EN

FotoFinder

handyscope pro

Original User Manual

Software

Setting the Pace in Skin Imaging Worldwide

www.fotofinder.de

FotoFinder handyscope pro App

Original user manual

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

Softwareversion from 1.9
Date: 10.02.2025

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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

Installation, updates as well as uninstalling can be done via the App Store or Play Store (depending on your operating system). The installing process is described within chapter Installing the app (cf. 4.1).

2.1 System requirements

In order to operate the FotoFinder handyscope pro, the following system requirements must be fulfilled:

- ARM based CPU
- Memory: 16 GB
- RAM: 2GB
- Bluetooth mode
- Operating system:

  iOS: 12.0 or higher
  Android: 5.0 or higher
- Internet connection for Login, Synchronization, Second Opinion and AI Score

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

The software is intended for the conditions mentioned in chapter *Patient population* (cf. 3.4).

3.5.1 Indications

ICD Code	Description
L57	Actinic keratosis
C44	Basal cell carcinoma
L82	Benign lichenoid keratosis
D48	Atypical nevus
D18	Hemangioma
L98	Hemorrhage
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
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
L43	Lichen ruber planus
D36	Benign neoplasm
L85	Keratoakanthoma
C80	Spinocellular Carcinoma
B35.0	Tinea barbae and tinea capitis
L21	Seborrhoeic dermatitis
L93.0	Discoid lupus erythematosus

Q84	Other congenital malformations of integument
Q84.8	Other specified congenital malformations of integument (Aplasia cutis congenita)
C44.9	Squamous cell carcinoma

Tab. 1: Indications

3.5.2 Contra-Indications

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.

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.

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.

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 The FotoFinder handyscope pro App

4.1 Installing the app

Installation of the free FotoFinder handyscope pro app on your smartphone / tablet is required to use your handyscope, as is registration with FotoFinder Hub® (www.fotofinderhub.de).

1. Open *App Store* or *Play Store* (depending on your operating system) on your smartphone / tablet and search for *handyscope*.
2. Install the handyscope pro app.

After installation, you will find the handyscope pro app icon on your device.

4.2 Preparing the device

NOTE

Please observe the operating instructions of the manufacturer DermLite LLC enclosed with the device. Attach your handyscope to your smartphone / tablet as described there and also follow the manufacturer's instructions for all other points, such as preparation, use and care!

4.3 Starting the program and login to the Hub

1. Tap on the handyscope pro app icon on your smartphone / tablet to open the app.

If you are already connected to your Hub account, synchronizing with your device will start automatically and the app interface will open.
Your FotoFinder Hub account (www.fotofinderhub.de) provides you with online storage. You can manage your images there, compare them and also use the Second Opinion service from there. Uploading from different devices, e.g. your smartphone with handyscope, is also possible, as is the creation of reports.

If you are not yet connected to your Hub account, you need to additionally confirm upon opening of the app by tapping *Start* and
on the following page select if

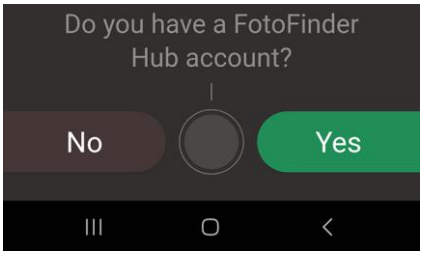


Fig. 1: Selection window for the Hub account, existing or new account

- you want to register for the first time with Hub,

or

- you already have a Hub account and just want to log in.

4.3.1 Creating a new FotoFinder Hub account

To use handyscope pro, you need a FotoFinder Hub account.
If you answered *No* to the question about an existing Hub account after opening the app, the input mask for new users opens.

1. Fill in all fields and set a password.
2. Confirm the reCAPTCHA query.
3. Accept the Terms and Conditions and the Privacy Policy.
4. Confirm that you are a medical doctor.
5. Tap on *Register*.

A registration email with a link will be sent to the email address you provided.

6. Click on this link in the email.

The FotoFinder Hub login page opens.

7. Enter your login details (email address and password) and click on *Log in*.

This completes your registration.

