



# FotoFinder **Hub**

## **Original user manual**

Software

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# FotoFinder Hub

## Original user manual



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



Manufacturer  
FotoFinder Systems GmbH  
Industriestraße 12, 84364 Bad Birnbach, Germany  
[www.fotofinder.de](http://www.fotofinder.de)  
[www.fotofinderhub.de](http://www.fotofinderhub.de)

Contact [info@fotofinder.de](mailto:info@fotofinder.de)

Support [support@fotofinder.de](mailto:support@fotofinder.de)

Phone: +49 (0) 8563 – 97720-0

Fax: +49 (0) 8563 – 97720-10

Tel.: +49 (0) 8563 – 97720-45

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## 1 About these operating instructions

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

- The product can only be used, operated and maintained properly and safely with the help of this user manual.
- This user manual refers only to the product indicated on the cover sheet.
- We reserve the right to change this user manual due to further technical developments.
- The operator must ensure that the user manual is read and understood by all persons concerned prior to work.
- The chapter on *Safety* (cf. chapter 3 Safety) 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

The FotoFinder Hub is a web-based application. The release of new software versions is exclusively managed by FotoFinder and published once available. No updates or installation are required for FotoFinder Hub, the latest released version can be accessed using the domain [hub.fotofinder.de](https://hub.fotofinder.de).

Deinstallation does not apply to the web-based application. In order to terminate the Hub service, the user must delete its account. Please make sure to store and export all relevant data from your account before deleting it. Cached data is deleted along with the account.

### 2.1 System requirements

#### 2.1.1 Physical Parameters

Environmental light conditions must allow for the handling of the application, i.e. image viewing, image modification and entering data. The workplace should avoid direct sunlight, reflections on the screen and inappropriate settings regarding contrast, lighting or color. The display used for displaying FotoFinder Hub must be aligned horizontally.

FotoFinder Hub can be opened on any device with a minimum screen size of 300 pixels. The recommended resolution is 1920 x 1080 pixels. No further restrictions are applicable.

#### 2.1.2 Social and Mental Environment

The social and mental environment must allow the user to operate the application without the negative influence of stress or distractions. No further restrictions are applicable.

#### 2.1.3 Supply Engineering

The applications require the following IT environment:

Operating system:

Web-based application, supports browsers with macOS and Windows operating system

Supported browser bases:

- Brave
- Firefox
- Chromium
- Safari

Hardware minimum requirements:

PC, smartphone or tablet meeting the following requirements:

- Display with a minimum of 300 pixel, recommended resolution: 1920 x 1080 pixel
- Uses a supported browser (base)
- Internet connection for Login, Synchronization, Second Opinion and AI Score

If the hardware device Hub is used with is also used in combination with FotoFinder mobile, please see the additional hardware requirements for FotoFinder mobile.

## 2.2 Considerations for IT-Security

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

### 2.2.1 Password

Authorization mechanisms are applied via log-in with e-mail and password. 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. In addition, passwords 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 regularly.

### 2.2.2 Access Protection

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

### 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

FotoFinder Hub serves as backup for synchronized data, e.g. from FotoFinder mobile applications. Backups are performed exclusively via MongoDB Atlas and Amazon AWS S3 (for details see chapter *Data storage*).

### 2.2.5 Support

In the event of problems with the software, you can contact the FotoFinder Support at [support@fotofinder.de](mailto:support@fotofinder.de).

### 2.2.6 Security patches

In case of security-relevant updates of FotoFinder software, the update is automatically published and directly available to the user via the web-browser. Internet is required to access FotoFinder Hub and its latest versions.

### 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

### 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 Hub 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 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 for mobile clients, the Android/iOS default specifications are applied. Additional firewall rules are applied for Hub via Amazon WAF configurations.

### 2.2.11 Network data streams

Communication with software clients / API clients

Data is synchronized with the FotoFinder Hub via an Internet connection (Ethernet or Wi-Fi). The application is publicly accessible. Communication to clients is realized via REST API. Data being sent from clients to Hub is encrypted according to https specification, TLS version 1.2 or higher / SSL version 2. Security strength is according to https specification; the client verifies SSL certificates of Hub (one-way). Data between clients is exchanged in JSON format (via API v2). The exchanged data contains license/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. Data between web browsers is exchanged via HTML content.

