EN

FotoFinder®

SKeen

Original user manual

Software

Setting the Pace in Skin Imaging Worldwide

www.fotofinder.de

skeen - Software

Original user manual

Please read the original user manual carefully before using the product.

Softwareversion from 1.0.0
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Content

1 Safety

1.1 Intended use

The FotoFinder software works in conjunction with the FotoFinder Hub online cloud. The software is designed for patient management, standardized documentation of microscopic and macroscopic images, and to assist in the initial assessment of skin conditions. The FotoFinder software 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 software is used in combination with FotoFinder or DermLite 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 and macroscopic images
- Documentation of images in sessions
- Assigning a session to a patient
- Assigning a body site (localization) to an image
- Request AI score (Artificial Intelligence)

The FotoFinder software connects online with the Moleanalyzer pro algorithms to generate the AI score. This function requires a specific license and plan, which are managed in the FotoFinder Hub account. The data is synchronized, stored and managed via this cloud solution.

The FotoFinder software is intended for skin lesions. The software must not be used to make or confirm a clinical diagnosis of melanoma, any other skin disease or skin cancer.
The software may only be used by physicians or healthcare professionals trained in the clinical diagnosis of skin cancer or other skin diseases.
The software does not provide a diagnosis. The AI score is based on statistics. The diagnosis and therapy decision are the responsibility of the physician!
The software is intended for transient use. In combination with the imaging device, the product is in continuous use for less than 60 minutes during a diagnosis session.

1.2 User groups

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

Target group	Qualification	Permitted work in the application
Medical or healthcare professionals	Trained and instructed, as well as professionally qualified by a completed professional training in the medical field.	– Accessing and managing patient records and respective data – Capturing images of skin – Viewing skin images – Diagnosing skin diseases – Treatment and therapy of skin and hair diseases

1.3 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 high risk of skin cancer / family history of skin cancer

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.

1.4 Indications and contraindications

The FotoFinder software may only be used for the following indications:

- Primary skin lesions with a diameter of up to 8 mm.
- Lesions on intact skin (i.e., non-ulcerated and non-bleeding lesions).
- Lesions without scarring or fibrosis due to previous trauma.
- Lesions that are not in close proximity to psoriasis, eczema, acute sunburn, or similar skin conditions
- Lesions that are not located on specific body sites (i.e., not on the acra, genitalia, eyes, mucous membranes, orifices)

Note the following contraindications for images when requesting an AI Score:
The captured lesion

- must not be covered by hair.
- must not have any foreign bodies or markings within a radius of 30 mm (i.e. tattoos, paint markings of any kind).

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.

NOTE

Clinically unambiguous melanomas may not be evaluated for the purpose of making a treatment decision with the FotoFinder software.

1.5 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.

1.6 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 can result in harm to the patient.
- Incorrect entry of information in the app, or incorrect assignment of patients or images by the user, may result in a misinterpretation of the latter. 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 information for use.

1.6.1 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)

