EN

FotoFinder

SKeen

Original user manual

Software

Setting the Pace in Skin Imaging Worldwide

www.fotofinder.de

skeen - Software

Original user manual

CE 0123

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

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Content

1 Introduction

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 skeen 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 4.14 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.
Deinstallation is only possible via the FotoFinder support. The application cannot be deinstalled by the user. Please note that any locally stored data as well as cached data is deleted when sending the device for deinstallation. Please make sure to synchronize all data with the FotoFinder Hub before sending the device to FotoFinder support.

2.1 System requirements

The operation of the FotoFinder skeen application is only possible in combination with the related FotoFinder skeen 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)

FotoFinder Hub In addition, a user account at the FotoFinder Hub (www.fotofinderhub.de) is required for the use of the FotoFinder skeen 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/ethernet. 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/ethernet 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)	– 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	– 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	Spinocellular 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 ulerythematosa reticulata
L66.9	Cicatricial alopecia, unspecified

L67	Hair colour and hair shaft abnormalities
L67.0	Trichorrhexis nodosa
L93.0	Discoid lupus erythematosus
Q84.0	Congenital alopecia
Q84	Other congenital malformations of integument
Q84.8	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 skeen 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. First login to the FotoFinder Hub (cf. chapter 4.3 FotoFinder Hub login)
4. Set up a PIN for skeen (cf. chapter 4.2 PIN (Personal Identification Number))

These steps are also required if you logged out of the FotoFinder Hub the last time you used it.

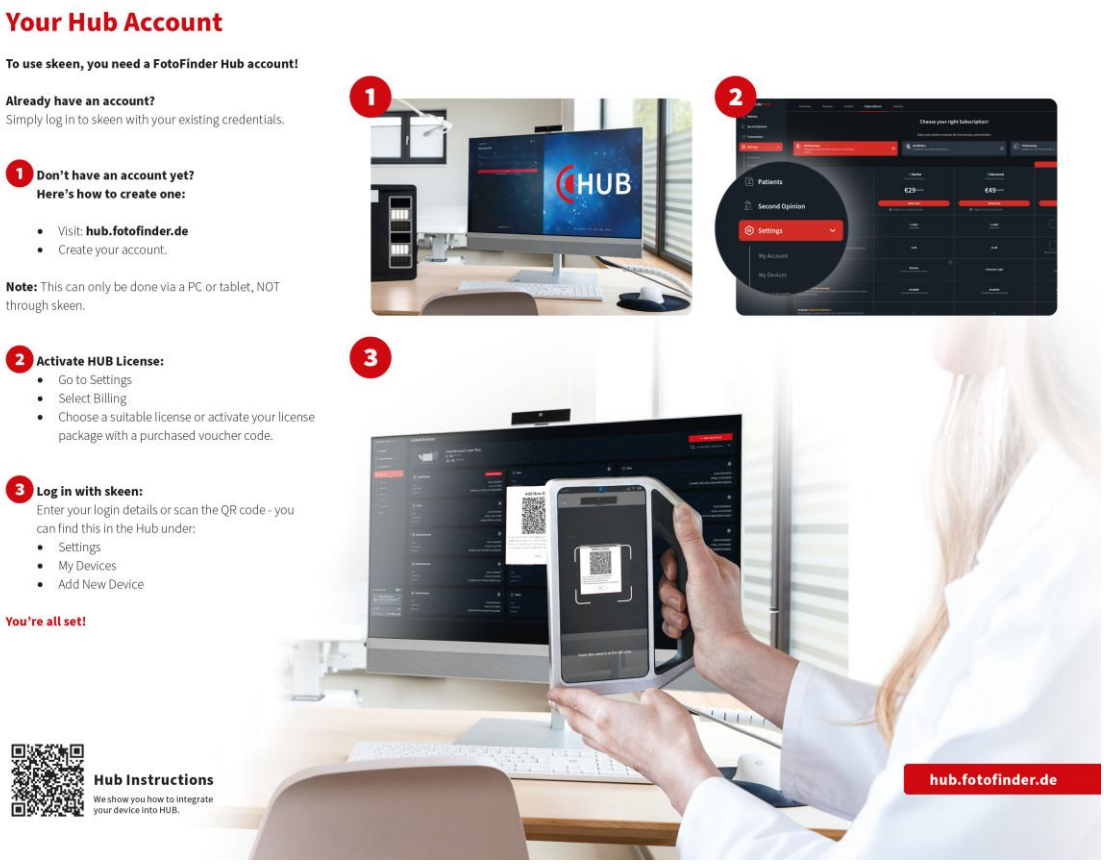
4.2 PIN (Personal Identification Number)

To use your device, you must 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 or activate the PIN in the *Settings / System configuration / Security* menu.