#### Communication with Amazon AWS

The AWS SDK internally uses HTTPS (REST API over TCP/IP) to communicate with Amazon S3. For MongoDB Atlas, the application connects via the MongoDB Wire Protocol over a secured TCP/IP connection using TLS encryption. Data being exchanged with Amazon AWS is encrypted according to https specification, TLS version 1.2 or higher / SSL version 2. Hub verifies SSL/TLS certificates provided by Amazon. Amazon S3 receives or exchanges binary data (images) encrypted via HTTPS / TLS. Data between MongoDB Atlas and Hub is exchanged in JSON format and is encrypted via TLS and at rest (AES-256).

#### Communication with external services

External service calls **Hub's** web API via internet (Wi-Fi/ethernet) to login, then retrieves image files and meta data using an API Key which is granted after logged in with Hub user credentials. Protocol is https, data being exchanged between external services is encrypted according to https specification (supports TLS 1.2 and higher). External services verify Hub's certificate according to https standard. External service downloads microscopic image as JPEG file from Hub and image metadata as XML files. External service retrieves and displays Hub account information, all via https.

### 2.3 Compatible FotoFinder Hardware

The software is intended for connectivity with the following accessories and other (medical) devices and products:

- FotoFinder mobile (variant: handyscope pro)
  - DermLite handyscope
  - Commercial smartphones and tablets that meet the system requirements (see handyscope pro manual)
  
- FotoFinder mobile (variant: skeen):
  - FotoFinder skeen (hardware device) with lens attachment and charging station (see FotoFinder skeen manual)
  
- meesma (no medical device, only for Aesthetics)

## 3 Safety

### 3.1 Intended use

FotoFinder Hub is a cloud-based image storage platform for mobile dermatoscopes. The purpose of FotoFinder Hub is to store and display images, patient information and analysis results. FotoFinder Hub is intended for the documentation of microscopic and macroscopic images of the intact human skin and to visualize skin changes over time. The FotoFinder Hub is not intended to provide a diagnosis, as it is the responsibility of the physician. FotoFinder Hub is intended to communicate with other FotoFinder software and exchange data. The FotoFinder Hub is intended to administer subscription and user management.

### 3.2 User groups

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

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

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. chapter 3.2 User groups).
- There are no additional requirements for the social or clinical environment of use.
- The product is not intended for use by laypersons.

### 3.4 Patient population

The software can be used to treat patients who fulfil the following criteria:

#### Indications

- Patients with skin lesions, moles in general
- Patients with multiple naevus syndrome
- Patients with generalised skin inflammation
- Patients with psoriasis vulgaris
- Patients suffering from scalp-related disorders

#### Mental illnesses

- No restrictions

#### Physical prerequisites

- The parts of the body / lesions to be examined must be free of open wounds or injuries.
- The parts of the body / lesions to be examined must not be located in body orifices or mucous membranes.

The intended patient population includes patients regardless of demographic factors (e.g. sex, age, occupation), physical factors (e.g. height, weight, strength) or social, religious and cultural background. It is possible to document different skin types within the FotoFinder software.

### 3.5 Indications and contraindications

#### Indications

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

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

*Tab. 1: Indications*

## Contraindications and exclusions

In general:

The software is not intended for storing images of mucous membranes, eyes, natural or artificial orifices or injured skin or to support initial assessment.

The software does not diagnose diseases. Diagnosis is the responsibility of the medical professional!

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

The AI Score is only able to evaluate lesions with a diameter of 2 mm to 20 mm.

Do not use the AI Score for the evaluation of lesions in a hairy area or in locations near contaminations or markings (e.g. tattoos) within an area of 30 mm.

The algorithm was trained with images of Fitzpatrick skin type I-III. Do not use the AI Score on patients with skin type IV or higher, as the performance of the algorithm was not assessed and therefore the accuracy of the algorithm cannot be claimed.

## 3.6 Clinical Benefits

With the FotoFinder Hub, the following clinical benefit for the user/patient is aimed:

The software allows patient management as well as the secure storage, documentation and analysis of dermoscopic images. This enhances the detection and accuracy of the physician's ability to localize changes and differences of skin lesions. The identification of such changes supports early skin cancer detection.

Users can upload an image with unclear diagnosis to the Second Opinion service in order to receive a Second Opinion from a specialist in dermoscopy (tele-dermatology service). This service supports medical professionals to conclude a correct diagnosis.

