



handyscope pro

Original Technical Manual

FotoFinder handyscope pro App



FotoFinder handyscope pro App

Original manual

Please read these original operating instructions carefully before using the device.



Copyright © 2021 by FotoFinder Systems GmbH
Softwareversion from 1.2.9(132)
Date: 07.10.2021

FotoFinder Systems GmbH
Industriestraße 12
84364 Bad Birnbach
Germany

www.fotofinder.de
www.fotofinderhub.de
info@fotofinder.de
Tel.: +49 (0) 8563 – 97720-0
Fax: +49 (0) 8563 – 97720-10

Content

1	Introduction	4
2	Safety.....	5
2.1	Intended use.....	5
2.2	Residual risks.....	6
2.3	Indication for use	6
2.4	User groups	7
3	The FotoFinder handyscope pro App	8
3.1	Installing the app.....	8
3.2	Preparing the device	8
3.3	Starting the program and login to the Hub	8
3.3.1	Creating a new Hub account	9
3.3.2	Login with an already existing account	9
3.4	Start page of the user interface	10
3.4.1	User information.....	10
3.4.2	Synchronizing with the Hub account.....	10
3.5	New session	11
3.6	AI Screening.....	13
3.6.1	Requesting the AI Score.....	13
3.6.2	AI-Score result information	15
3.7	Academy	15
3.8	Sessions.....	16
3.8.1	Open and edit capturing in full screen mode	17
3.8.2	Assigning images to a patients afterwards	18
3.8.3	Saving the localization	19
3.9	Images	20
3.10	Second Opinion.....	20
3.10.1	Requesting a Second Opinion	21
3.10.2	Opening a Second Opinion.....	22
3.11	Adding a new patient	23
3.12	Patients.....	23
3.12.1	Adding a new patient.....	23
3.12.2	Patient overview	23
3.12.3	Opening a patient file	24
3.13	Credits / Plan	25
3.14	Feedback & Support.....	25
3.15	Settings.....	25
4	Appendix	26

1 Introduction

NOTE

Caution: The failure to observe these operating instructions may lead to hazards for both the user and the patient!

Please observe the following points and operating instructions when using the device:

- The device can only be used, operated and maintained for its intended purpose with the help of these operating instructions.
- These operating instructions only apply to the product specified on the cover page.
- We reserve the right to change these operating instructions on account of technical developments.
- These operating instructions are part of the delivery scope.
- These operating instructions are only intended for instructed and authorized professional personnel.
- The operator has to ensure that the operating instructions are read and understood by all parties concerned before the device is placed into operation.
- The chapter on *Safety* (cf. chapter 2 Safety) provides an overview of all important safety aspects for the optimal protection of the staff and for the safe and faultless operation of the device.
- The manufacturer is not liable for damages caused by non-compliance to these operating instructions.
- All serious 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.
- Reprints, translations and duplication in any form, in whole or in parts, require the written approval of the editor.
- The copyright remains with the manufacturer.

2 Safety

2.1 Intended use

The FotoFinder **handyscope pro** app 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. The FotoFinder **handyscope pro** app 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 **handyscope pro** app is used in combination with the DermLite **handyscope**, which serves as a lens attachment for smartphone and tablet cameras.

The application is available for both Android and IOS operating systems.

The following features are available:

- Acquisition and management of patient data
- Capturing and managing microscopic images
- Documentation of images in sessions
- Assigning a session to a patient
- Assigning a body site (localization) to an image
- Requesting a second opinion (Second Opinion) from experts
- Request AI score (**Artificial Intelligence**)

The FotoFinder **handyscope pro** app connects online with the **Moleanalyzer pro** algorithms to generate the AI score and use the second opinion service. These functions are only accessible via paid credits. Credit management is only available through a FotoFinder **Hub** account. The app data is synchronized, stored and managed via this cloud solution.

The FotoFinder **handyscope pro** is intended for 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 app may only be used by physicians or healthcare professionals trained in the clinical diagnosis of skin cancer or other skin diseases.

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

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

2.2 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 named on the cover sheet 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 misdiagnosis of the latter. The consequences may be unnecessary excision, undetected or delayed diagnosis of skin cancer.
- Misuse by the user cannot be ruled out despite the provision of information for use.

2.3 Indication for use

The FotoFinder **handyscope pro** app 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 for which an AI score is additionally to be requested:
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).

NOTE

Clinically definite melanomas may not be evaluated for the purpose of making a treatment decision with the FotoFinder **handyscope pro** app.