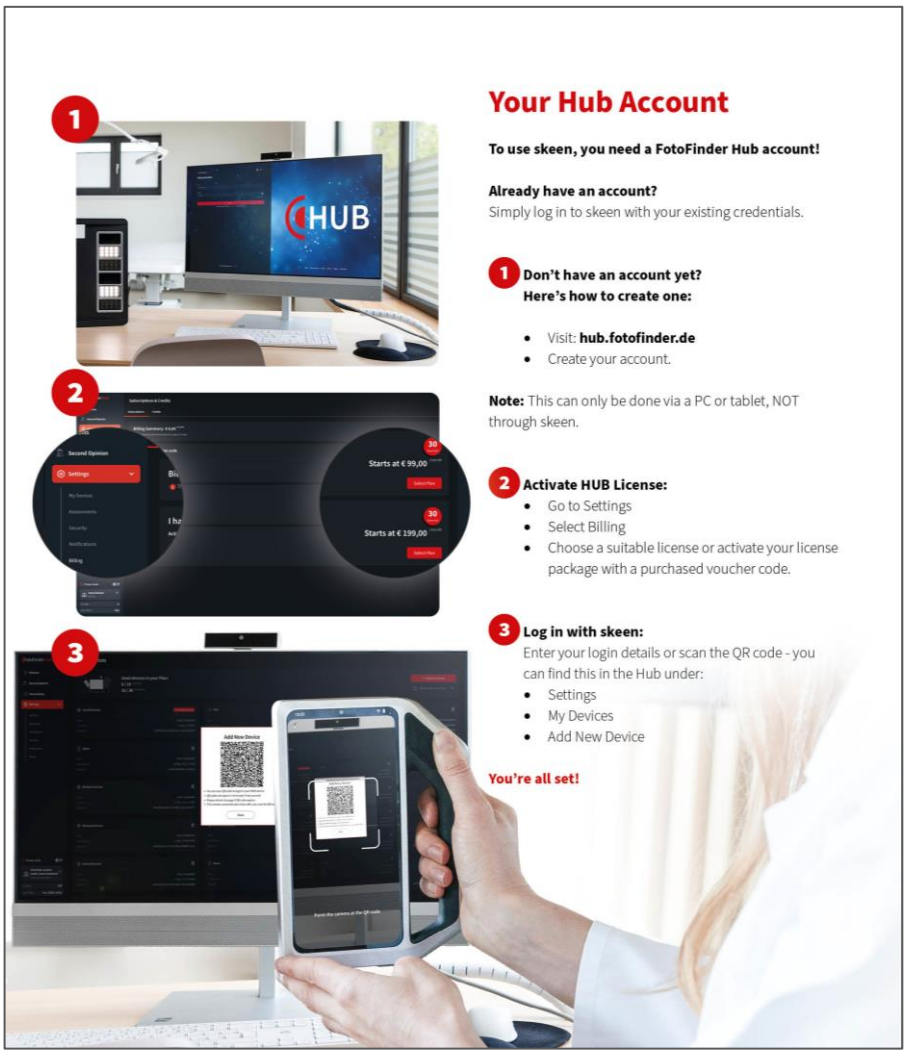
Those residual risks may lead to therapeutic patient data being published along with the name of the patient in the worst case.

2 FotoFinder skeen software

2.1 Installation und updates

The FotoFinder skeen software is already installed on your device. Updates are carried out automatically via Internet connection (Wi-Fi).

2.2 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.

2.3 General operating information

2.3.1.1 Software navigation

The software can be easily navigated using gestures. Swipe the screen from left to right with one finger to navigate backwards, for example.

2.3.1.2 Standby mode

The device switches to standby mode after a few minutes of inactivity. To reactivate the device, press the button on the side of the device or swipe your finger across the screen from bottom to top.

2.4 Home screen

Fig. 1: 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.

2.5 Menu Bar

You can open the main menu using the menu button at the top left.

The following submenus are available:
Patients
(cf. 2.6)
Sessions
(cf. 2.8)
All images
Here you can open a complete overview of your previous images.
Settings
(cf. 2.11)
About FotoFinder
(cf. 2.10)
FAQ
Log out

2.6 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.

2.6.1 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.

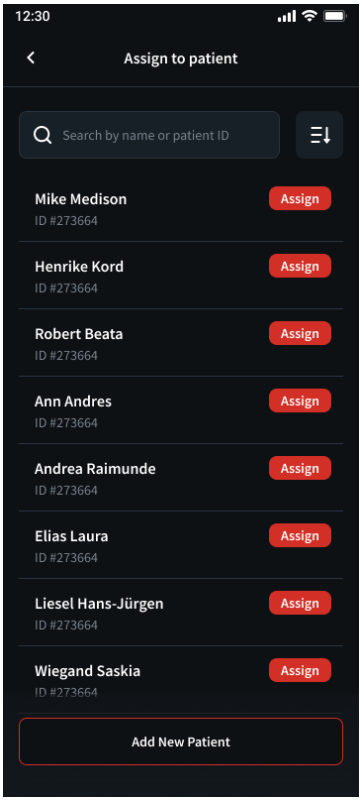
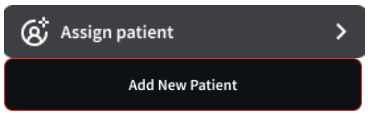


Fig. 2: Example view patient list

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.

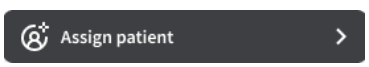
2.6.2 Create new patient



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.

2.6.3 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.

2.7 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.

2.7.1 Create images with patient selection

1. Select a patient from the patient list (cf. chapter 2.6.1 Search and select existing patients).
2. Adjust the required settings. The following buttons are available:

Polarized / Non-polarized

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. 2.9)


Save localisation (cf. 2.7.3)or


Delete image

At the bottom of the screen there are two buttons:

5. Tap on Screening 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.

2.7.2 Capturing images in screening mode (without patient selection)

As an alternative to the capture process with patient selection (cf. 2.7.1), you can continue without patient selection and use the skeen in screening mode.