The analysis of a lesion by artificial intelligence algorithm (convolutional neural network – CNN) provides more information about the lesion and its potential to be malignant to support the medical professional in their decision.

### Performance characteristics

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

- Diagnostic accuracy of teledermatologists is improved compared to face-to-face dermatologists

## 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.

### 4 FotoFinder Hub®

#### 4.1 FotoFinder Hub login

1. Open the website <https://hub.fotofinder.de>.

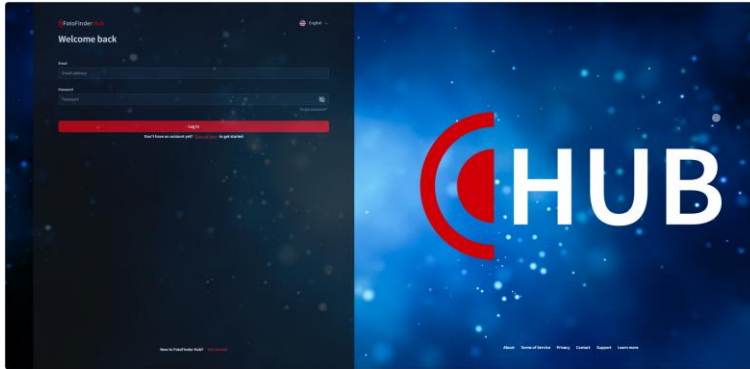


Fig. 2: FotoFinder Hub login page

To use FotoFinder Hub, you need a FotoFinder Hub account.

##### 4.1.1 Creating a new FotoFinder Hub account

2. Click on *Log in here*.

The input screen for new users opens.

3. Complete all fields.

4. Tick the box for the *reCAPTCHA* query ("I am not a robot").

This opens the automatic test used to identify you as a human and prevent automated bots from accessing the website.

5. Follow the instructions on the screen and click on *CONFIRM*.

If the test is completed without errors, you are returned to the input screen and the *reCAPTCHA* field is marked with a green tick.

6. Confirm

- the Terms and Conditions, as well as the Privacy Policy and
  - the General Terms and Conditions
- by ticking the box to the left of each of them.

7. Click on *Register*.



You will receive a registration e-mail with a link to your specified e-mail address.

8. Click on this link in the e-mail.

The FotoFinder Hub login page opens. Your registration is now complete. You can log in to the FotoFinder Hub with the newly created account.

##### 4.1.2 Logging in with an existing FotoFinder Hub account

2. Enter your registered e-mail address and password on the website <https://hub.fotofinder.de>.

3. Click on *Log in*.

This will open the FotoFinder Hub user interface.

## 4.2 The Desktop

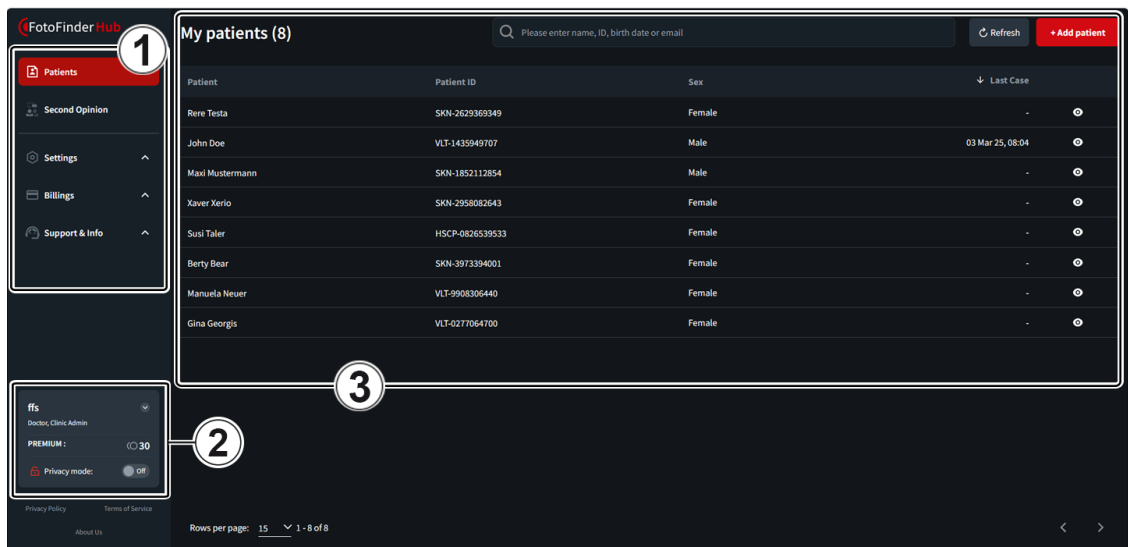


Fig. 3: Example view in the FotoFinder Hub

- 1 Main menu
- 2 User data and account information
- 3 Viewing and editing section