2.4 User groups

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

Target group	Qualification	Permitted work in the app
Doctor	Professional qualification as a doctor	<ul style="list-style-type: none"> – FotoFinder Hub registration – Full range of app features, incl. AI score request
Medical staff	Trained and instructed, as well as professionally qualified by a completed professional training in the medical field	<ul style="list-style-type: none"> – Areas of application according to the intended use (cf. chapter 2.3 Indication for use) with the exception of <ul style="list-style-type: none"> ■ FotoFinder Hub registration ■ Artificial Intelligence (AI score) request ■ Request second opinion service (Second Opinion)

3 The FotoFinder handyscope pro App

3.1 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.



3.2 Preparing the device

NOTE

Please observe the operating instructions of the manufacturer 3Gen 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!

3.3 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.

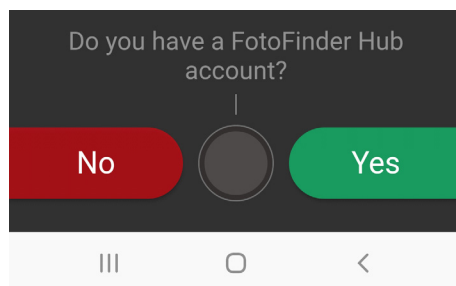


Fig. 1: Selection window for the Hub account, existing or new account

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

- you want to register for the first time with Hub, or
- you already have a Hub account and just want to log in.

3.3.1 Creating a new Hub account

Fig. 2: Input mask for Hub registration

If you answered *No* to the question about an existing Hub account, the input mask for new users will open.

1. Fill out all the fields.
2. Tap *Submit*.

A registration email with a link will be sent to your specified email address.

3. Click on this link in the email.

The Hub page will open.

4. Fill out the open fields there.
5. Confirm the *terms and conditions* and that you are a doctor by checking each box.
6. Finally, click on *Complete Registration*.

Your registration is now complete.

3.3.2 Login with an already existing account

Fig. 3: Login window for the Hub account

If you answered *Yes* to the question about an existing Hub account, the login screen will open.

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

The FotoFinder **handyscope pro** app connects to your Hub account and automatically starts synchronizing your Hub account with your device (assuming an existing online connection).

3.4 Start page of the user interface

3.4.1 User information

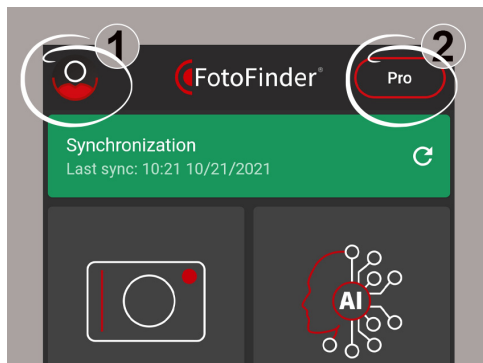


Fig. 4: User interface of the home page - header with the user information

1 User

Tapping the User icon will take you to the *My Account* section. There

- you will find your stored user information
- you can edit your Hub account, or
- you can log out (disconnect from Hub account).

2 Hub Plan

Here you can see with which plan you are logged into FotoFinder Hub with (e.g. *Pro*).

3.4.2 Synchronizing with the Hub account

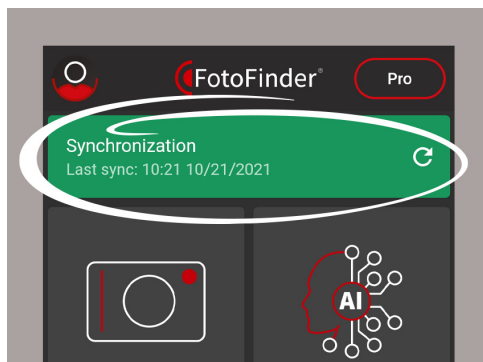


Fig. 5: User interface home page – example view of the Synchronization

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 3.15 Settings).

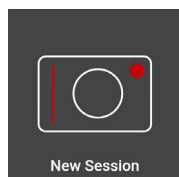
Also during new capturings the images are continuously transferred to the Hub account.

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.

3.5 New session



1. Tap on *New Session*.
The capturing mode will open.
2. If not already done, switch on the attached **handyscope** with the red power switch. If prompted, you must also allow the camera access of the app in your device settings.

NOTE

Please observe the operating instructions of the manufacturer 3Gen enclosed with the device.

