



SKeen

Original user manual

Software

skeen - Software

Original user manual



Please read this original user manual carefully before using the product! You can also find our manuals here:
www.fotofinder.de/documentation



Please visit our website if you have any questions. You will find numerous videos with brief instructions, as well as other helpful answers:
<https://www.fotofinder.com/service-support/faq-tutorials>



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1 About these operating instructions

Please note the following points when using the product and this user manual:

- The product can only be used, operated and maintained properly and safely with the help of this user manual.
- This user manual refers only to the product indicated on the cover sheet.
- We reserve the right to change this user manual due to further technical developments.
- The operator must ensure that the user manual is read and understood by all persons concerned prior to work.
- The chapter on *Safety*(cf. 3) provides an overview of all important safety aspects for the protection of personnel and the safe operation of the product.
- The manufacturer is not liable for any damage resulting from non-compliance with this user manual.
- Reprints, translations and reproductions in any form, including excerpts, require the written consent of the publisher.
- Copyright belongs to the manufacturer.
- Safety incidents occurring in connection with the product must be reported to the manufacturer and the competent authority of the respective country in which the operator is established.
- The development and production of all products of FotoFinder Systems GmbH is carried out in accordance with the current ISO 13485 standards.

2 Installation, updates and uninstalling

FotoFinder Systems GmbH has pre-installed the software on the FotoFinder skreen hardware device. The device automatically checks for new updates daily and installs them overnight, provided there is sufficient battery power and a valid Internet connection (WLAN).

The user can also install the updates manually via *Settings* (cf. chapter 4.19 Settings). This option should be used if the device is not left switched on overnight and is therefore not updated automatically.

The user is informed about changes contained in the update.

You will receive an automatic notification about possible updates to the Android operating system and can schedule the installation yourself. You can also initiate these updates in the *Settings / System configuration* menu. FotoFinder Systems recommends that these installations are always carried out promptly.

Removal is only possible with the help of the FotoFinder Support department. The application cannot be removed by the user. Please note that all data stored and cached locally will be deleted when the device is returned for removal of the application.

NOTE

Please make sure that you synchronise all data with FotoFinder Hub before you send the unit to the FotoFinder Support department.

2.1 System requirements


The operation of the FotoFinder skreen application is only possible in combination with the related FotoFinder skreen hardware device. This is configured by default to ensure proper operation of the software. The following additional requirements must be fulfilled:

- Operating system: Android: 10 or higher
- Internet connection for Login, Synchronization, and AI Score (WiFi)

NOTE

Supported Wi-Fi security standards:

- WEP
 - WPA/WPA2 Personal
 - WPA2/WPA3 Personal
 - WPA3 Personal
 - WPA-Enterprise
 - Public Wi-Fi with web browser confirmation (Captive Portal)
-

 **FotoFinderHub** In addition, a user account at the FotoFinder Hub (www.fotofinderhub.de) is required for the use of the application (cf. chapter 4.3 FotoFinder Hub login). The FotoFinder Hub is a web-based application. Therefore, the available version at the time of access is the minimum required software version for the use of FotoFinder mobile.

2.2 Considerations for IT-Security

Additional information regarding IT-Security is listed in a Manufacturers Disclosure Statement for Medical Device Security (MDS2 form) and can be requested at info@fotofinder.de.

2.2.1 Password / PIN code

The access-controlled Android sandbox environment is used for securing patient-related data. In addition, authorization mechanisms such as log-in via e-mail and password as well as PIN Code and Biometric information are applied for the application. The password should be at least 8 characters long and consist of letters as well as numbers and special characters (!, &, %). It is important to avoid using words in the dictionary or names or personal data. The PIN code is 4 characters long. In addition, passwords/PIN should not be stored in obvious locations (such as on the desk). In order to ensure sufficient security, it is also essential to change the password/ PIN regularly.

2.2.2 Access Protection

In order to avoid unauthorized access to data, the screen should always be locked after using the mobile device.

If the device is not locked by the user, a sleep mode is activated after a few minutes of inactivity. Additional measures for user management are available in the FotoFinder Hub.

2.2.3 Update operating system

The operating system should be updated as regularly as possible to receive improvements regarding IT security.

2.2.4 Backup

Backups are performed exclusively via FotoFinder Hub. Hub uses Amazon AWS S3 for backups (for details see chapter 2.2.8 Data storage).

2.2.5 Support

In the event of problems with the software, you can contact the FotoFinder Support. In some cases, it can be necessary to send a log file to the FotoFinder Support, to ensure error analysis. Therefore, no patient information is transmitted, but metadata of the device and software, like device model and operating system, application version, errors etc. The data is transferred in encrypted form as a ZIP file and can only be decrypted and read by the software development department.

2.2.6 Security patches

In case of security-relevant updates of FotoFinder software, the update is installed automatically at night. Please ensure a full battery and internet connection. Safety-related changes included in the updates are communicated to the user via a push notification.

2.2.7 Patient rights

FotoFinder software ensures patient rights according to the GDPR using the following software features:

- Right of rectification (Chapter 3 Art. 16)
Feature in FotoFinder software: Change patient data
- Right to erasure (right to be forgotten) (Chapter 3 Art. 17)
Feature in FotoFinder software: Delete patient
- Right of data portability (Chapter 3 Art. 20)
Feature in FotoFinder software: Print Report containing all images (via FotoFinder Hub)

2.2.8 Data processing

FotoFinder Systems processes personal data in accordance with the principles Confidentiality, Integrity, Availability, Accountability and Authenticity. FotoFinder software is ad-free. The contents of your FotoFinder database will be managed in accordance with the data protection regulations. The database including the stored images will in particular not be processed, used, stored or made accessible to third parties. The data will not be linked to third party data about the user or the device and will not be used for third party advertising, your advertising or branding purposes. The database will only be viewed to the extent necessary to diagnose and resolve any existing malfunctions. FotoFinder AI Score analysis uses blob images to process the image data. The AI Score service does not analyze any data without the customers' intent. The algorithm has no access to patient data. The generated data is solely used for analytical reasons.

2.2.9 Data storage

FotoFinder uses cloud services of Amazon for data storage. Structural and blob image data are hosted on AWS servers based in the EU in Ireland and Germany (MongoDB, AWS S3). All data is encrypted at transport and rest according to HIPAA requirements via a HTTPS encryption. We have configured secure and encrypted storage with backups. AWS data center is certified according to ISO/IEC 27001:2013, 27017:2015, 27018:2019, ISO/IEC 9001:2015 and CSA STAR CCM v3.0.1. We dispose of Business Associate Agreements required by HIPAA (Health Insurance Portability and Accountability Act of 1996) for AWS and MongoDB. When using the Moleanalyzer pro and in particular the calculation of the AI Score, data storage is handled differently based on which type of AI license is used: When requesting the AI Score, a copy of the micro image to be analyzed is uploaded via a safe connection (secured via HTTPS & SSL certified) to a secure FotoFinder cloud server. The image is stored there for the duration of the AI Score analysis and then deleted immediately afterwards. Only the AI Score is sent back to the customer again via a safe connection (secured via HTTPS & SSL certified). Uploaded images are therefore only stored externally for the duration of the analysis which takes from a couple of seconds to maximum a couple of minutes. No patient information is sent besides the single micro images. Other patient information remains stored on the local system at the customer site. Personal data will be stored for the duration of the business relationship and beyond in accordance with the statutory retention periods.