4.3 FotoFinder Hub login



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 skeen 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 skeen 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 easily controlled using gestures. Swipe the screen from left to right with one finger to navigate backwards, for example.
You will also find a back button in every menu.

4.5 Home screen

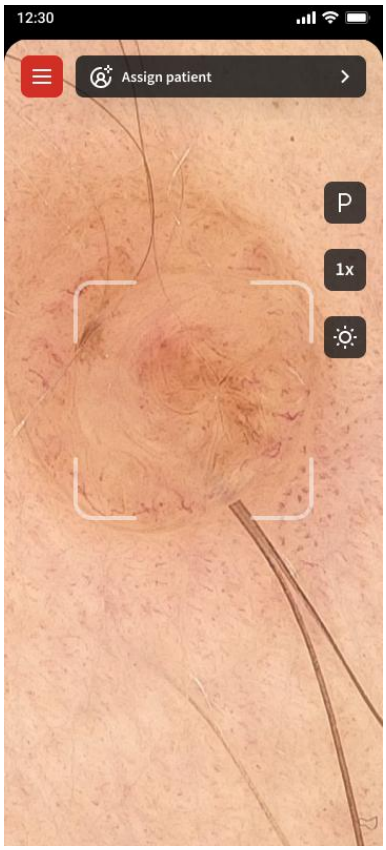


Fig. 2: Home screen with example preview image

After connecting to your FotoFinder Hub account, you will see the home screen of the skeen software.

The device and the software are immediately ready for recording.

4.6 Menu Bar

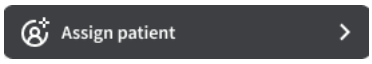
You can open the main menu using the menu button at the top left.
The following sub-menus are available:

- My patients
  (cf. 4.7)
- Sessions
  (cf. 4.10)
- All images
- Settings
  (cf. 4.14)
- About FotoFinder
  (cf. 4.13)
- FAQ
- Log out

4.7 Patients

Your skeen displays all the patients saved in your FotoFinder Hub account and their images. You can also create new patients with skeen, which are then also synchronised with the Hub.

4.8 Search and select existing patients



Patient search field

1. Tap in the patient search field to open your patient list.
   Alternatively, you can also open the patient list via the menu button at the top left in the *My Patients* submenu.

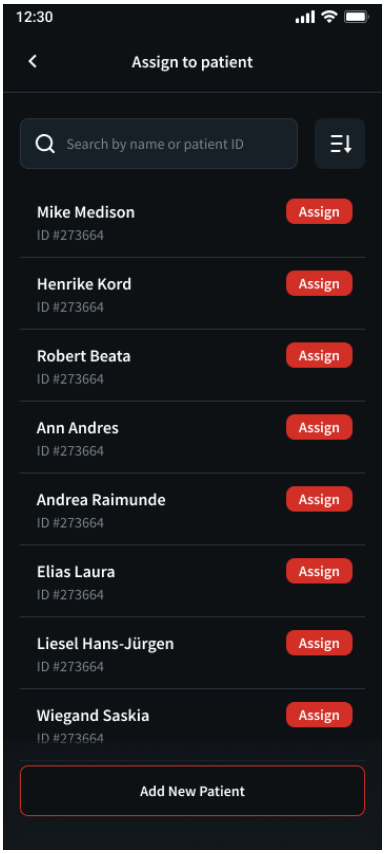
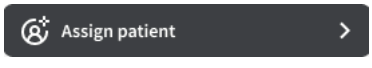


Fig. 3: Example view patient list

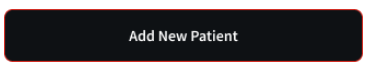
2. Select a patient by tapping on the respective line.

You will return to the home screen and the selected patent will be listed at the top.