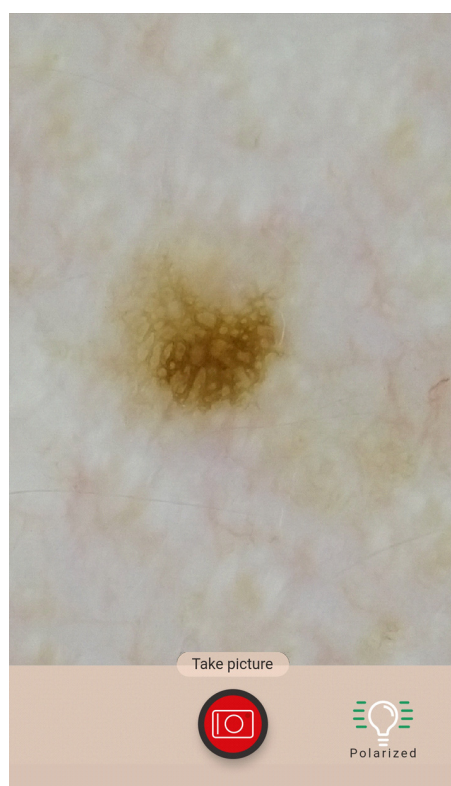
The illumination for polarized images switches on automatically.

ATTENTION

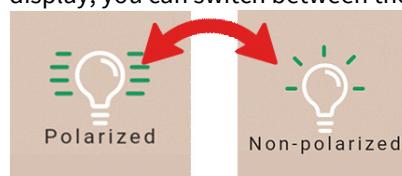
Do not look directly into the LED light. Patients must close their eyes during the examinations.

Please observe the following for high-quality micro images:

- To take non-polarized micro images, always use alcohol solutions which contain 70% alcohol (e. g. Kodan® spray). 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.



At the bottom right, you can see which capturing mode (polarized / non-polarized) is activated. By tapping on this display, you can switch between the two modes.



3. Place the **handyscope** with the lens on the lesion to be captured. Make sure that the lesion is in the center of the image.
4. Tap on the bottom center on the trigger or directly in the preview image to take an image.

Fig. 6: Example view of an image capturing

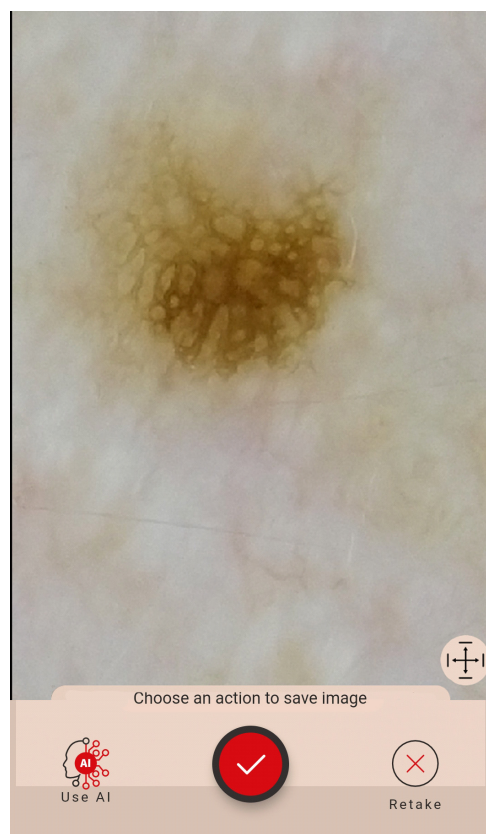
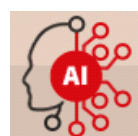


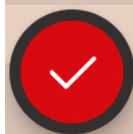
Fig. 7: Example view of a frozen capture

The image will be frozen and the created image will be displayed to you.

5. 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.
6. At the bottom, the menu will change when the image is frozen and offers the following options:



Use AI-Score (cf. chapter 3.6 AI Screening)



Save the image



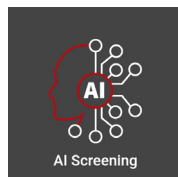
Discard the image and go back to capturing

Retake

NOTE

If you create images without having selected a patient beforehand, as described here, these images are not yet assigned to a patient. In this case, the patient name is indicated as Unknown. Assign images to a patient for a better overview and later (cf. chapter 3.15 Settings) comparability.

3.6 AI Screening



The *AI Screening* menu 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

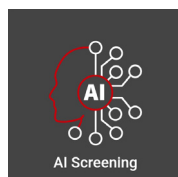
The AI score is based on statistics. Therefore, the accuracy of the AI Score cannot be guaranteed and it is intended only as an additional, supportive assessment tool for the physician.

The AI Score is not a substitute for the physician's overall clinical diagnosis!

NOTE

The AI score is a charged service.

3.6.1 Requesting the AI Score



1. Tap on *AI Screening*.
2. Capture an image, just as described under *New Session* (cf. chapter 3.5 New session) . Alternatively, you can also call up an already existing image.

NOTE

The lesion must be completely visible in the image.