2.2.10 Firewall

No firewall rules apply, the Android/iOs default specifications are applied

2.2.11 Network data streams

Communication with FotoFinder Hub

The application communicates with the FotoFinder Hub to synchronize the patient data and images via WiFi / mobile data SSL certificates are exchanged with the data transfer. Data is encrypted according to https specifications (TLS 1.2 / SSL version 2 and higher).

Data between the application and Hub is exchanged in JSON format (via API v2). The exchanged data contains licence/user information, patient data, images, sessions and Second Opinion results. Images are uploaded as binary images and stored in Amazon AWS S3 with appropriate authorization.

Communication with Machine Learning Server / Online AI Server

The application communicates with the Machine Learning Server via Wi-Fi / mobile data to generate the Online AI Score. SSL certificates are exchanged with the data transfer. The data transfer is encrypted according to https specification (TLS 1.2 and higher). The application sends a microscopic image as JPEG file to the Machine Learning Server, which retrieves the Online AI Score and sends it back to the application via https. The Machine Learning Server does not save any patient-related data.

3 Safety

The application is a variant of the FotoFinder mobile product group.

3.1 Intended use

FotoFinder mobile is a mobile application that works in conjunction with the FotoFinder Hub online cloud. The application is designed for patient management, standardized documentation of microscopic images, and to assist in the initial assessment of skin conditions. FotoFinder mobile enables digital documentation of intact human skin by healthcare professionals. The microscopic images are stored together with the relevant patient data, which makes it possible to visualize changes in lesions during subsequent follow-up examinations of the patient. The FotoFinder application is used in combination with hardware imaging devices, which allow to capture microscopic images using a mobile device.

The following features are available:

- Acquisition and management of patient data
- Capturing and managing microscopic images
- Documentation of patient examinations
- Assigning images to a patient
- Assigning a localization to an image
- Requesting a second opinion (Second Opinion) from experts (not for all variants)
- Request AI Score (Artificial Intelligence)

FotoFinder mobile connects online with the Moleanalyzer pro algorithms to generate the AI Score. The connection to the FotoFinder Hub allows to use a second opinion service (not for all variants). These functions are only accessible via paid subscriptions. Subscription management is only available through a FotoFinder Hub account. The app data is synchronized, stored and managed via this cloud solution.

FotoFinder mobile is intended for the documentation of skin lesions. The app must not be used to make or confirm a clinical diagnosis of melanoma, any other skin disease or skin cancer.

The application does not provide a diagnosis. The AI Score is based on statistics. The diagnosis and therapy decision are the responsibility of the physician!

The application is intended for transient use. In combination with the hardware imaging device, the product is in continuous use for less than 60 minutes during a diagnosis session.

3.2 User groups

The following target groups with necessary qualifications may work with the application:

User group	Demographic data	Expected/Intended qualification, job experience, skills
Medical or healthcare professionals (Primary user group)	<ul style="list-style-type: none"> - Typical job title: Dermatologist, Physician, Doctor/Physician in training - Age: in average between 24 and 65 - Sex: all sexes - Sensory abilities: normal abilities required to fulfil job - Cognitive abilities, including memory: normal abilities required to fulfil job 	<ul style="list-style-type: none"> - Professional qualification as physician (or in training of such) - Trained in diagnosing skin disease - Experience with IT - Video training by FotoFinder employee or distribution company employee

The application may only be used by physicians or healthcare professionals trained in the clinical diagnosis of skin cancer or other skin diseases.

3.3 Use environment

The product is intended for use in a professional medical environment (e.g. clinic, hospital) by the users described in the chapter on User groups (cf. 3.2). The product is not intended for use by laypersons.

There are no other applicable requirements for the social or clinical environment of use.

3.4 Patient population

Patients with one of the following characterizations are intended to be examined with the software:

- General persons with skin lesions, moles
- Patients with multiple nevus syndrome
- People with general inflammatory skin

The intended patient population includes patients regardless of demographic factors (e.g. gender, age, profession), physical factors (e.g. weight, height, strength) or social, religious and cultural background.

3.5 Indications and contraindications

Indications

ICD Code	Description
L57	Actinic keratosis
C44	Basal cell carcinoma
L82	Benign lichenoid keratosis
D48	Atypical nevus
D18	Hemangioma
L98	Hemorrhage
L81	Lentigo simplex
C43	Malignant melanoma
D03	Malignant melanoma in situ
D03	Lentigo maligna
C43	Lentigo maligna melanoma
C43	Superficial spreading malignant melanoma
C43	Nodular malignant melanoma
C43	Acrolentiginous malignant melanoma
C43	Amelanotic malignant melanoma
C43	Desmoplastic malignant melanoma
C43	Malignant melanoma, not further classified
D22	Melanocytic nevus
D22	Papillary melanocytic nevus
D22	Acral melanocytic nevus
D22	Blue nevus
D22	Spindle-cell nevus
D22	Spitz nevus
D22	Halo nevus
D22	Melanocytic nevus with congenital part
L81	Naevus spilus
L81	Lentigo simplex
L81	Agminated melanocytic nevus
L81	Irritated seborrheic keratosis
L82	Seborrheic keratosis
L82	Lentigo solaris/senilis
D23	Dermatofibroma
D04.9	Bowen´s Disease
L40	Psoriasis
L43	Lichen ruber planus
D36	Benign neoplasm
L85	Keratoakanthoma
C80	Spino-cellular Carcinoma
L63	Alopecia areata
L64	Alopecia androgenetica
L66	Scarred alopecia
B35.0	Tinea barbae and tinea capitis
F63.3	Trichotillomania
L21	Seborrhoeic dermatitis
L63.0	Alopecia (capitis) totalis
L63.1	Alopecia universalis
L63.2	Ophiasis
L65.0	Telogen effluvium
L65.1	Anagen effluvium
L65.2	Alopecia mucinosa
L66.0	Pseudopelade
L66.1	Lichen planopilaris
L66.2	Folliculitis decalvans
L66.3	Perifolliculitis capitis abscedens (dissecting cellulitis)
L66.4	Folliculitis ulerythematososa reticulata
L66.9	Cicatricial alopecia, unspecified

L67	Hair colour and hair shaft abnormalities
L67.0	Trichorrhexis nodosa
L93.0	Discoid lupus erythematosus
O84.0	Congenital alopecia
O84	Other congenital malformations of integument
O84.8	Other specified congenital malformations of integument (Aplasia cutis)
C44.9	Squamous cell carcinoma

Tab. 1: Indications

Contra-Indications

In general:

- FotoFinder mobile is only intended to be used on lesions captured on intact skin. Do not assess lesions located in areas of wound / injuries or in close proximity to psoriasis, eczema, acute sunburn or similar skin conditions.
- Do not analyze images of lesions <2 mm or >8 mm with FotoFinder mobile, as the field of view is limited and bigger lesions cannot be displayed or analyzed correctly.
- The software is not intended to support pre-assessment or store images from mucosa, eyes, natural or artificial body orifices.
- The software does not diagnose a disease. It provides comparison images and provides aid for dermatologist to differentiate between the diseases mentioned in the *indications* section.