4.3.2 Logging in with an existing FotoFinder Hub account

If you answered *Yes* to the question about having an existing Hub account, the log-in form will open.
You have two log-in options:

- Log-in with email address and password or
- Log-in via QR code from Hub

Logging in with email address and password:

1. Enter the email address and password you used to register with Hub.
2. Tap on *Sign in*.

Logging in via QR code from Hub

1. Open the FotoFinder Hub on a desktop browser. Go to the *Settings / My Devices* menu. Click on *Add new device*.

A QR code opens.

2. On your mobile device, tap on the log-in screen to *Sign in with QR code*.
3. Scan the QR code shown with your mobile device.

After logging in, the FotoFinder handyscope pro app connects to your Hub account and automatically starts synchronising your Hub account with your device (provided you are connected to the Internet).
The home screen of the app opens.

4.4 Home screen

4.4.1 User data

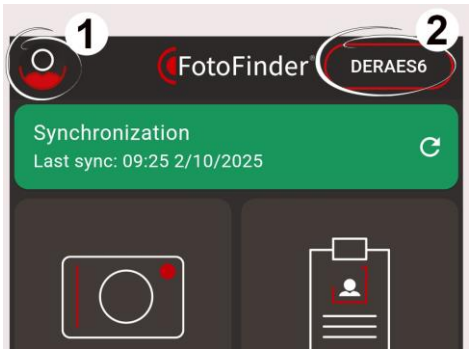


Fig. 2: Home screen of the user interface (header with user data)

1 My Account
(cf. chapter 4.13 Settings)

2 Credits / Hub Plan
(cf. chapter 4.11 Credits / Plan)

4.4.2 Synchronizing with the Hub account

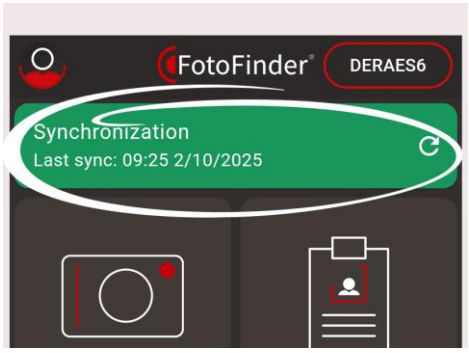


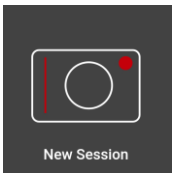
Fig. 3: User interface home page – example view of the Synchronization

If you are connected to your Hub account, synchronization with your device takes place automatically when the app starts. The prerequisite is an existing WLAN connection. In addition, it also works via a mobile network if you have activated this option in the *Settings* (cf. chapter 4.13 Settings).
Also during new capturings the images are continuously transferred to the Hub account.

The green bar shows you the time of the last synchronization. By tapping on the refresh arrow you can start a new synchronization at any time.

In the app, the icon of the crossed-out cloud indicates that the correspondingly marked images has not yet been uploaded to the Hub.

4.5 New session



1. Tap on *New Session*.

This starts the capturing mode.

2. If not already done, switch on the attached handyscope using the red power button. You may also need to allow the app's camera access in your device settings.

NOTE

Please refer to the attached operating instructions of the manufacturer DermLite LLC.

The lighting for polarised images turns on automatically.

ATTENTION

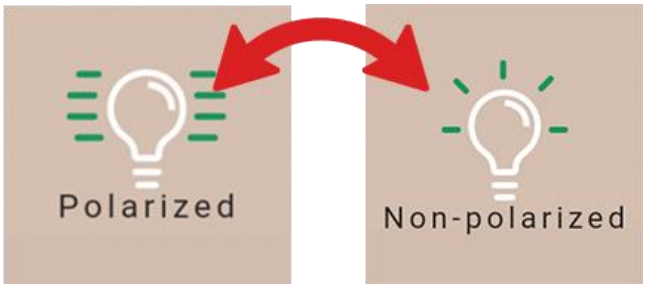
Do not look directly into the LED light. Patients must close their eyes during examinations.

Please observe the following for high-quality micro images:

- To take non-polarized micro images, always use alcohol solutions which contain 70% alcohol. The skin needs to be moistened completely. Try to prevent bubble formation and the inclusion of hair during capture. Shave if necessary.
- When capturing polarized images without immersion solution, ensure sufficient disinfection
- Make sure, that the lens and the attachment are both completely clean before start capturing.