## 4.3 Patients



Click on *Patients* in the main menu on the left to open the patient list.

My patients (8)  Refresh + Add patient

Patient	Patient ID	Sex	Last Case
Rere Testa	SKN-2629369349	Female	-
John Doe	VLT-1435949707	Male	03 Mar 25, 08:04
Maxi Mustermann	SKN-1852112854	Male	-
Xaver Xerio	SKN-2958082643	Female	-
Susi Taler	HSCP-0826539533	Female	-
Berty Bear	SKN-3973394001	Female	-
Manuela Neuer	VLT-9908306440	Female	-
Gina Georgis	VLT-0277064700	Female	-

Fig. 4: Example view of a patient list

### 4.3.1 Privacy mode

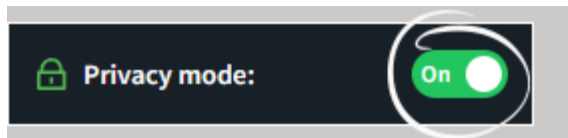
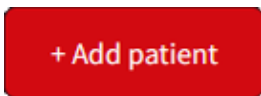


Fig. 5: View of Privacy mode button activated

Enable or disable *Privacy mode* here. If activated, only the first letters of the first and last names are shown in the patient overview and in the patient file.

### 4.3.2 Add new patient



1. Click on *Add patient* at the top right above the patients list. This opens an input mask.
2. Record all known patient data. Mandatory fields are marked with an asterisk (\*).
3. Click on *Save*.  
The patient has been created and the new patient file opens.

#### NOTE

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

- Sex
- ID

### 4.3.3 Searching for a patient



*Fig. 6: Patient search box*

1. Enter the surname, first name (or parts thereof), patient ID, date of birth or e-mail. When searching by name, hits from the patient list are displayed as you type.

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 NOTE

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If the *Privacy mode* (cf. chapter 4.3.1 Privacy mode) function is enabled, only the initials are displayed instead of the full name of the patient.

---

2. Click on a patient to access the respective patient file.

## 4.3.4 Patient file

All of a patient's data are stored in the patient file.

To open a patient file:

Patients

1. Open the patient list.
2. Click on the desired patient in the patient list.

This opens the patient file:

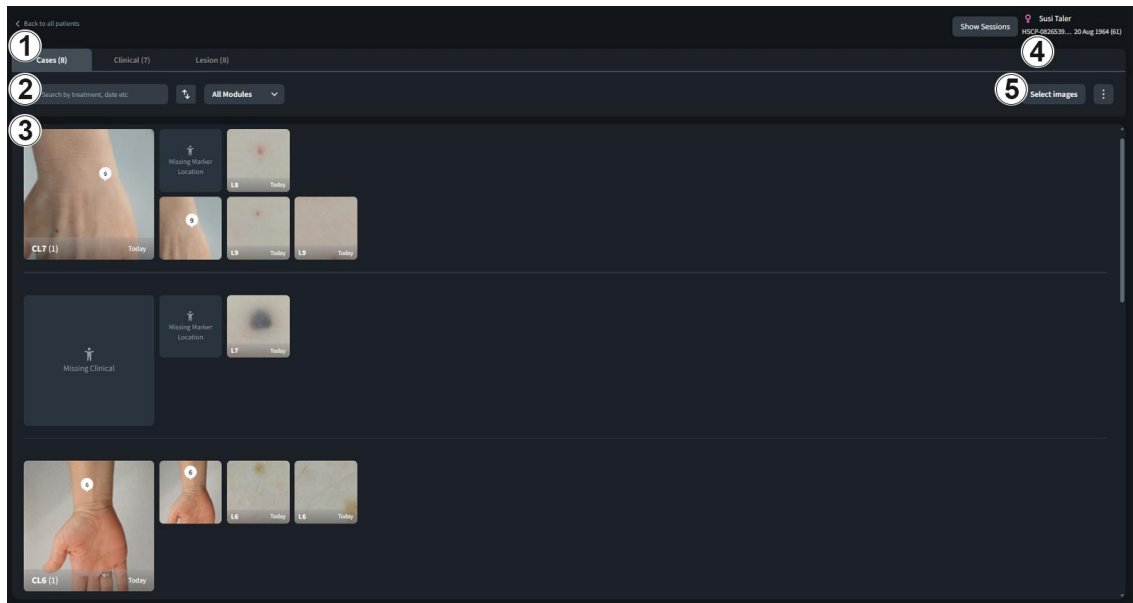


Fig. 7: Example view of a patient file

- 1 Filter by capture type  
Depending on your selection, not only the displayed captures but also the display tools are adjusted (see below)
- 2 Search field, sorting tool, filter by module (Dermoscopy, Aesthetics)
- 3 Image preview area
- 4 Patient data
- 5 Image selection button and functions menu (cf. chapter 4.3.4.1 Image selection button and functions menu)

Explanation of abbreviations:

You will see various abbreviations in the image names of saved captures:

CL: Clinical Image - clinical overview image

L: Lesion – micro image capture

The type of the display and other buttons depends in part on the selected filter (e.g. Clinical or Lesion).



Fig. 8: Example view from a patient file with captures from Dermoscopy

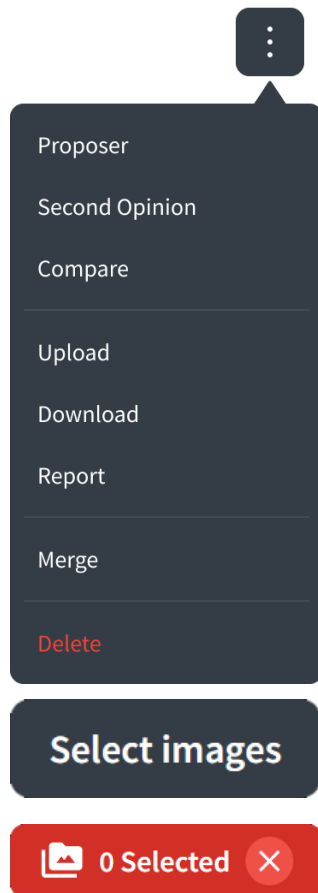
- 1 Clinical image with two markers (numbers 4 and 5)
- 2 Localisation of the marker
- 3 associated micro images of the lesions (L4 and L5)

In the *Clinical* and *Lesion* views, these three buttons are also available for selecting a view:



- List view
- Grid view
- Body localisation view (images are only displayed if a localisation has already been assigned to them).

### 4.3.4.1 Image selection button and functions menu



Click on the three dots to open the functions menu. At least one image must be selected for the functions. Multiple selection is also possible.

1. Activate the image selection by clicking on the *Image Selection* button.

The button has now turned red and a small white circle can be seen in each preview image.

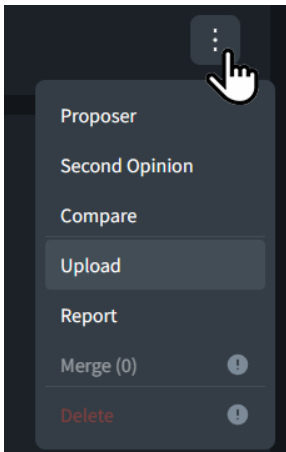
2. Click on the white circles of the desired images to select them.
3. Select the desired action in the functions menu. Only the previously selected images will be considered.

### 4.3.5 Manually uploading images to the Hub

*(not included in every subscription plan)*

You can upload images in jpg, jpeg or png formats to the FotoFinder Hub.

1. Open the desired patient file (cf. 4.3.4).
2. Click on the three dots to open the functions menu and select *Upload*.



This opens the Upload screen.

3. Select whether your images should be assigned to the Dermoscopy or Aesthetics module. Your selection will then start accordingly in the following screen.

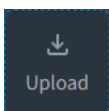
The cases are marked with the respective symbol:



Dermoscopy case



Aesthetics case



4. Depending on whether you want to upload a clinical image or a capture of a lesion, click on the *Upload* button in this area. You can select several images of a patient one after the other.