In combination with the AI Score of the FotoFinder Moleanalyzer pro applies:

- Do not use the AI Score for the evaluation of lesion on hairy area or in locations near contaminations or markings (e.g. tattoos) within an area of 30mm.
- The algorithm was trained with images of Fitzpatrick skin type I-III. Do not use the AI Score on patients with skin type IV or higher, as the performance of the algorithm was not assessed and therefore the accuracy of the algorithm cannot be claimed.

3.6 Clinical Benefits

With FotoFinder mobile, the following clinical benefits for the user / patient are aimed:

- The application makes the mole mapping and follow-up more efficient.
- The analysis of a given lesion by an artificial intelligence algorithm (convolutional neural network – CNN) gives more information about the lesion and its potential to be malignant.
- Users can upload an image with unknown diagnosis to the Second Opinion service to receive a second diagnosis opinion from a specialist in dermoscopy (tele-dermatology service).

Performance characteristics

The following performance characteristics are specified for and met by the FotoFinder mobile:

- The software allows micro imaging with a magnification of 20x.
- Image quality and diagnostic performance of dermatologists with mobile solutions is comparable to using a digital dermoscope / videodermoscope (as examined in publications).

3.7 Residual risks

WARNING

Despite compliance with all regulations and the implementation of risk-minimizing measures, not all risks can be completely excluded. Residual risks that exist in connection with the use of the product are listed below.

- Improper operation by untrained personnel may result in harm to the patient.
- Incorrect entry of information in the software, or incorrect assignment of patients or images by the operator, can lead to a misinterpretation. The consequences can be an unnecessary treatment or delayed treatment of a skin condition.
- Misuse by the user cannot be ruled out completely despite the provision of written user instructions and training.
- If the user bases the diagnosis solely on the results of the software (incl. AI Score), it may lead to unnecessary or delayed treatment of a skin condition.
Misinterpretation of the algorithm cannot be ruled out.

3.7.1 IT-Security

The following residual risks regarding IT-Security cannot be ruled out completely despite the implementation of risk control measures:

- **Accessing and using another user's credentials, such as username and password (Spoofing)**
- Maliciously changing or modifying persistent data and the alteration of data in transit (Tampering)
- Performing prohibited operations in a system that lacks the ability to trace the operations (Repudiation)
- Reading a file that one was not granted access to, or reading data in transit (Information disclosure)
- Attempting to deny access to valid users, such as by making a web server temporarily unavailable or unusable (Denial of Service)
- Gaining privileged access to resources in order to gain unauthorized access to information or to compromise a system (Elevation of privilege)

Those residual risks may lead to therapeutic patient data being published along with the name of the patient in the worst case.

3.8 Foreseeable misuse

The following points describe foreseeable misuse of the software:

- The physician incorrectly assumes that the software provides a diagnosis.
- The physician bases their diagnosis exclusively on results of software.
- The application for documentation is performed on non-intact skin, mucous membranes or in body orifices.
- The physician believes that the accuracy of the AI Score can be claimed and assumes that the score is indicative of the malignancy of the mole.
- The physician requests an AI Score for an image that does not meet the requirements, e.g., due to body hair, visible tattoo, or size of the lesion.

NOTE

For information on the foreseeable misuse of connected hardware components, please refer to the user manual of the respective device.

4 FotoFinder skreen software

4.1 First login

The following steps are carried out in sequence when logging in for the first time:

1. Select the language
2. Set up a WLAN connection
3. FotoFinder Hub login (cf. chapter 4.3 FotoFinder Hub login)
4. Set up a PIN (cf. chapter 4.2 PIN (Personal Identification Number))

4.2 PIN (Personal Identification Number)

You can assign a four-digit PIN when logging in for the first time. You must enter the PIN at the start of each use.

You can change and activate or deactivate the PIN in the *Settings/System configuration/Security* menu.

4.3 FotoFinder Hub login

Your Hub Account

To use skreen, you need a FotoFinder Hub account!

Already have an account?

Simply log in to skreen with your existing credentials.

1 Don't have an account yet? Here's how to create one:

- Visit: hub.fotofinder.de
- Create your account.

Note: This can only be done via a PC or tablet, NOT through skreen.

2 Activate HUB License:

- Go to Settings
- Select Billing
- Choose a suitable license or activate your license package with a purchased voucher code.

3 Log in with skreen:

- Enter your login details or scan the QR code - you can find this in the Hub under:
- Settings
 - My Devices
 - Add New Device

You're all set!

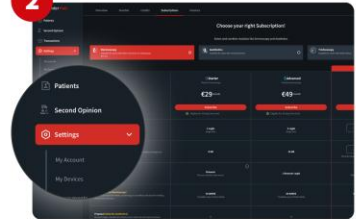


Hub Instructions
We show you how to integrate your device into HUB.

1



2



3



Your photos are stored in the FotoFinder Hub. This cloud solution stores your images and data securely and can be accessed from anywhere. The combination of skreen and Hub automatically synchronises all data, provides access to the integrated AI and serves as an online portal for the analysis and further use of your images. If skreen does not have an online connection, you can also capture pictures in offline mode.

4.4 General operating information

4.4.1 Sleep mode

The device switches to sleep mode after a few minutes of inactivity.

There are various ways to reactivate the device:

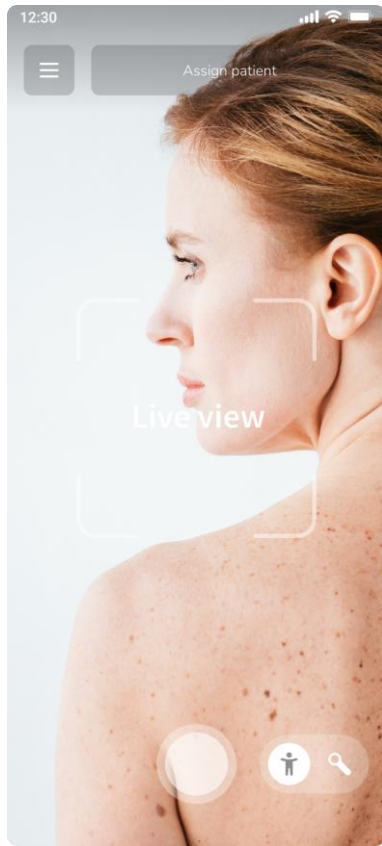
- press the function button on the side of the device, or
- swipe your finger across the screen from bottom to top, or
- tap the screen twice

4.4.2 Software navigation

The software can be controlled with gestures. For example, swipe your finger from left to right across the screen to return to the previous view or to open the main menu.