Fig. 4: View of image capture

The capturing mode (polarised/non-polarised) that is activated is displayed at the bottom right. By tapping on this display, you can switch between the two capturing modes.



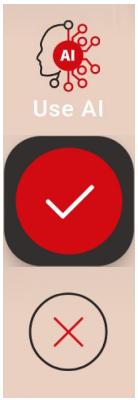
3. Place the handyscope with the lens on the lesion to be captured. Ensure that the lesion is at the centre in the image.
4. Tap the shutter button at the bottom centre or directly on the preview image to take a picture.

Fig. 5: View of frozen image

The image is frozen and the captured image is displayed.

5. You can zoom in on the image using the two-finger zoom: to do this, tap on the image with two fingers and drag your fingers apart. Reverse the process to zoom out of the image again.

6. The menu at the bottom changes and offers you the following options:



Get AI Score (cf. chapter 4.6 AI Screening)

Save Image

Discard image and return to image capture

NOTE

If you take image captures as described here without having selected a patient first; these images are not yet assigned to a patient. The patient's name is shown as *unknown*. Assign images to a patient for better clarity and later comparability (cf. chapter 4.7.2 Assigning images to a patients afterwards).

4.6 AI Screening

The *AI Screening* function gives the option of viewing lesions after they have been captured using Artificial Intelligence.
The FotoFinder handyscope pro 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. It is intended as additional support for the doctor.
The AI Score is not a substitute for the physician's overall clinical diagnosis!

NOTE

Depending on the FotoFinder Hub plan booked, requesting an AI Score may be included. Please refer to your selected plan for details.
You can also see whether credits will be charged when requesting an AI Score.

4.6.1 Get AI Score

You have various options within the application for requesting the AI Score for a captured lesion. Either directly after capturing an image or for a previously saved image.

NOTE

The lesion must be completely visible in the image.

How to proceed directly after image capture:

1. Create an image as described under *New Session* (cf. 4.5).
2. Tap on *Use AI* when you are satisfied with your captured image.

How to proceed for a previously saved image:

1. Open the desired image. This can be done via the *Images*, *Patients* or *Sessions* menu.
2. Tap on the AI button.

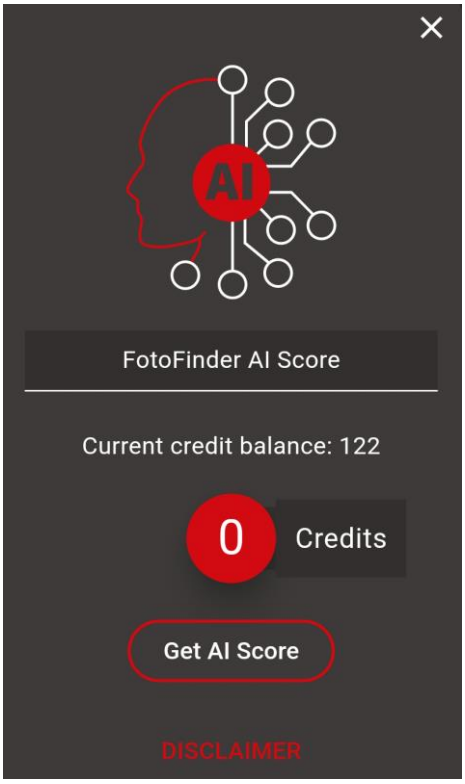


Fig. 6: Example view of Get AI Score

This opens a screen displaying:

- your current credit balance
- the credits to be paid for the AI Score retrieval. This is 0 if AI screening is part of your Hub plan.

NOTE

Please also note the disclaimer.