#### NOTE

Related images (clinical image & captures of lesions in this area) can be precisely assigned using markers on the clinical image (cf. chapter 4.5 Marker).

Upload

5. After selecting the images, click on the upload button below.

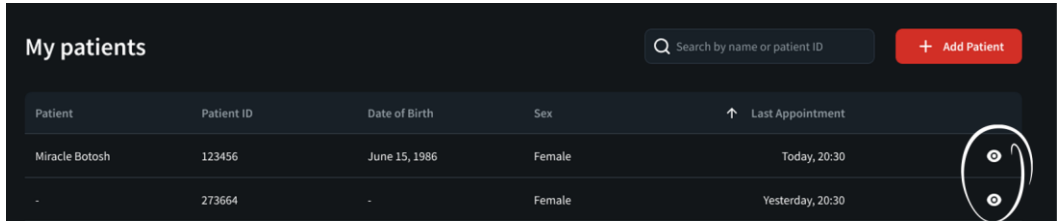
The uploaded images are created in the patient file as a new case or new cases.

## 4.3.6 Editing a patient profile

To view and, if necessary, edit a patient profile, there are two ways to get there:

 Patients

1. Open the patient list (cf. chapter 4.3 Patients).
2. Click on the eye symbol at the end of the line:



Patient	Patient ID	Date of Birth	Sex	↑ Last Appointment
Miracle Botosh	123456	June 15, 1986	Female	Today, 20:30
-	273664	-	Female	Yesterday, 20:30

This opens the patient profile.

3. Proceed as guided by the menu.

Alternatively:

1. Open the desired patient file (cf. chapter 4.3.4 Patient file).
2. Click on the patient's name at the top right.
3. Proceed as guided by the menu.

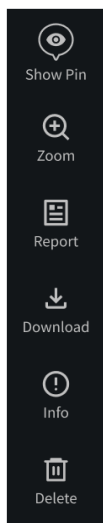
## 4.4 Working with the images

### 4.4.1 Detailed view of captures

1. Open the desired patient file (cf. chapter 4.3.4 Patient file).
2. Click on an image.

The detailed view of the image opens.

Additional functions are available in the detailed view:  
Display and editing tools (on the left-hand side of the screen)



- Show Pins: Showing and hiding markers in clinical overview captures (clinical images)

#### NOTE

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No empty markers are shown in the Hub, only markers with assigned captures!

---

- Zoom: Enlarges the displayed capture
- Report: Creates a PDF file with the existing image information (not included in every subscription plan)
- Download: Downloads images
- Info: Shows capture information (e.g. recording device, zoom level, lighting)
- Delete: Deletes image

Further captures (below the preview image)

- If several follow-ups of the selected capture already exist, these are displayed below the preview image.
- If you click on a marker in the preview image, the captures assigned to it are displayed below the preview image.