3. Tap on *Start AI* as soon as you are satisfied with your image. A window opens displaying
 - your current credit balance
 - the credits to be paid for the AI score.

NOTE

Please also note the disclaimer.

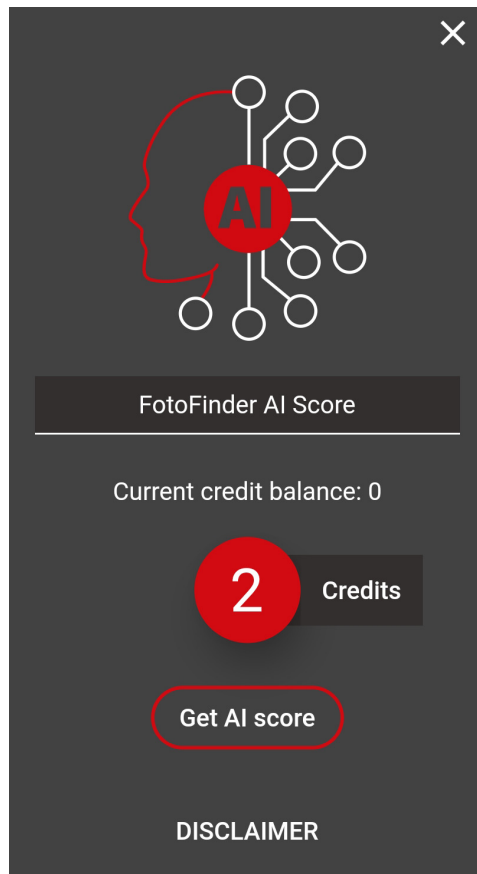


Fig. 8: Example view of requesting the AI Score

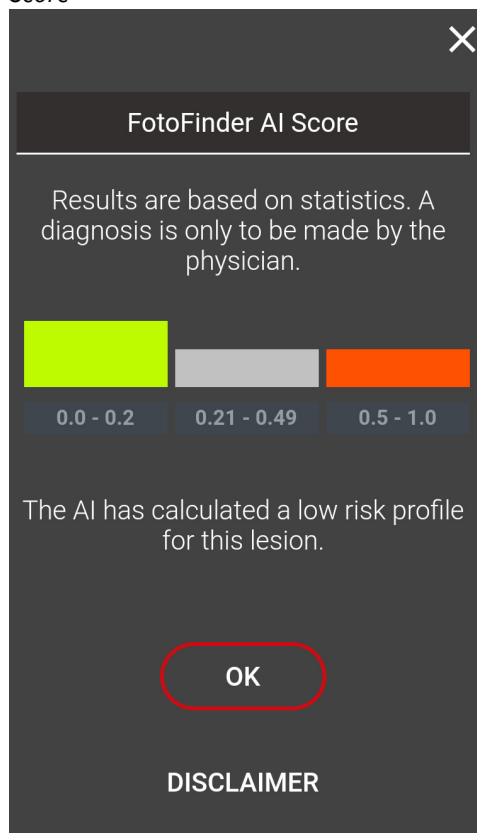


Fig. 9: Example view of an AI Score

4. Tap *Get AI Score* if you want to continue.
To cancel the process, tap the X in the upper right corner.

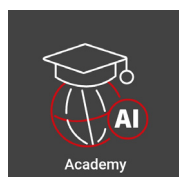
5. After a short loading process, the AI score will be displayed.

3.6.2 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. Thus, the score does not make any statement regarding the medical risk or malignancy of a 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

3.7 Academy



In the *Academy* section the following various options are available:

AI Challenge

Here you can playfully compete against the AI yourself.

FotoFinder Academy

Here you can find information about upcoming training courses, the FotoFinder Academy.

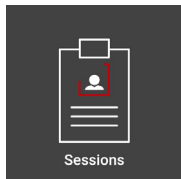
AI Contributor

Doctors who want to contribute to the continuous improvement of FotoFinder AI can contact us here.

FotoFinder Newsflash

Here you will find the latest information about the FotoFinder Hub, the app, or other updates.

3.8 Sessions



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

- Capturing date and
- Patients.