3. Tap on *Get AI Score* if you want to continue.
   To cancel the operation, tap on the *X* in the top right corner.

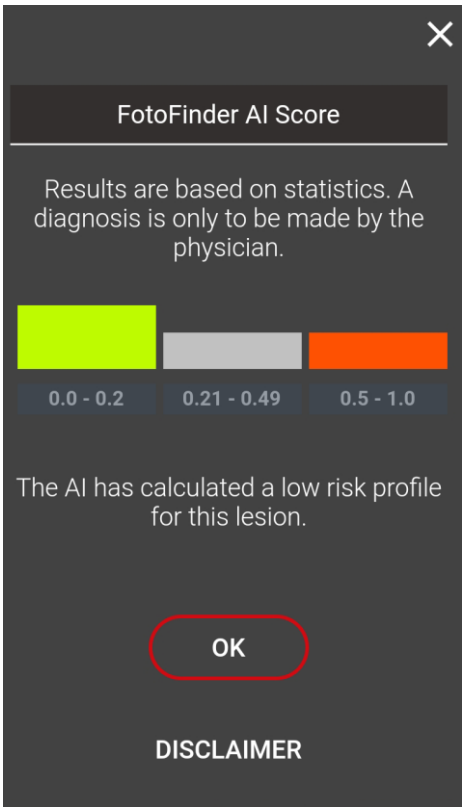


Fig. 7: Example view of the AI Score

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

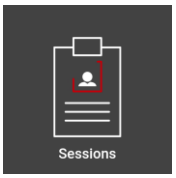
4.6.2 AI Score result information

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

4.7 Sessions



Under *Sessions* you will find a list of your already created sessions, divided by

- Capturing date and
- Patients.

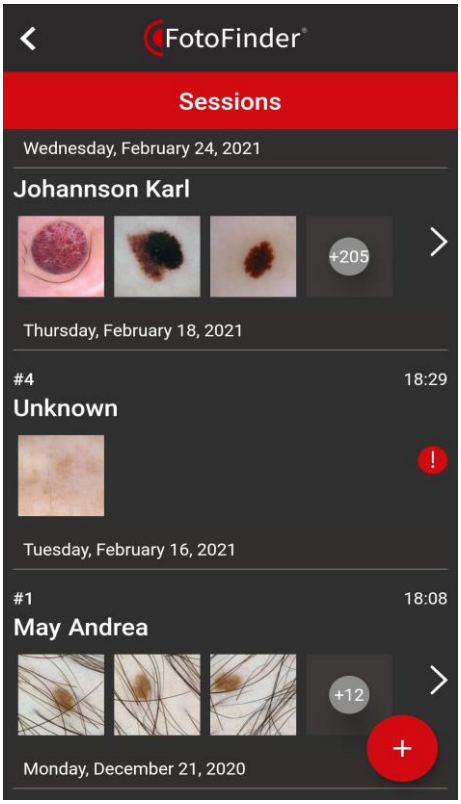


Fig. 8: Example view of the Sessions

The red exclamation mark on the right edge of a session indicates that this image has not yet been assigned to a patient. Assign the images to a patient for a better overview (cf. 4.7.2).

The crossed-out cloud indicates that the session has not yet been uploaded to your Hub account. This may be due to

- the images have just been created
- you have not yet had an Internet connection.

4.7.1 Open and edit capturing in full screen mode

You can open the capturing sessions individually, view and further edit the images in full screen mode. To do this, proceed as follows:

1. Tap on *Sessions*.

The session overview will open.

2. From this session overview, tap on the desired session.

The detailed view of the selected session will open.

3. Tap on the required image.

The preview window opens in full-screen mode with further menu options:

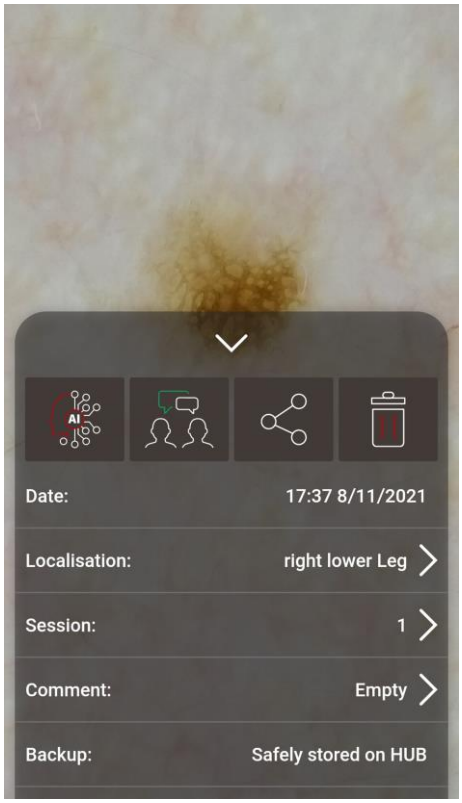
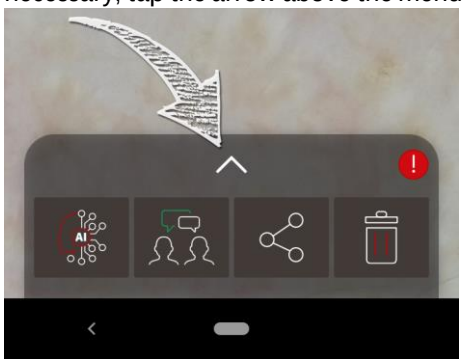