4 FotoFinder sken software

4.5 Home screen



After logging in, you see the start screen of the software.

Fig. 2: Start screen with example preview image

4.6 Main menu

You can access the main menu either

- by swiping across the screen from left to right, or
- using the Menu button at the top left



In the main menu you see

- the user data
- Hub plan information and
- the following submenus:
 - My patients (cf. 4.7)
 - Gallery (cf. 4.8)
 - Settings (cf. 4.19)
 - About FotoFinder (cf. 4.18)
 - FAQ
 - Contact Support
 - Logout

4.7 Patients

Your skreen shows you all the patients and their captures saved in your FotoFinder Hub account. In addition, you can create new patients on the skreen, which are then also synchronised with the Hub.

NOTE

You can identify patients who have not yet been synchronised with FotoFinder Hub by the symbol with a crossed-out cloud next to the patient ID:



4.7.1 Searching for an existing patient and calling up captures



1. Tap on the *Menu* button and on *My Patients* in the menu.

or:



1. Tap on the patient search box to open your patient list.

The patient list opens:

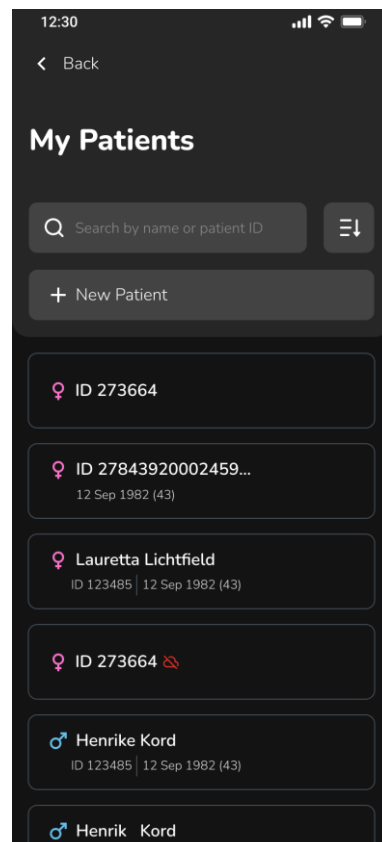


Fig. 3: Example view of a patient list

2. If necessary, use the search box to search by name or patient ID.
3. Select a patient by tapping on the respective line.

The gallery of the patient opens.

4.7.2 Creating a new patient



1. Tap on the Menu button and on *My Patients* in the menu.

Or:



1. Tap in the patient search box.



2. Tap on *New patient*.
3. Fill out all the compulsory fields in the subsequent window, and tap on *Create new patient*.

The patient has been created and is currently selected.

NOTE

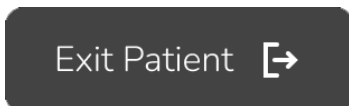
Patients can also be created anonymously. In this case, you only enter

- Sex
- ID

4.7.3 Removing the current patient from the selection



1. Open the patient gallery.



2. Tap on *Exit Patient* at the bottom right.

This will return you to the start screen. No patient is selected.

4.7.4 Switching directly to another patient

1. Swipe across the screen from left to right.
The main menu opens.
2. Tap on *My Patients*.
The patient list opens.
3. Select a patient by tapping on the respective line.
The patient just selected is now active.

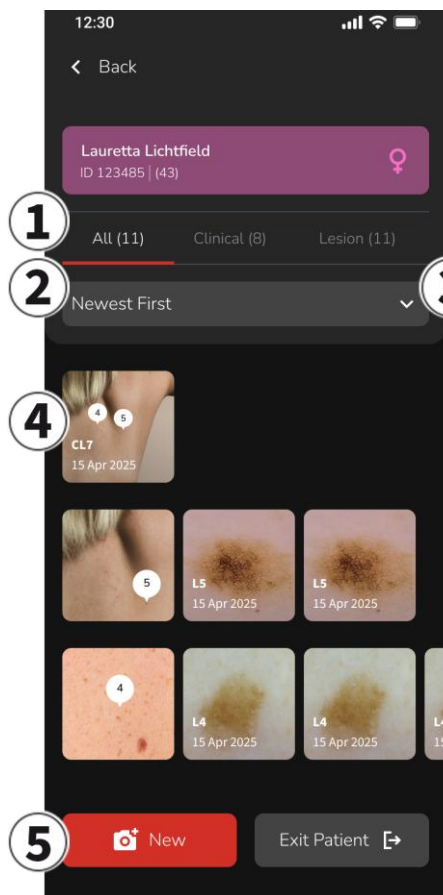
4.8 Gallery

4.8.1 Gallery view

The gallery displays existing captures in a clear manner, and is structured with multiple areas.

NOTE

The gallery of an individual patient is shown below. The gallery for all patients differs slightly in structure (cf. 4.8.2).



- 1 Filters:
 - All (11)
 - Clinical (8)
 - Lesion (11)
 - All captures (default view)
 - Clinical: Only clinical overview image captures
 - Lesion: Only micro image captures (and any existing clinical overview captures associated with them)
- 2 Sorting: by time of capture (in ascending or descending order)
- 3 View selection¹
 - List view
 - Grid view
 - Body localisation view (images are only displayed if a localisation has already been assigned to them)

(¹only available if the filter *Clinical* or *Lesion* is set):
- 4 Displaying
 - Clinical overview images (CL = clinical images)
 - if applicable with marker(s) (e.g. ¹³) and
 - corresponding micro images (L = lesion) and
 - Localisation
- 5 Buttons for further actions (only in the gallery of an individual patient)

Fig. 4: Example view of the gallery of an individual patient

4.8.2 To open the gallery: All patients



If no patient is currently selected:

1. Tap on the *Menu* button.
2. Select *Gallery* from the menu.

Alternatively:

If a patient is currently selected:

1. Swipe across the screen from left to right to open the main menu.
2. Select *Gallery* from the menu.

After opening the gallery, all captures are displayed by default grouped by patient.

4.8.3 To open the gallery: Individual patient

If no patient is currently selected:

1. Open the gallery for all patients.
 2. Tap on the desired patient name.
- The gallery of the individual patient opens.

Alternatively:

If a patient is currently selected:



1. Tap on the *Gallery* button at the top left.

4.9 Creating images

NOTE

The software supports both clinical overview image captures and micro image captures for lesions. For clinical overview image captures, remove the magnetic attachment lens from the device. For micro image captures, the attachment lens, including the front cap, must be attached to the device.

4.9.1 Workflows

The app can be used in different ways, depending on which workflow best suits you and your current use case.