4.8.1 Create new patient



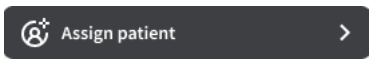
1. Open the patient list.



2. Tap on *Add New Patient*.
3. Fill in all the required fields in the following window and tap *Add New Patient* again.

The patient has been created and is currently selected.

4.8.2 Remove current patient from selection



1. Open the patient list.
2. Tap on *Unlink* right next to the patient name.

You return to the home screen without a selected patient.

4.9 Creating images

NOTE

The software supports both overview images and micro images. For overview images, remove the magnetic attachment lens from the device. For micro images, the attachment lens with front cap must be attached to the device.

1. Select a patient from the patient list (cf. 4.8).
2. Adjust the required settings. The following buttons are available:

Polarized / Non-polarized

or

Polarization offers you a special type of light that minimizes reflections on the skin. By pressing this button, you can switch between polarized and non-polarized light.
Polarized light is active by default.

Micro image magnification

(15x, 20x or 40x is possible)
If you tap this button, you can choose between the different zoom levels for micro-image capturing.
No zoom is possible for overview images without an attachment lens.

NOTE

- A magnification of 20x is required for the analysis with AI score.
- Micro images with 15x magnification are well suited for trichoscopic examinations.

Brightness

When you tap this button, you can choose between three different brightness levels.

3. To take micro images, place the skeen with the attachment lens on the area of skin to be captured and hold it as still as possible.

   For overview images, hold the device (without attachment lens) so that you can see the desired image section in the preview window.

4. Press the shutter release button on the handle of the skeen or tap the preview image to release the shutter.

The captured image is displayed.
The following functions are available on the right-hand side of the screen:

 AI Score (cf. 4.11)

 Trichoscopy Analysis – optional (cf. 4.12)

 Save localisation (cf. 4.9.1)or

 Delete image

At the bottom of the screen there are two buttons:

5. Tap on Save if you want to capture more micro images. Alternatively, you can use the button on the handle.

The image you have just captured is displayed in small format at the bottom left and you can see the live image again in the preview window.

6. Create further images as described above.
7. Tap on Session overview, or on the preview thumbnail at the bottom left if you want to see an overview of all images created during this session.
8. Tap *Finish* in the *Session overview* if you do not want to add any more images to this session.

This ends the session, and the images are synchronised from skeen to your Hub account. You can also view the images online via your PC in the Hub and use other functions.

4.9.1 Saving the localisation

You can save a localisation for micro images immediately after capturing the image. Alternatively, you also have this option at a later stage (cf. chapter 4.9.2 Saving the localisation at a later stage).

Immediately after capturing the image, the button shown in the margin appears on the right-hand side of the screen.

1. Tap on it.

This opens the localisation menu:

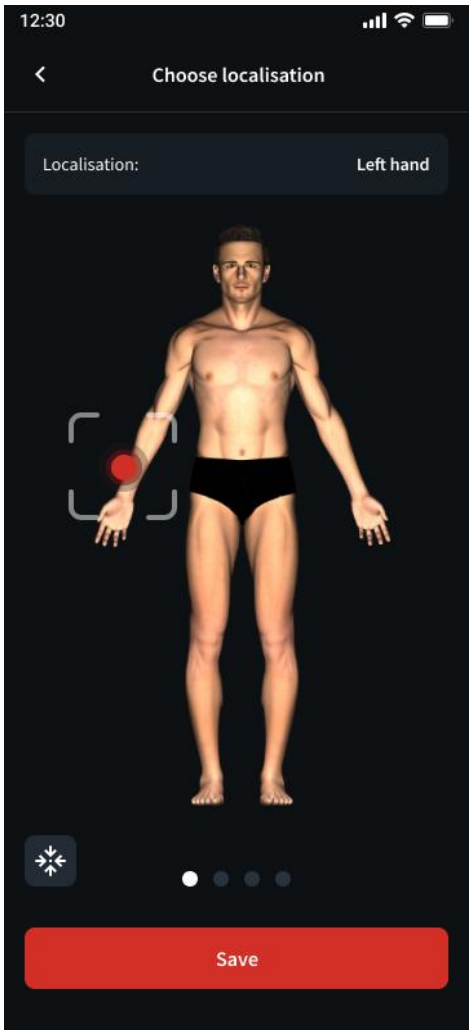


Fig. 4: Example view of the localisation menu

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

4.9.2 Saving the localisation at a later stage

1. Open the image for which you want to save a localisation (cf. chapter 4.10 Sessions).
2. Tap the localisation button in the preview window.
3. Continue as described (cf. chapter 4.9.1 Saving the localisation).