Fig. 9: Example view of the full screen mode with additional details

To open the other image details and edit them if necessary, tap the arrow above the menu buttons.



The red exclamation mark in the right corner indicates that detailed data is still missing for this image, e.g. the localization.

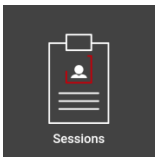
Tap on this icon to be led directly to the AI Score request (cf. chapter 4.6 AI Screening).

Tap on this icon to be led directly to the Second Opinion request (cf. chapter 4.9 Second Opinion).

Tap this icon to share the images, for example as an email attachment.

Tap this icon to delete the selected image.

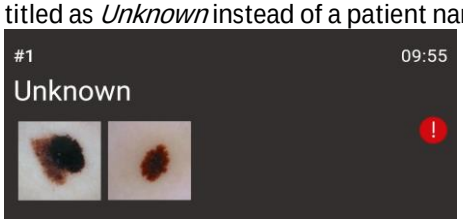
4.7.2 Assigning images to a patients afterwards



If images are created without a patient selected beforehand, these images will not be assigned to a patient automatically. This can also be done subsequently:

1. Tap on *Sessions*.

Images without patient assignment are marked with a red exclamation mark on the right edge and titled as *Unknown* instead of a patient name.



2. Tap on a respective session.

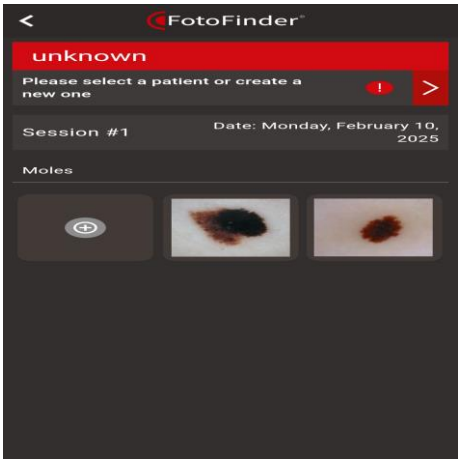


Fig. 10: Example view of a session without patient assignment

The detailed view will appear.

3. Tap on the red bar at the top.

The patient overview will open.

4. Select an existing patient in the patient overview by tapping on it, or select the option to create a patient by tapping on the red plus icon  at the bottom right. In this case, enter the patient data and confirm the process with *Save*.

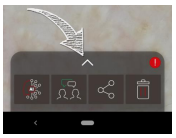
4.7.3 Saving the localization

NOTE

Localization can only be saved for images that are already assigned to a patient.

1. Open the image overview, for example, via the start menu buttons *Sessions* or *Images*.
2. Tap on the respective image.

The full screen view will open.



3. Open the other image details by tapping the small arrow above the menu buttons.

4. Tap on *Localization* at the image details section.

Fig. 11: Example view of the localization menu

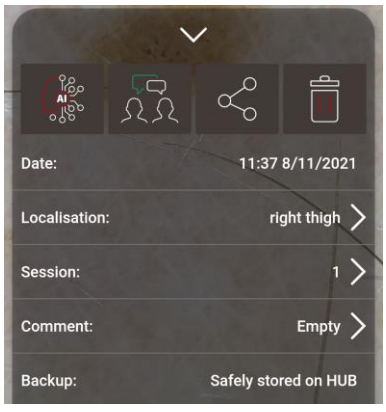
The localization menu will open.