Here are a few examples:

1. Clinical overview image capture
 2. Setting a marker
 3. Micro image capture
-
1. Micro image capture
 2. Clinical overview image capture
 3. Setting a marker and assigning a micro image
-
1. Micro image capture (without corresponding clinical overview capture)
-
1. Clinical overview capture (no corresponding micro image capture)

4.9.2 Creating a clinical overview image capture



1. Detach the attachment lens from the screen by pulling it. The mount is magnetic.
2. The device detects that the attachment lens has been removed, and switches to *Clinical* capture mode. This is displayed in the preview window at the bottom right.
3. Select a patient from the patient list or create a new patient (cf. 4.7). Note: If you skip this step, you will be prompted to do so after the capture because you can only save the capture with a patient assigned.
4. Align the device so that the desired area of the body can be seen in the preview window.
5. Keep the device as still as possible, and press the shutter release on the handle of the screen, or select the shutter release button in the preview image.

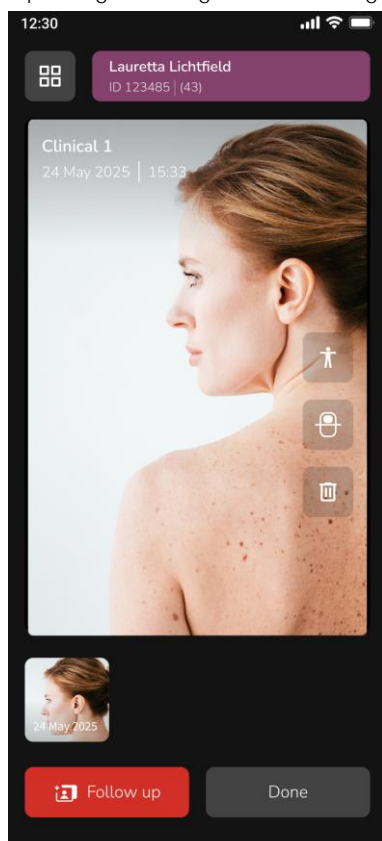
The captured image is displayed.

If you have not selected a patient before capturing the image:

6. You will find the buttons *Save* and *Discard* at the bottom edge of the screen. Tap on *Discard* if you are not happy with the capture and want to delete it or tap on *Save* (alternatively on the preview screen itself) to save the capture.




Patient management opens. Select an existing patient and tap on *Assign*. Or: Create a new patient.

After capturing the image and selecting the patient, you see the following view:



The image number (in this case, Clinical 1) and the capture date and time are displayed in the preview window.

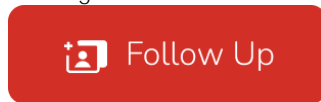
The following functions are available on the right-hand edge of the screen:

-  Assigning a localisation (cf. 4.11)
-  Image comparison (cf. 4.13)
-  Deleting an image

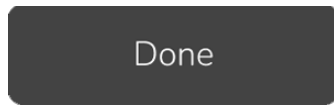
Below the preview window, you will also see captures after saving: If the capture just created is a follow-up capture, the respective reference captures are displayed here. If it is the first capture, only this one will be shown.

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The following buttons are available to you at the bottom edge of the screen:



Tap on *Follow up* to create further captures for this same case.



Tap on *Done* if you do not want to create any further captures for this case right now. This returns you to capture mode and you can start with a new case.

NOTE

In this view you can set markers by tapping on the clinical overview image capture (cf. chapter 4.10.2 Setting a marker).

4.9.3 Creating micro image captures



1. Attach the attachment lens to the skreen. You will find information on this in the user manual for the FotoFinder skreen hardware (www.fotofinder.de/documentation).
2. The device detects that the attachment lens has been attached, and switches to *Micro* capture mode. This is displayed in the preview window at the bottom right.
3. Select a patient from the patient list or create a new patient (cf. 4.7).
Note: If you skip this step, you will be prompted to do so after the image capture because you can only save a capture with a patient assigned.
4. Place the skreen with the attachment lens on the area of the skin to be captured.
5. Make the desired adjustments to the capture settings. The following buttons are available for this purpose:

Micro image magnification



Tap this button to be able to select from the different zoom levels (15, 20 or 40x are available).



NOTE

- For analysis with AI score, a micro image capture with 20x magnification is required.
- Micro image captures with 15x magnification are very suitable for trichoscopic examinations.



Single Shot/Double Shot



Select whether you wish to capture a single image (Single Shot) or two images (Double Shot). In Double Shot mode, both a polarised image and a non-polarised image are captured.



Polarised/Not polarised



The polarisation provides you with a special kind of light which minimises reflections on the skin. You can switch between polarised (X) and non-polarised (O) light. Polarised is active by default.

6. Keep the skreen as still as possible and press the shutter release on the handle of the skreen, or tap on the shutter release button on the preview screen.

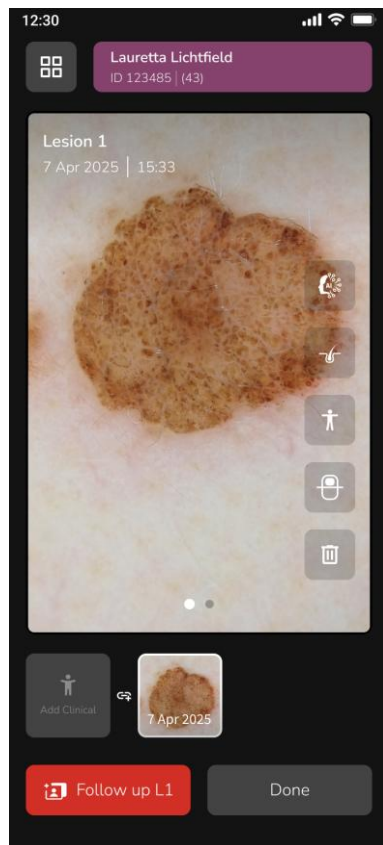
NOTE

Please note that when selecting *Double Shot*, the capture duration is a little longer, and the device must be held still until the second capture has been completed.

The captured image is displayed.

- If you have not selected a patient before image capture:
You will find the buttons *Save* and *Discard* at the bottom of the screen. Tap on *Discard* if you are not happy with the capture and want to delete it or tap on *Save* to save the capture. Patient management opens.
- Select an existing patient and tap *Assign*. Or: Create a new patient.

After capturing the image and selecting the patient, you see the following view:



The lesion number (in this case, Lesion 1) and the capture date and time are displayed in the preview window.

The following functions are available on the right-hand edge of the screen:



AI Score (cf. 4.15)



Trichoscopy analysis – optional (cf. 4.16)



Assigning a localisation (cf. 4.11)



Image comparison (cf. 4.13)

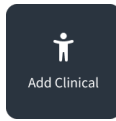


Deleting an image



The thumbnail of the capture just created is shown in the centre below the preview window. If you have previously created a follow-up capture, further micro image captures of the same lesion are displayed to the right of this.

Below the preview window, on the left, you can see the *Add clinical overview image* button. You can select a saved clinical overview image or create a new one.



1. Tap *Add clinical overview image*.
The gallery of saved overview images opens.
2. Tap on one of the clinical overview images to select it directly, or tap the *New clinical image* button to start the capture mode for clinical overview images.

