clarification of the warning regarding the timing of data transmission and deletion in Chapter 5. Renaming of the former Chapter 8 to Subsection 8.1, “Requirements for End Devices and Software,” as part of the reorganization. Addition of a clarification regarding AI-based skin type determination to the section “Notes on the Scope of Application of These Instructions for Use.” Addition of a note on recommended camera specifications in Chapter 8.1.
Rev. 04	2026-07-06	Clarification of the scope of application of the user manual and the software version information. More specific instructions on locating the body region in Chapter 6.2, as well as the addition of notes on image quality when uploading photos in Chapter 6.3 and on app store availability in Chapter 6.6.
Rev. 03	2026-06-08	Adjustment of the date format to ISO 8601.
Rev. 02	2026-05-20	Formal and regulatory revision of the instructions for use. Addition of a warning symbol and additional safety-related information on the title page. Restructuring of the document chapters, including the introduction of the “Performance Characteristics” chapter and the reorganization of the warnings and instructions for use. Clarification of the processes for registration, payment, case submission, and the diagnostic workflow. Update of the software version information to “Software version 1.35.0 and higher.” Revision of the symbol explanations in accordance with regulatory requirements. Addition of a revision history. Editorial and linguistic revision of individual chapters and application notes.
Rev. 01	2025-04-04	Initial approval