5. Select another body view by swiping to the right or left as required.
6. You can zoom into the image with the two-finger zoom: To do this, tap the image with two fingers and drag them apart. Moving the fingers the opposite direction, you will zoom out of the image again.
7. Tap on the corresponding body part.

The body location is indicated by a red dot and is also listed above the virtual patient.

8. Tap on *Save*.

The selected localization is now saved in the image details.



4.8 Images

Under *Images* you will find an overview of the created images, sorted by date.
Tap on one of the images (cf. chapter 4.7.1 Open and edit capturing in full screen mode)to enter full screen mode.

4.9 Second Opinion

With *Second Opinion*, an additional service is available to you for a fee. You can obtain a second opinion from experienced, international dermatologists.
All data from this additional service can also be found in your Hub account.
Start *Second Opinion* by tapping on the corresponding icon in the start menu.

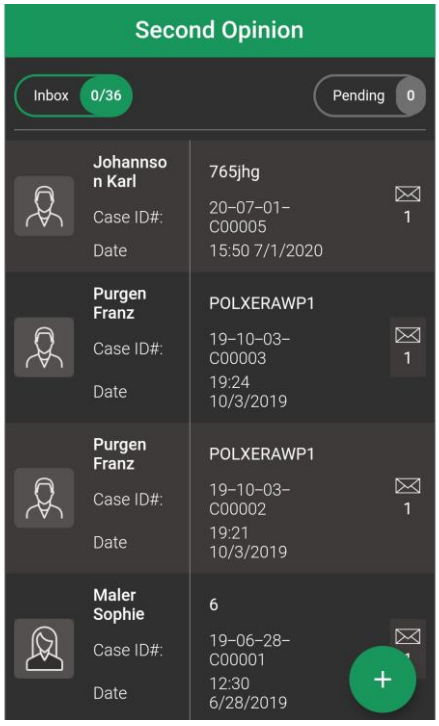


Fig. 12: Example view of the Second Opinion overview

The *Second Opinion* overview will open. Here you can choose between two lists:

- *Inbox*: Here you can see all already requested and received second opinions.
- *Pending*: Here you will find your requested second opinions for which no response has yet been received.

4.9.1 Requesting a Second Opinion

1. Tap the green plus icon at the bottom right corner of the *Second Opinion* overview.

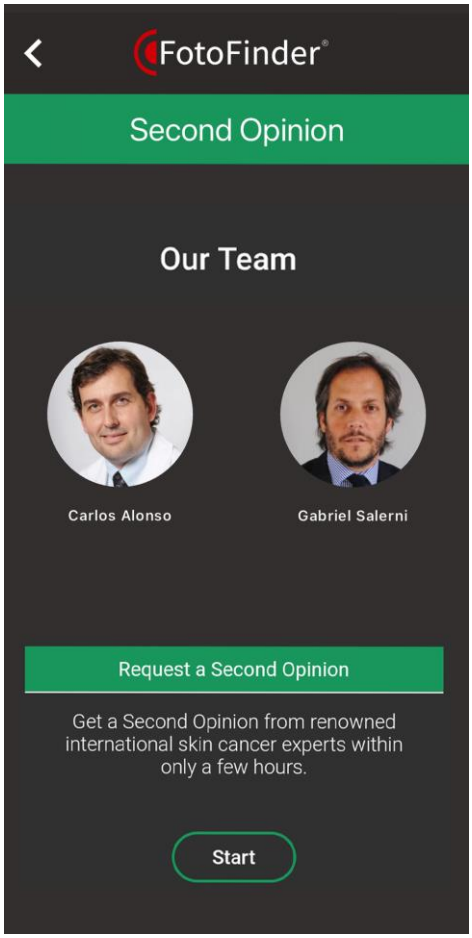


Fig. 13: Second Opinion Intro window

An intro window with the expert team opens.

2. Tap on *Start*.

The image overview will open.

3. Select the desired image by tapping on the image.

A request is only possible if the image is assigned to a patient.