To create a marker in the clinical overview image immediately:

3. Tap on the desired position for the marker in the clinical overview image.
There is now a blank marker in this position. The numbering is consecutive. A red frame around the marker shows that it is currently selected.
4. Adjust the position of the marker as required using drag & drop.
5. Drag the miniature view of the previously created micro image capture from below the preview window up onto the new marker.

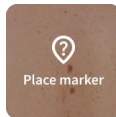
The micro image is now assigned to this marker, and a miniature version of it can be seen in the marker.

To continue without markers:

3. Click on *Done*.

In this case, the lesion is assigned to the new clinical overview image, but without a marker and thus without any exact placement in the clinical overview image.

You can use the *Place marker* button to set a marker and assign the lesion at a later time.



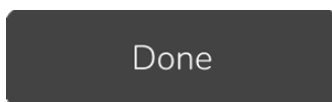
NOTE

You will find further information in the respective chapter (cf. 4.10)</dg_ref_source<

You will find the following buttons at the bottom of the screen:



4. Tap on *Follow up L...* to create further micro images pertaining to the same lesion. The lesion number is displayed on the button.

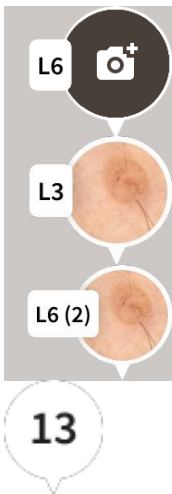


5. Tap on *Done* to end capture mode for the lesion.

4.10 Marker

You can use markers to mark skin areas on clinical overview captures for a microscopic examination. You can assign micro images to these markers and, e.g., compare them directly at follow-up appointments.

4.10.1 Marker views

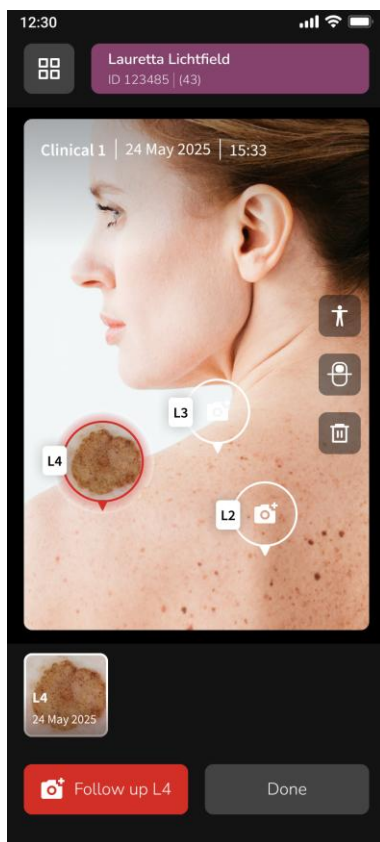


Marker to which no micro images have been assigned yet. This marker has the number L6.

Marker with one micro image. This marker has the number L3.

Marker with two micro images. This marker has the number L6.

If many markers are created on one clinical overview capture, only the numbers (in this case, 13) of the markers are displayed. The preview is not shown until you zoom in further on the image.



Information on the example view shown alongside:

- Three markers have already been created.
- One marker (L4) has been selected by tapping on it, and it is therefore displayed with a red frame.
- Below the preview image, the capture saved at marker L4 can be seen. You can open the micro image preview by tapping on it.

Fig. 5: Example view of a clinical overview image with marker

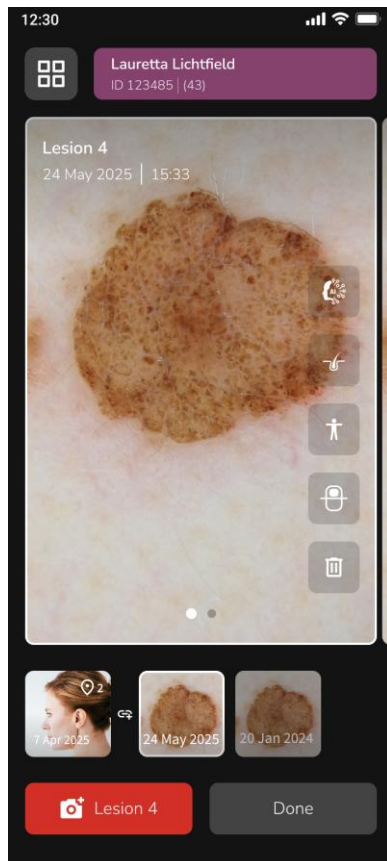
4.10.2 Setting a marker

1. Open the clinical overview image in which you want to set a marker. You can access it, e.g., using the gallery, the patient list or directly after capturing the image.
2. Tap on the position in the clinical overview image where you want to set the marker.
An empty marker now appears at this position. The numbering is consecutive. A red frame around the marker shows that it is currently selected.
3. Tap on the marker to start capture mode.
4. Create the capture. For more information on capturing images, refer to the relevant chapters.

4.10.3 To view captures of a marker:

1. Open the gallery (cf. 4.8).
 2. Tap directly on the desired lesion.
- or:
1. Open the clinical overview image which contains the desired marker.
 2. Tap on the marker twice.

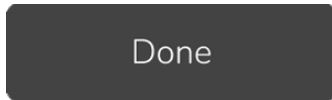
The preview image of the lesion opens.



- Tap in the preview window to open the capture in full screen mode.
- You can use finger zoom to zoom in on the capture in full screen mode.

Fig. 6: Example view of a lesion

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Below the preview image, you can see the corresponding clinical overview image on the left. To the right of it, you can see all the captures of this lesion as tiles. If there are multiple captures, you will need to scroll to the right to see them all.

Tap on *Follow up L...* to create further captures of this lesion.

Tap on *Done* to return to the previous view.

4.10.4 Moving a marker

1. Tap on the corresponding marker.
The marker is now highlighted in red and can be edited.
2. Press and hold the marker and move it to the desired position (drag & drop).
The marker is saved in this new position.

4.10.5 Deleting a marker



1. Tap on the corresponding marker.
The marker is now highlighted in red and can be edited.
2. Tap on the marker once more and press and hold it down this time. Once you begin to move the marker, a *Delete* button appears below the preview screen.
3. Drag and drop the marker to the Delete symbol.
The marker is deleted.

4.11 Assigning a localisation

You can save a localisation for your captures using a body mannequin. You can do so immediately after capturing the image or at a later time.

NOTE

To save a localisation, the capture must already have been assigned to a patient.

NOTE

We recommend that you save a localisation to be able to find lesions more easily at follow-up appointments. The gallery (cf. chapter 4.8 Gallery) also includes the body localisation view which displays existing captures grouped by localisation, provided that one has been saved.

1. Open the capture to which you want to assign a localisation. Note: The capture is already open immediately after capturing the image.



The button shown here appears at the bottom of the screen.

1. Tap on it.

The localisation menu opens:



2. If required, select a different body view by swiping to the right or left.
3. You can use two-finger zoom to enlarge the view of the localisation mannequin at the desired position.
4. Tap on a part of the body to define it as a localisation.