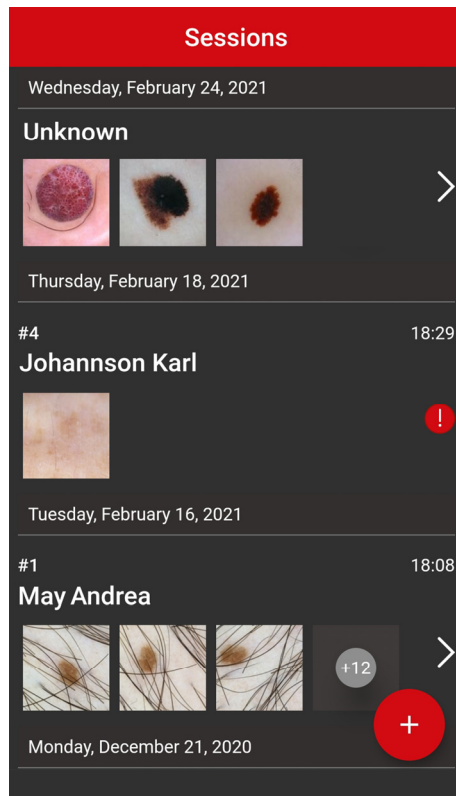


Fig. 10: Example view of the Sessions



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. chapter 3.8.2 Assigning images to a patients afterwards).



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.

3.8.1 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:

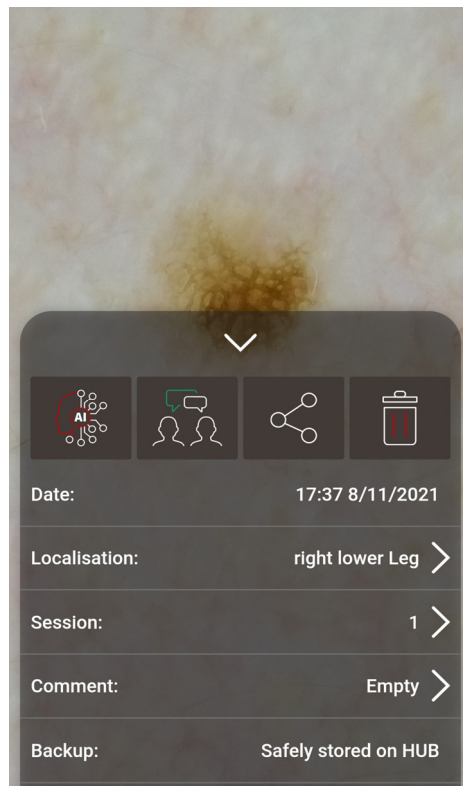
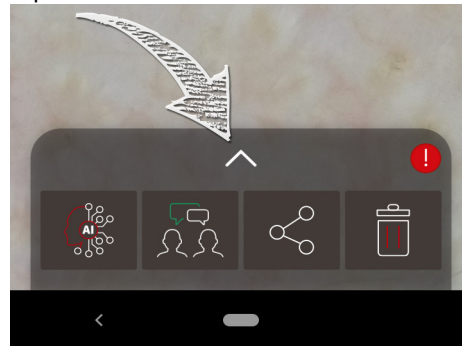


Fig. 11: Example view of the full screen mode with additional details

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 3.6 AI Screening).



Tap on this icon to be led directly to the Second Opinion request (cf. chapter 3.10 Second Opinion).



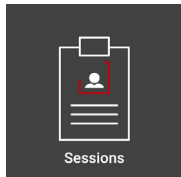
Tap this icon to share the images, for example as an email attachment.



Tap this icon to delete the selected image.

3.8.2 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:

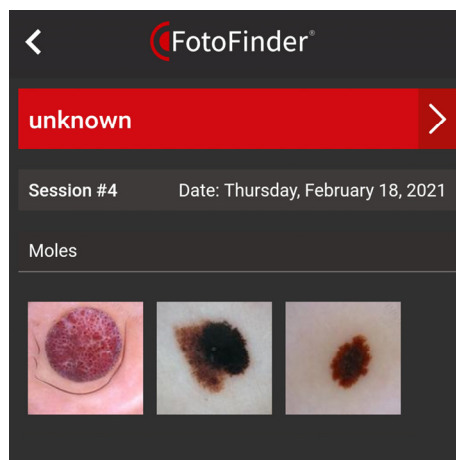


1. Tap on *Sessions*.

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.



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 (cf. chapter 3.11 Adding a new 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*.

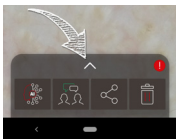
Fig. 12: Example view of a session without patient assignment