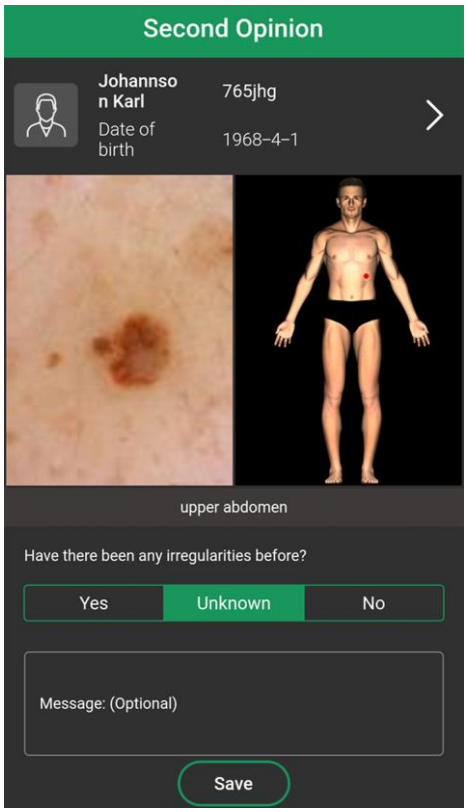


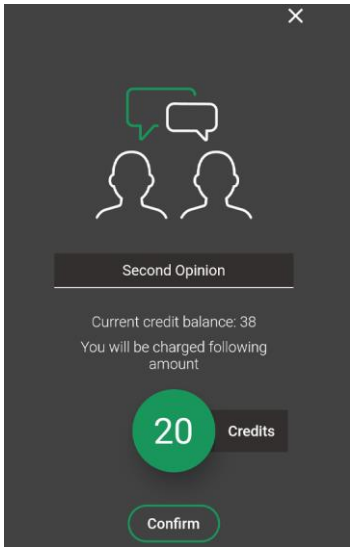
Fig. 14: Second Opinion input window

The selected image and the patient data are displayed in a new window.

4. Below the image, select whether the patient has already experienced irregularities.
5. If necessary, enter additional message below.
6. Tap on *Save*.

A window will open, displaying:

- your current credit balance
- the credits to be paid for the Second Opinion request.



7. Tap *Confirm* if you want to continue.

   To cancel, tap the *X* in the upper right corner.

You will receive a response within 24 hours.

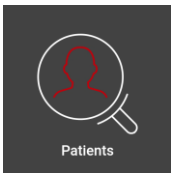
4.9.2 Opening a Second Opinion

1. Start *Second Opinion* by tapping on the corresponding icon in the start menu.

The *Second Opinion* overview opens.

2. Open the received second opinion by tapping on the respective entry.

4.10 Patients



Tap on *Patients* in the Start menu.
This opens the Patient Management screen.

4.10.1 Patient overview

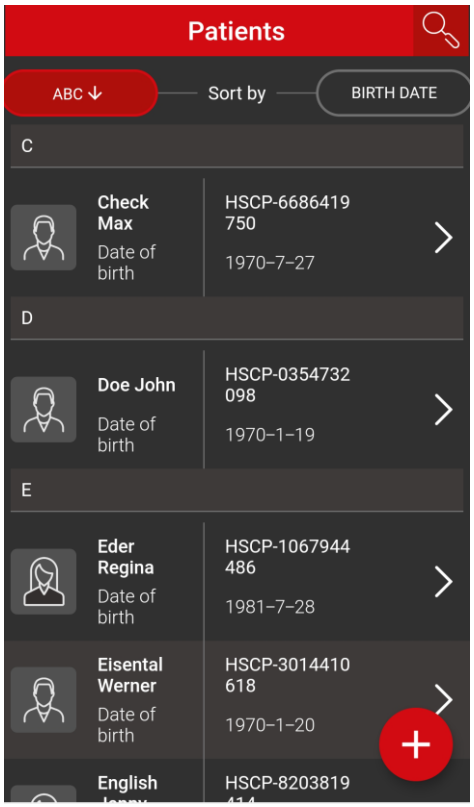


Fig. 15: Example view of Patient overview

When starting the Patient Management screen, you will see the patient overview.

You can sort the list either alphabetically or by date of birth by tapping the *abc* or *Date of birth* buttons.

Alternatively, you can use the search field with the magnifying glass at the top of the screen.