4.10 Sessions

You can find an overview of the capture sessions you have already created under *Sessions*.

1. Tap the menu button at the top left.

2. Tap on *Sessions*.

You will see an overview of your previous capture sessions, grouped by day and patient.

3. Tap on a session to open it and you will see all the individual images captured.

You will find the following buttons on the right-hand side of each image captured:

AI Score
(cf. 4.11)

Save localisation
(cf. 4.9.1)

Delete image

4.10.1 Assigning a session to another patient afterwards

If you have assigned an admission session to the wrong patient, you can change this assignment afterwards:

1. Use the menu button at the top left to open the submenu *Sessions*.

You will see an overview of your previous sessions, grouped by day and patient.

2. Tap on the required session.

The session opens.

3. Tap on the pencil icon to the right of the patient selection field.

The patient list opens.

4. Select a patient by tapping on the corresponding line. Alternatively, you can create a new patient (cf. chapter 4.8 Search and select existing patients).

The images from this session are now assigned to this patient.

4.11 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!

4.11.1 Requesting the AI-Score (AIMEE)

1. Open the relevant micro image. The AI Score is only available for micro images with 20x magnification.

2. Tap on the AI button.

After a short loading process, the AI Score is displayed.

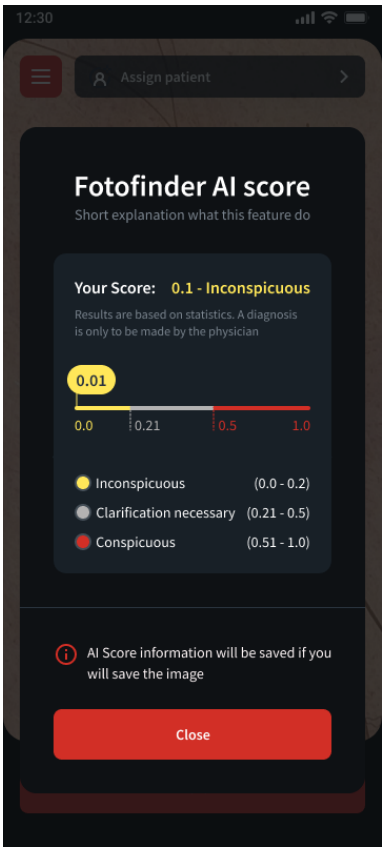


Fig. 5: AI Score Example view

4.11.2 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

4.12 Trichoscopy Analysis

With the optional Trichoscopy Module you can analyze hair density, shaft diameter (vellus, intermediate, and terminal), and follicular unit composition (single, double, and multi). It also calculates the Anagen-to-Telogen (A/T) ratio, helping you assess hair growth and shedding patterns.

NOTE

The Trichoscopy Module is sold separately and can be activated in the FotoFinder Hub (hub.fotofinder.de).

You can conduct the Trichoscopy Analysis for

- a previously saved microimage or
- a microimage that has just been created

.

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

This opens a dialogue.

2. Tap on *Start Trichoscopy Analysis*.

This starts the analysis. The progress is displayed:

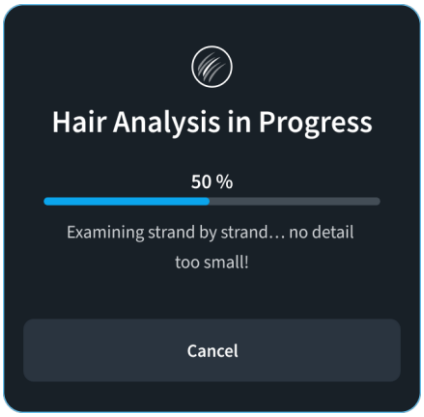


Fig. 6: Progress window of the trichoscopy analysis

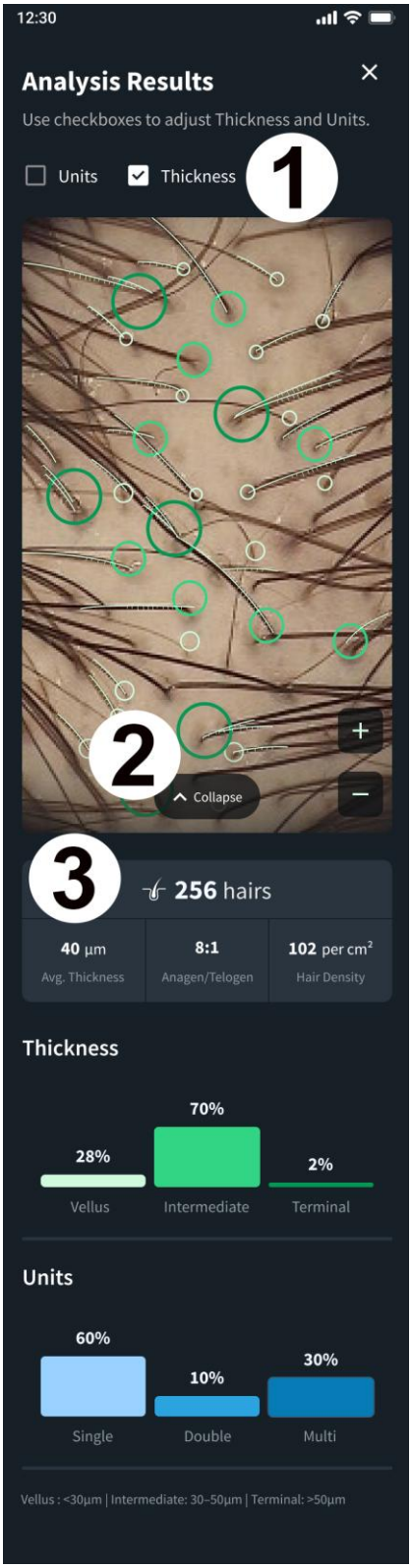


Fig. 7: Example view of trichoscopy analysis results

The results are displayed after the analysis.

1 You can select which results are marked by circles in the microimage by ticking the corresponding boxes above the microimage (Units, Thickness, or both).

2 The analysed microimage is first displayed in reduced size. You can use the button to enlarge it. You can also zoom in on the image.

3 Analysis results

4.13 About FotoFinder

In this software section you will find

- the manufacturer's contact details
- the software version
- your device ID
- terms of service
- Terms & Privacy

Explanation of the symbols:

CE Mark

Manufacturer

Country of origin / Date of manufacture

Serial Number / Software Version

Displays the Swiss authorized representative:
Johner Medical Schweiz GmbH, Tafelstattstrasse 13a, 6415 Arth, Switzerland

Medical device

Unique Device Identification

Electronic user manual

UK Conformity Assessed
Responsible Person for UK: FotoFinder Systems Ltd., 100 Addison Road, W148DD London, United Kingdom

4.14 Settings

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

- AI Configuration

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

- Camera

  Here you can change the resolution of the camera.

- Synchronisation

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

- System configuration

  Here you can set the time zone, Wi-Fi, security (PIN) or automatic system updates, among other things.

- Tutorial

  Here you can have the functions of the app shown to you in a short tutorial.

- Software Update

  Here you can manually start a software update and see which version is currently installed.

FotoFinder

EU - KONFORMITÄTSERKLÄRUNG

EU - DECLARATION OF CONFORMITY

Hersteller / ***Manufacturer:*** **Adresse /** ***address:***	FotoFinder Systems GmbH Industriestraße 12 84364 Bad Birnbach Deutschland/Germany
Single Registration Number (SRN):	DE-MF-000007084
Benannte Stelle / ***Notified Body***	TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 München / Munich Germany
Zertifikations-Nr. / ***Certificate No.***	G10 115802 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, Version 1.9
FotoFinder skeen, Version 1.1

Zweckbestimmung / ***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.

FotoFinder

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:***	426015845HSA001YV

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.*

FotoFinder Systems GmbH Industriestr. 12 84364 Bad Birnbach Germany

Bad Birnbach, 05.03.2025

Julian Mayer, Authorized Officer

FotoFinder