The body part is marked with a red dot and is also listed at the top right.

5. Tap on *Save*.

The selected localisation is now saved in the image details during capture.



A green check on the localisation button shows that a localisation has been saved for the capture.

Fig. 7: Example view of the localisation menu

4.12 Creating follow-up captures



1. Select the desired patient.
2. Open the gallery.

3. Tap on the capture for which you want to create a follow-up capture. This can be a lesion or a clinical overview image capture.

A view of the existing capture opens.



4. Tap on *Follow-up capture*.

Capture mode starts:

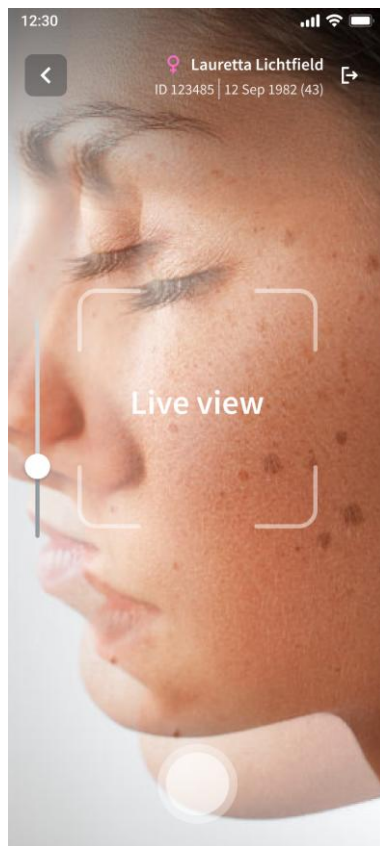


Fig. 8: Example view of a follow-up capture for a clinical overview image

5. Press the shutter release button.

The capture is displayed. Any existing markers are included in this follow-up capture.

Ghost function

For follow-up captures, the existing reference capture is displayed transparently over the live image.

The intensity of the display can be adjusted using the slide controller next to the live image. This shows you how to position the patient so that both images are ideally comparable.

4.13 Comparing images

When comparing images, two captures are displayed superimposed, and can thus be compared.

1. Open a capture.



2. Tap on the Image comparison button. It is on the right in the preview window.

Two captures are displayed superimposed. Use the two-finger zoom method to zoom further into the captures.

4.14 Deleting images

Immediately after capturing an image, or when opening an image later, you will find the Delete symbol in the preview window itself.



1. Tap on the Delete symbol.
2. A dialogue box opens. Confirm the deletion, or select *Cancel* if you do not wish to delete this capture.

4.15 The AI Score



The *AI Screening* menu allows you to assess lesions after capturing with Artificial Intelligence. The FotoFinder software uses a Convolutional Neural Network (CNN) algorithm called AI Score. The sensitivity as well as specificity of the algorithm has been proven in a clinical study.

NOTE

Please note that retrieving the AI Score is not available in all countries.

- The AI Score is based on comparisons with images of malignant skin tumors (melanoma, basal cell carcinoma, lentigo maligna, squamous cell carcinoma, actinic keratosis). The Score indicates how similar a lesion is to typical malignant skin tumors.
- The AI Score is not used to assess the malignancy of the examined lesion! It only provides an assessment of whether a lesion is possibly malignant.

NOTE

The AI Score is based on statistics. Therefore, the accuracy of the AI Score cannot be guaranteed and it is intended only as an additional, supportive assessment tool for the physician. The AI Score is not a substitute for the physician's overall clinical diagnosis!

4.15.1 Calling up AI Score (AIMEE)

1. Open the desired micro image capture.

NOTE

It must be a capture with 20x magnification.



2. Tap on the AI symbol.
After a short loading process, the AI Score is displayed.

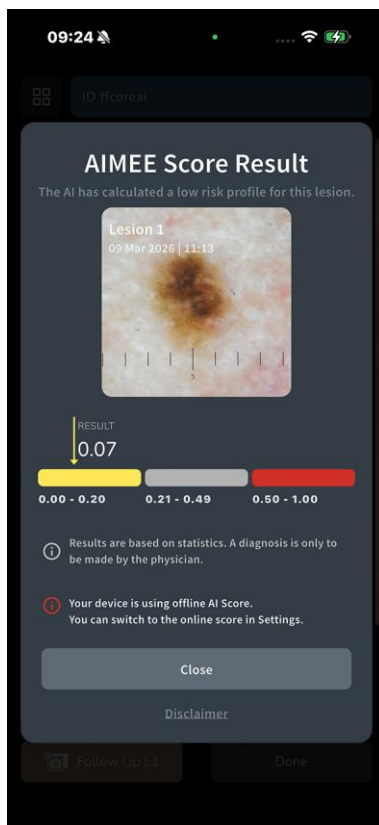


Fig. 9: AI Score example view

4.15.2 AI Score result information

The AI Score is designed to assess whether a lesion is potentially malignant. This is merely a confidence score of the algorithm, i.e. an assessment of the similarity to malignant lesions. The AI Score is based on comparisons with images of malignant skin tumors (Melanoma, Basal Cell Carcinoma, Lentigo Maligna, Squamous Cell Carcinoma, Actinic Keratosis). The AI Score makes no statement regarding the medical risk and does not assess the malignancy of the examined lesion.

Lesions with a high score should be observed with great attention.

- 0 - 0.49 inconspicuous, follow-up in a reasonable time
 - 0 - 0.2 inconspicuous
 - 0.21 – 0.49 further clarification necessary
- 0.50 - 1.0 conspicuous, should be observed with great attention

4.16 Trichoscopy Analysis

You can use the optional trichoscopy module to analyse the hair density, the shaft diameter (vellus, intermediate and terminal) and the composition of the follicular units (single, double and multiple). It also calculates the ratio of anagens and telogens (A/T) based on a momentary capture.

NOTE

The trichoscopy module is available separately and can be booked with every premium tariff using FotoFinder Hub (hub.fotofinder.de).

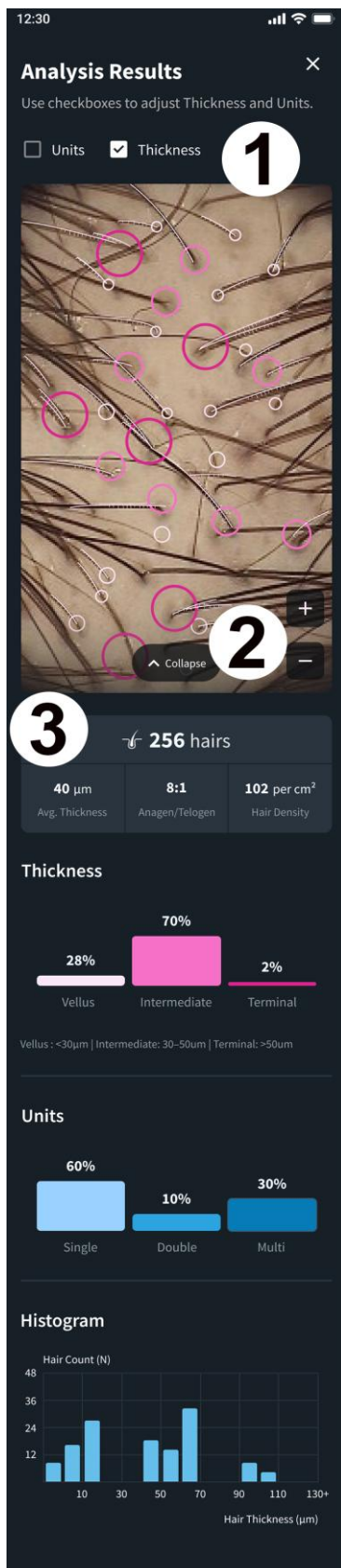
You can conduct the trichoscopy analysis for

- a previously saved micro image or
- a micro image that has just been created.