4.10.2 Add new patient

1. In the Patient Management screen, tap on the red plus sign at the bottom right.

This opens an input mask.

2. Record all patient data.
3. Tap on *Save*.

The new patient is now created.

4.10.3 Open patient file

1. Open the Patient Management screen.
2. Tap on a patient name.

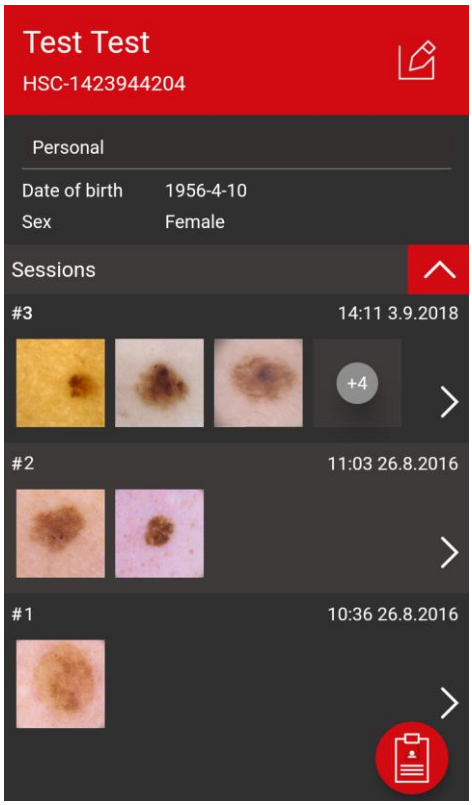


Fig. 16: Example view of a patient file

This opens the patient file.

In addition to the patient data, you will find an overview of all previous capturing sessions for this patient.

Open capturing session

Tapping a session opens it in detail and displays all the images captured during that session. Here you can also open individual images in full-screen mode and edit them further.

Change to capturing mode

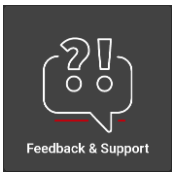
Tap on the symbol in the bottom right corner to switch directly to recording mode (cf. 4.5).

4.11 Credits / Plan

Credits / Plan shows:

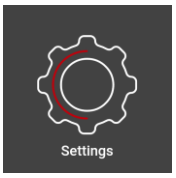
- information on your Hub account, e.g.:
  - plan booked
  - image storage location used
- your available credits
- information on the device you are using
- a link to the Hub

4.12 Feedback & Support



In the *Feedback & Support* section you can send us feedback about the app, or request help from our support.
You can also find the detailed hardware description for your handyscope and other helpful links here.

4.13 Settings



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

- My Account

  Here you can:
  - find your stored user data
  - call up your Hub account or
  - sign out (disconnect from the Hub account).

- Safety

  Here you can define a PIN to open the FotoFinder handyscope pro app to protect your patient data from unauthorised access.

- Camera

  Here you can change the zoom value of the camera and adjust the settings for the attachment you are using.

- Synchronisation

  Here you can manually trigger synchronisation with the Hub account.

- Mobile Network Synchronisation

  If you enable this feature, your device will also synchronise with your Hub account over a mobile network. This may incur additional costs from your data provider.
  Otherwise, synchronisation only takes place when connected via WLAN.

- Bluetooth

  Here you can establish the Bluetooth connection to your handyscope. You can also change the lighting modes (polarised, non-polarised, off) and save them as the default setting.

- Help

  (cf. chapter 4.12 Feedback & Support)

- How to

  (cf. chapter 4.12 Feedback & Support)

- About

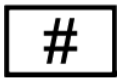
  This displays:
  - FotoFinder contact details
  - your app version
  - general information on the app (cf. chapter 4.14 Explanation of the symbols)
  - our Terms and Conditions
  - information on data protection

4.14 Explanation of the symbols

CE Mark

Manufacturer

Country of origin / Date of manufacture



Model number / version

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

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

Medical device

Unique Device Identification

Electronic user manual

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
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 1.0

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.*

Bad Birnbach, 10.02.2025

Julian Mayer, Authorized Officer

FotoFinder Systems GmbH Industriestr. 12 84364 Bad Birnbach Germany

FotoFinder®