3.8.3 Saving the localization

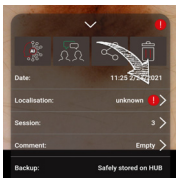
NOTE

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

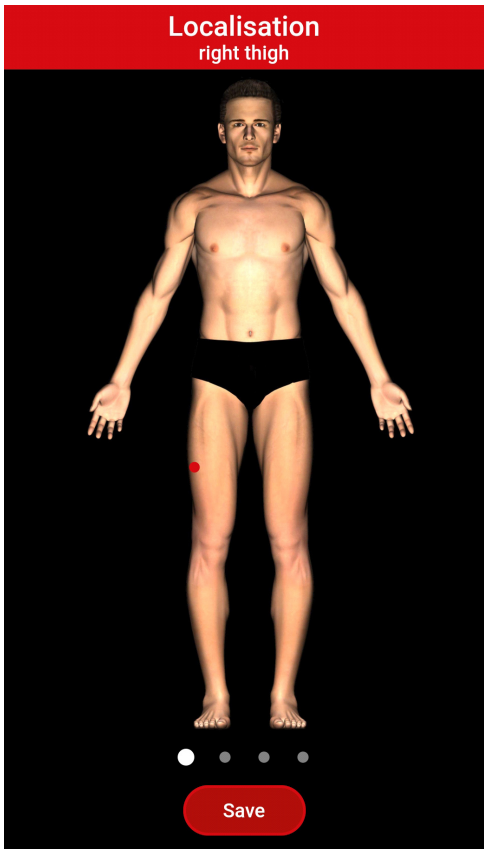
- 1. Open the image overview, for example, via the start menu buttons *Sessions* or *Images*.
 - 2. Tap on the respective image.
- The full screen view will open.



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



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



The localization menu will open.

- 5. Select another body view by swiping to the right or left as required.
 - 6. Tap on the corresponding body part.
- The body location is indicated by a red dot and is also listed above the virtual patient.
- 7. Tap on *Save*.

The selected localization is now saved in the image details.

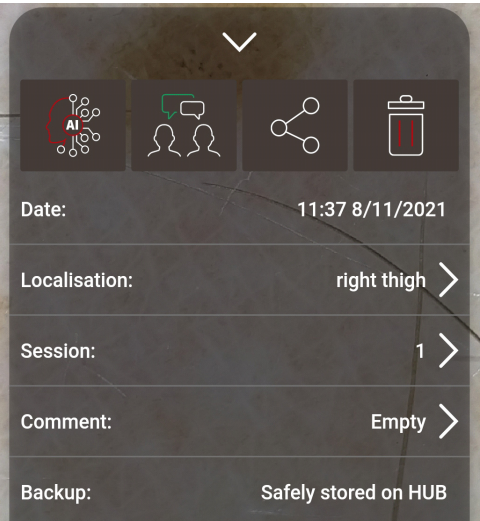
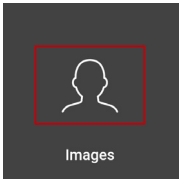


Fig. 13: Example view of the localization menu

3.9 Images












Under *Images* you will find an overview of the created images, sorted by date. Tap on one of the images (cf. chapter 3.8.1 Open and edit capturing in full screen mode) to enter full screen mode.

3.10 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.

Second Opinion			
Inbox 0/36		Pending 0	
	Johannson Karl	765jhg	
	Case ID#:	20-07-01-C00005	1
	Date	15:50 7/1/2020	
	Purgen Franz	POLXERAWP1	
	Case ID#:	19-10-03-C00003	1
	Date	19:24 10/3/2019	
	Purgen Franz	POLXERAWP1	
	Case ID#:	19-10-03-C00002	1
	Date	19:21 10/3/2019	
	Maler Sophie	6	
	Case ID#:	19-06-28-C00001	1
	Date	12:30 6/28/2019	

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.

Fig. 14: Example view of the *Second Opinion* overview

3.10.1 Requesting a Second Opinion



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

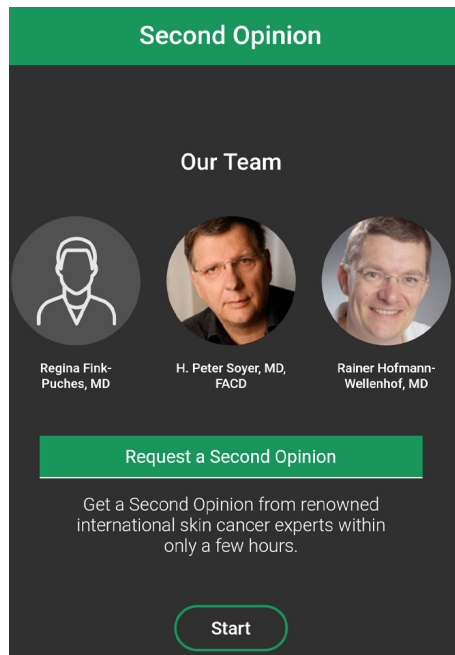


Fig. 15: Second Opinion Intro window

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.