NOTE

The images are only saved in screening mode if you tap *Save* after an image and select a patient.

1. Adjust the required settings for capturing:
   - Polarized / Non-polarized
   - Micro image magnification
   - Brightness
2. Place the skeen with the attachment lens on the area of skin to be captured and hold it as still as possible.
3. 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. 2.9)


Delete image

At the bottom of the screen you will see two buttons:

4. Tap *Discard* if you want to delete the image. Alternatively, you can use the shutter release button on the handle.

The image is deleted and you will see the live image again in the preview window.

5. Tap *Save* if you want to assign the image to a patient.

The patient management (cf. 2.6) opens.

2.7.3 Save localisation

NOTE

You can only save a localisation for images that are already assigned to a patient.

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 session you want.

The session will open and you will see all the relevant images.

3. Tap the localisation button on the right of the preview image.

The localisation menu opens:

Fig. 3: Example view of localisation menu

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

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

7. Tap on *Save*.

The selected localisation is now saved in the image details.

2.8 Sessions

Under *Sessions* you will find a list of all recording sessions.

Tap on a Session to open it and you will see all the images.
You will find the following buttons on the right-hand side of each image:

AI Score
(cf. 2.9)

Save localisation
(cf. 2.7.3)

Delete image

2.8.1 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 in 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 2.6.1 Search and select existing patients).

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

2.9 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!

2.9.1 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.

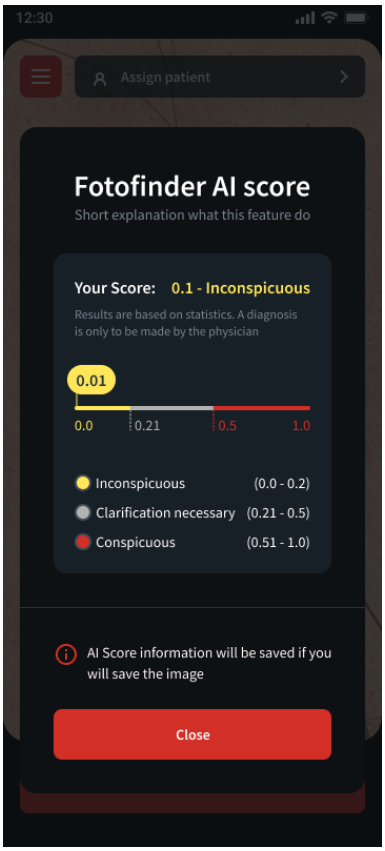


Fig. 4: AI Score Example view

2.9.2 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

2.10 About FotoFinder

In this software section you will find

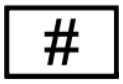
- the manufacturer's contact details
- the software version
- your device ID
- terms of service
- Terms & Privacy

Explanation of the symbols:

CE Mark

Manufacturer

Country of origin / Date of manufacture



Model number

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

Medical device

Unique Device Identification

Observe User manual

2.11 Settings

You can adjust several functions in the menu *Settings*.

- AI configuration

  Here you can 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 camera resolution.

- Synchronization

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

- System configuration

  Here you can make settings for the time zone, Wi-Fi or automatic system updates, among other things.

3 Appendix

FotoFinder

EU - KONFORMITÄTSERKLÄRUNG
EU - DECLARATION OF CONFORMITY

Hersteller / *Manufacturer:*	FotoFinder Systems GmbH
Adresse / *address:*	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
Zertifikats-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 handyscope pro

in the following variants

FotoFinder handyscope pro, Version 1.8
FotoFinder skeen, Version 1.0

Zweckbestimmung / *Intended Use:*

The FotoFinder software works in conjunction with the FotoFinder Hub online cloud. The software is designed for patient management, standardized documentation of microscopic and macroscopic images, and to assist in the initial assessment of skin conditions. The FotoFinder software enables digital documentation of intact human skin by healthcare professionals. The 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 software is used in combination with FotoFinder or DermoLite imaging devices, which allow to capture microscopic images using a mobile device.

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

FotoFinder

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

Basis UDI-DI / *Basic UDI-DI:* 426015845MAP001XZ

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, 24.05.2024

Julian Mayer, Authorized Officer