1. Open the preview window and tap on the trichoscopy symbol. This icon is only displayed when an image is captured, not in the live preview.

The analysis starts. The progress is displayed:



The results are displayed after the analysis.

- 1 By setting the respective check marks above the micro image, you can select which results in the micro image are marked by circles (units, thickness or both).
- 2 The analysed micro image is first shown in miniature. The *Expand* button can be used to magnify it again. You can also zoom in on the image.
- 3 Analysis results

Fig. 10: Example view of the trichoscopy analysis results window

4.17 Support

4.17.1 FAQs & tutorials



Please visit our website if you have any questions. You will find numerous videos with brief instructions, as well as other helpful answers:
<https://www.fotofinder.com/service-support/faq-tutorials>

4.17.2 Fault diagnostics tools

1. Open the main menu.
2. Select *Settings* and then tap on *System*.

You will find sub-items with various diagnostic tools here, such as AI Score. You can start these fault diagnostics tools to find possible causes of faults, such as issues with the online connection or your Hub account.

4.17.3 Contact FotoFinder Support

If you continue to experience problems with the application

- after checking our FAQs (cf. 4.17.1) and
- using the fault diagnosis tools (cf. 4.17.2),

please contact FotoFinder Support:

In the main menu, you will find the item *Contact Support*.

Provide as much detail as possible here about the problems you are experiencing so that we can assist you as effectively as possible.

4.18 About FotoFinder

You find this software area in the main menu.

It includes

- the manufacturer's contact details
- indication of the software version
- device IDs
- service conditions
- privacy policy

Explanation of symbols:

CE mark



Manufacturer



Country of origin/date of manufacture



Serial number/software version



Indicates the Swiss representative:

Johner Medical Schweiz GmbH, Tafelstattstrasse 13a, 6415 Arth, Switzerland



Medical device



Unique Device Identification



Electronic user manual

eIFU indicator



UK conformity assessed

Party responsible for UK: FotoFinder Systems Ltd., 75 High Street, Bagshot, Surrey, GU19 5AH, United Kingdom

4.19 Settings

In the *Settings* menu, you can customise various functions.

■ AI

Choose between

- *Online*: Access to the AI algorithm via the Hub
- *Offline*: Use of the locally installed classification program (AI algorithm)

■ Tutorials

This is where you can display the functions of the app in short tutorials for each.

■ Synchronisation

Here, you can see when synchronisation with the Hub last took place. You can start synchronisation at any time (with an active WLAN connection) using the Update button.

■ System

App settings:

Here you can, for example, set preferences for language and security (PIN).

Network:

This is where you can adjust the WLAN settings.

Devices settings:

This is where you can adjust the time settings, camera profiles and update settings, for instance.

Diagnostics tools:

This is where you will find various fault diagnosis tools for AI, the network, account and hardware.

5 Appendix

FotoFinder

EU - KONFORMITÄTserklärung
EU - DECLARATION OF CONFORMITY

Hersteller / Manufacturer:
Adresse / address:

FotoFinder Systems GmbH
Industriestrasse 12
84864 Bad Bimbach
Deutschland/Germany

Single Registration Number (SRN):
DE-MF-00007084

Benannte Stelle / Notified Body
TÜV SÜD Product Service GmbH
Riederstraße 65
80339 München / Munich
Germany

Zertifizierungs-Nr. / Certificate No.
GLO 11.5802.0002

Wir erklären hiermit in eigener Verantwortung, dass nachstehendes Produkt
We declare under our sole responsibility that the product

FotoFinder mobile

in den folgenden Varianten / in the following variants:
FotoFinder handyscope pro for iOS, Version 1.9
FotoFinder handyscope pro for Android, Version 1.9
FotoFinder skin, Version 2.1
FotoFinder DermLite for iOS, Version 2.1

Zweckbestimmung / Intended User:

FotoFinder mobile is a mobile application that works in conjunction with the FotoFinder Hub online cloud. The application is designed for patient management, standardized documentation of microscopic images, and to assist in the initial assessment of skin conditions. FotoFinder mobile enables digital documentation of intact human skin by healthcare professionals. The microscopic images are stored together with the relevant patient data, which makes it possible to visualize changes in lesions during subsequent follow-up examinations of the patient.

The FotoFinder application is used in combination with hardware imaging devices, which allow to capture microscopic images using a mobile device.

The following features are available:

- ▶ Acquisition and management of patient data
- ▶ Capturing and managing microscopic images
- ▶ Documentation of patient examinations
- ▶ Assigning images to a patient
- ▶ Assigning a localization to an image
- ▶ Requesting a second opinion (Second Opinion) from experts (not for all variants)
- ▶ Request AI score (Artificial Intelligence)

FotoFinder mobile connects online with the MolAnalyzer pro algorithms to generate the AI score. The connection to the FotoFinder Hub allows to use a second opinion service (not for all variants). These functions are only accessible to paid subscribers. The application is supported and managed through a FotoFinder Hub account. The app data is synchronized, stored and managed via this cloud solution.

FotoFinder

FotoFinder mobile is intended for the documentation of skin lesions. The app must not be used to make or confirm a clinical diagnosis of melanoma, any other skin disease or skin cancer.

The application does not provide a diagnosis. The AI score is based on statistics. The diagnosis and therapy decision are the responsibility of the physician.
The application is intended for transient use. In combination with the hardware imaging device, the product is in continuous use for less than 60 minutes during a diagnosis session.

der Risikoklasse / of risk class: IIa (Annex VIII MDR)


Basis UDI-DI / Basic UDI-DI: 426015945H5A001YV

den Grundlegenden Anforderungen gemäß Anhang I der Medizinprodukteverordnung (EU) 2017/745 entspricht / meets the essential requirements of the regulation (EU) 2017/745.

Konformitätsbewertungsverfahren / Conformity assessment
(EU) 2017/745, Annex IX Chapters I & III

Diese Erklärung ist gültig, bis sie durch eine neue Version ersetzt wird / This declaration is valid until superseded by a new version.

Bad Bimbach, 23.05.2026


 Susanne Rumreich, PRRC