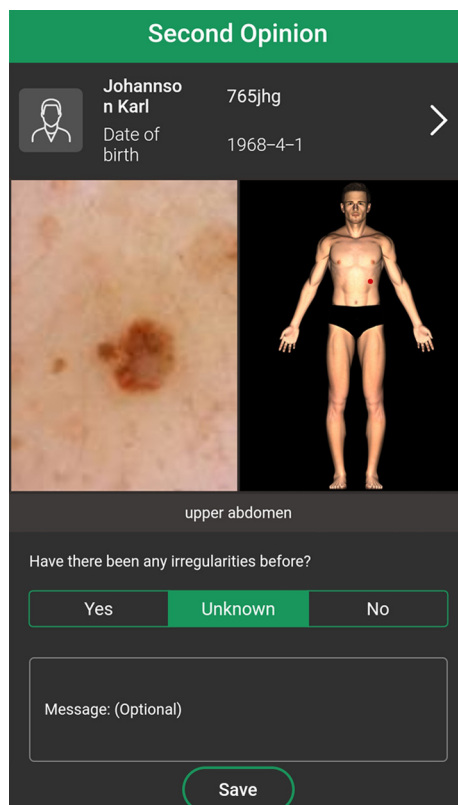


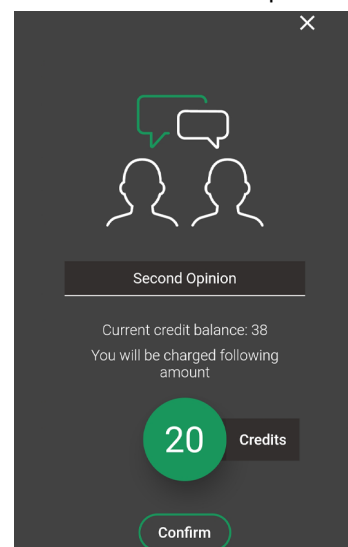
Fig. 16: Second Opinion input window

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.



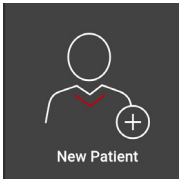
7. Tap *Confirm* if you want to continue.
To cancel, tap the X in the upper right corner.
You will receive a response within 24 hours.

3.10.2 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.

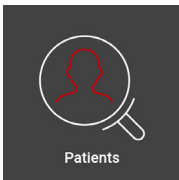
3.11 Adding a new patient



Here you can create new patients.

1. Tap on *New patient* in the start menu.
An input mask opens.
2. Enter all patient data.
3. Tap on *Save*.
The new patient is now created.

3.12 Patients



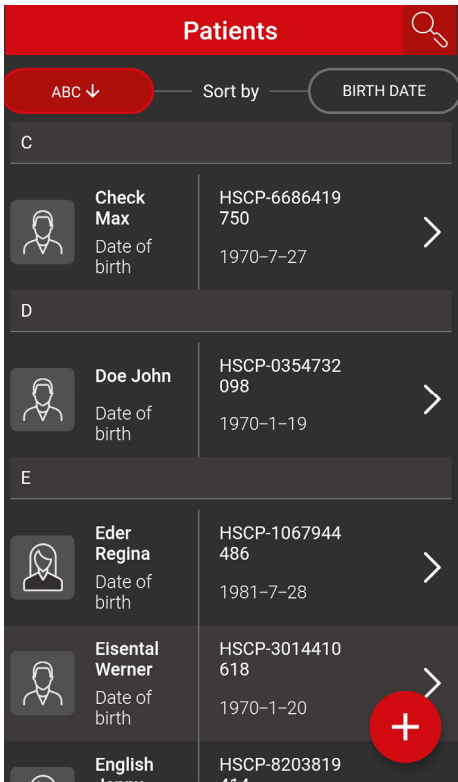
Tap on *Patients* in the start menu to get to the patient administration.

3.12.1 Adding a new patient



- In patient administration, you can enter new entries the same way (cf. chapter 3.11 Adding a new patient) as in the *New patient* menu.
1. In the patient administration, tap on the red plus at the bottom right.
An input mask opens.
 2. Enter all patient data.
 3. Tap on *Save*.
The new patient is now created.

3.12.2 Patient overview



When you start patient management, the patient overview will first appear.

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

A search bar at the top is also available.