## 4.4.1.1 Detailed clinical image

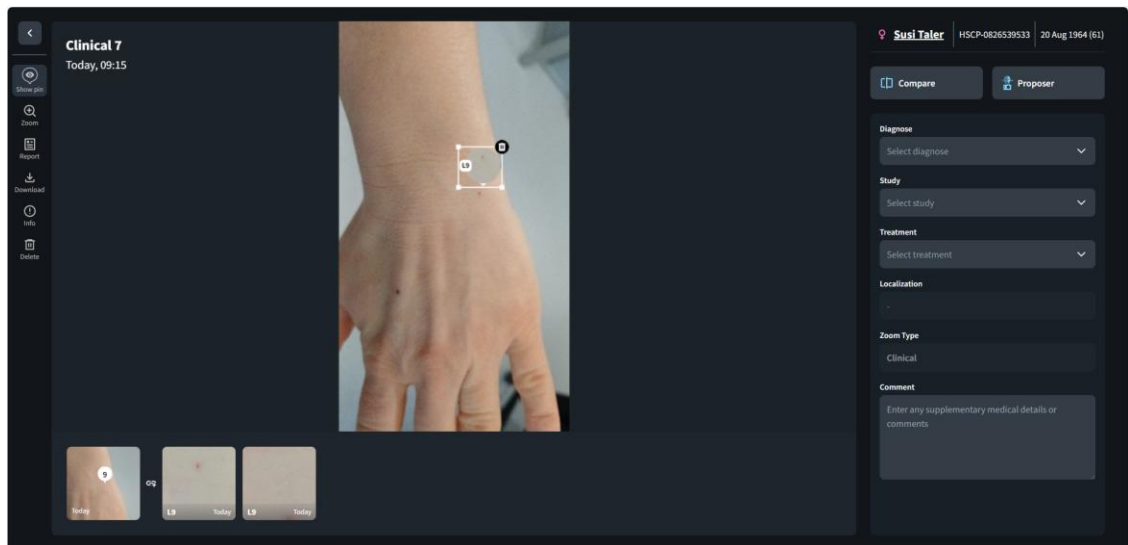


Fig. 9: Example of a detailed clinical image

Additional functions (on the right-hand side of the screen):



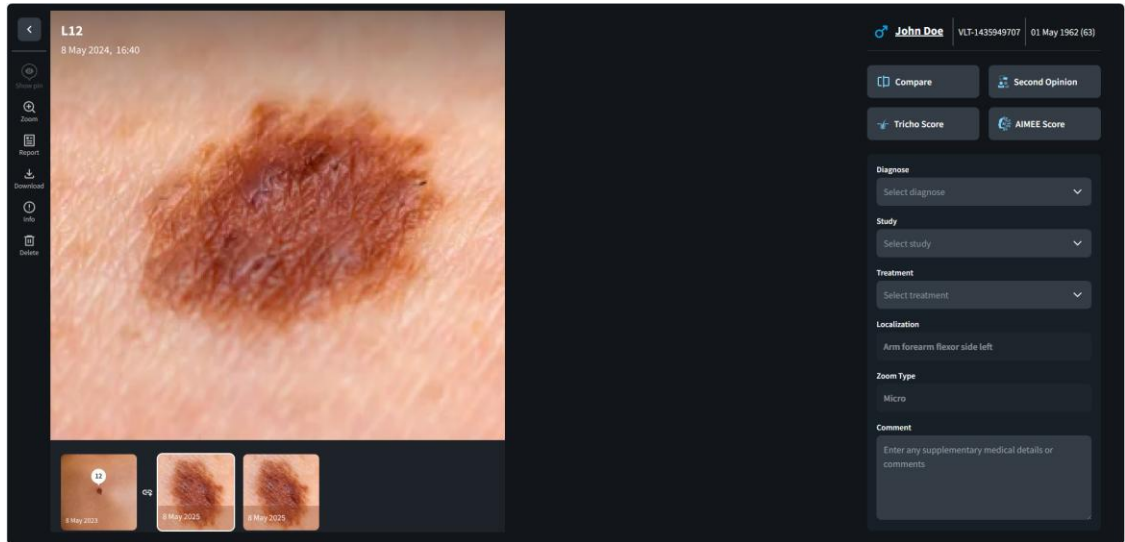
-  **Compare** Image comparison  
(cf. chapter 4.5.2 Image comparison)
-  **Proposer** Proposer  
(cf. chapter 4.8 Proposer)

Image information (on the right-hand side of the screen)

You can add further image information, such as diagnosis, study, treatment or a comment in various fields on the right-hand side.

#### 4.4.1.2 Detailed micro image



*Fig. 10 Example of detailed micro image*

Additional functions (on the right-hand side of the screen):





-  **Compare** Image comparison  
(cf. chapter 4.5.2 Image comparison)
-  **Second Opinion** Second Opinion service  
(cf. chapter 4.7 Second Opinion)
-  **Tricho Score** Tricho score
-  **AIMEE Score** AIMEE score  
(cf. chapter 4.6 AIMEE Score (AI Score))

Image information (on the right-hand side of the screen)

You can add further image information, such as diagnosis, study, treatment or a comment in various fields on the right-hand side.

## 4.5 Marker

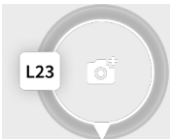
Markers can be used to mark skin areas on clinical images for microscopic examination and to assign existing lesion images.

### NOTE

Assignment is only possible if the images are assigned to the same case. You can see this in the patient file.

Setting a marker and assigning a micro image

1. Open the clinical image in which you want to set a marker.
2. In the clinical image, click on the area where you want to set the marker.