Fig. 17: Example view of the patient overview

3.12.3 Opening a patient file

1. Open the patient overview.
2. Tap on a patient name.

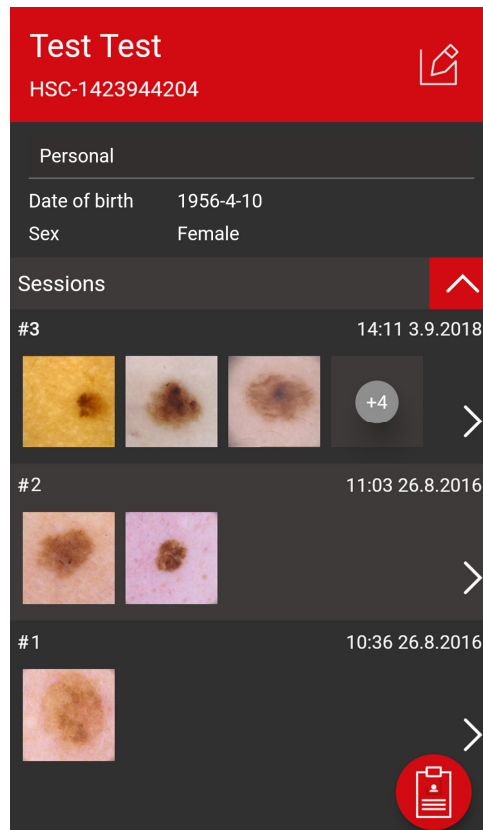


Fig. 18: Example view of a patient file

The patient file will open.

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

Opening an imaging session

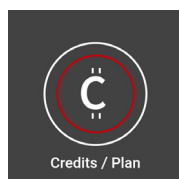
By tapping on a session, it will be opened in the detail view and all images of this session will be displayed. There you can also open individual images in full-screen mode and edit them further.

Switching to capturing mode



Tap the icon at the bottom right to go directly to (cf. chapter 3.5 New session) the capturing mode.

3.13 Credits / Plan

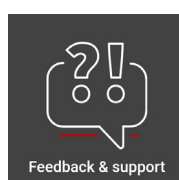


For the AI Score request (cf. chapter 3.6 AI Screening) and for the Second Opinion request (cf. chapter 3.10 Second Opinion) so-called credits are required. You can purchase these credits through your Hub account.

At *Credits / Plan* you can find

- the stand of your existing credits
- the possibility to buy additional credits
- info about your Hub account, e.g.:
 - active Plan (e.g. *Pro*)
 - image storage space used
- info about the device you are using
- a link to the Hub

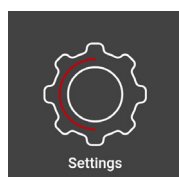
3.14 Feedback & Support



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.

3.15 Settings



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

- **Security**
If desired, you can store a PIN for running the FotoFinder **handyscope** app here to protect your patient data from unauthorized access.
- **Camera**
Here you can change the zoom value of the camera.
- **Bluetooth**
Here you can establish the Bluetooth connection to your **handyscope**.
- **Mobile data synchronization**
If you activate this function, synchronization of your device with your Hub account will also take place via mobile network. This may include additional costs with your data provider. Otherwise, synchronization only takes place when connected via WLAN.

In addition, you can find information on data privacy, our terms and conditions, and contact details in this section.

4 Appendix



KONFORMITÄTSERKLÄRUNG

DECLARATION OF CONFORMITY
DECLARATION DE CONFORMITE
DICHIARAZIONE DI CONFORMITA
DECLARACIÓN DE CONFORMIDAD

FotoFinder Systems GmbH
Industriestraße 12
84364 Bad Birnbach
Deutschland

Wir erklären hiermit in eigener Verantwortung, dass nachstehendes Produkt

We declare under our sole responsibility that the product

Nous déclarons sous notre propre responsabilité que le produit

Dichiariamo sotto nostra responsabilità che il prodotto

Declaramos bajo nuestra exclusiva responsabilidad la conformidad del producto

FotoFinder handyscope App

der Klasse / of class/ de la classe / della classe/ de la clase : 1
(93/42 EWG / EEC / CEE)

der Klasse / of class/ de la classe / della classe/ de la clase : A
(IEC 62304:2006)

allen Anforderungen der Medizinprodukterichtlinie 93/42 EWG sowie der IEC 62304:2006 Medical Device software - software lifecycle processes entspricht, die anwendbar sind.

meets all requirements of the directive 93/42 as well as the IEC 62304:2006 which apply to it.

remplit toutes les exigences de la directive sur les dispositifs médicaux 93/42 CEE et IEC 62304:2006 qui le concernent.

soddisfa tutte le disposizioni della direttiva 93/42 CEE e IEC 62304:2006 che lo riguardano.

al que se refiere esta declaración, con las disposiciones aplicables de la 93/42 CEE y IEC 62304:2006.

Konformitätsbewertungsverfahren:/ Conformity assessment:/ Procédure d'évaluation de la conformité:/
Procedimento di valutazione della conformità:/ Procedimiento de Valoración de Conformidad:
Annex VII, 93/42 EWG / EEC / CEE

Bad Birnbach, 25.05.2021


Julian Mayer, Authorized Officer