A blank marker has now been added at this position. The numbering is consecutive. If captures of lesions are available for the current case, these are displayed below the preview image.

3. Drag and drop the capture of the lesion from below onto the empty marker.



The lesion is then assigned to this marker and can be seen reduced in size.

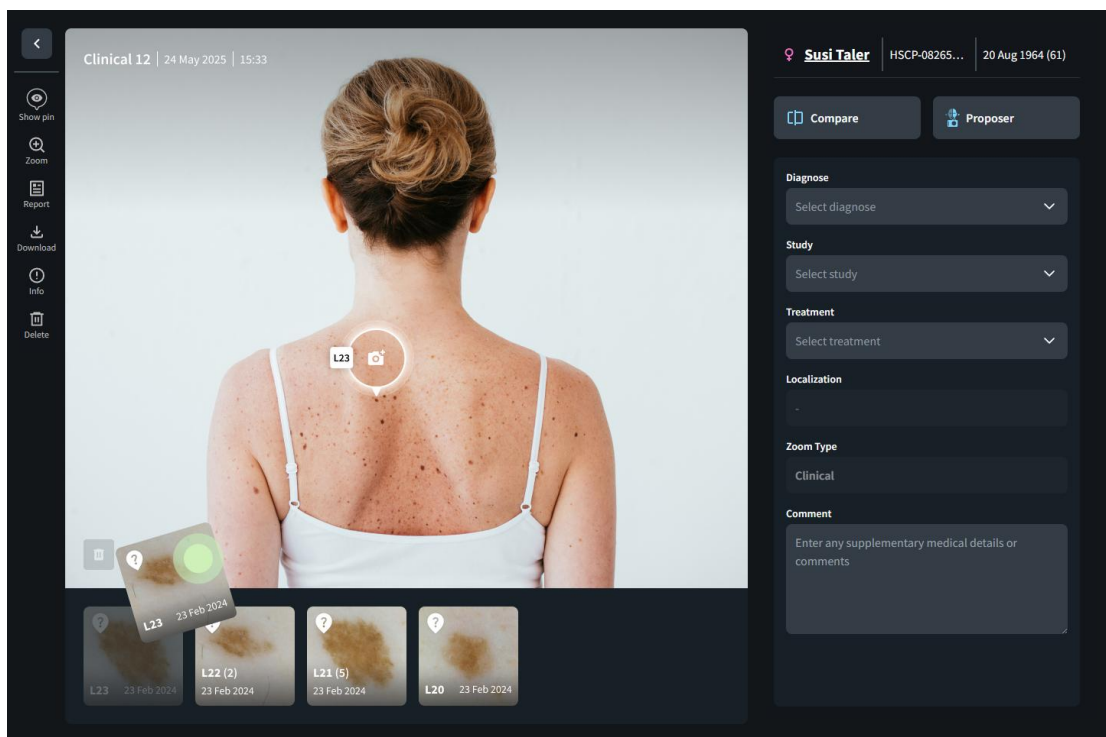


Fig. 11: Example view of assigning a marker to a micro image using drag and drop

### NOTE

You can move the position of a marker using drag and drop.

### NOTE

Empty markers are not saved in the FotoFinder Hub.

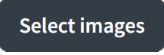
Any empty markers that may exist from other applications (e.g. the FotoFinder skreen app) are not displayed in the FotoFinder Hub.

## 4.5.1 Creating a report

*(Not included in every subscription plan)*

You can use this function in the patient file or in the detailed view of an image.

In the patient file:



Select images

1. Select the desired images by placing a tick directly in the respective image (cf. chapter 4.3.4.1 Image selection button and functions menu).
2. Open the functions menu and select *Report*.



This opens a PDF file with the previously selected images and the available image information.

In the detailed view:



Report

1. Click on *Report* in the display and editing tools on the left-hand side of the screen.

This opens a PDF file with the image and the available image information.

## 4.5.2 Image comparison

*(Not included in every subscription plan)*

You can use this function in the patient file or in the detailed view of an image.

In the patient file:

Select images

1. Select the desired images by placing a tick directly in the respective image (cf. chapter 4.3.4.1 Image selection button and functions menu).
2. Open the functions menu and select *Compare*.



This opens the image comparison screen.

In the detailed view:

Compare

1. In the functions on the right, click on *Compare*.

This opens the image comparison screen.

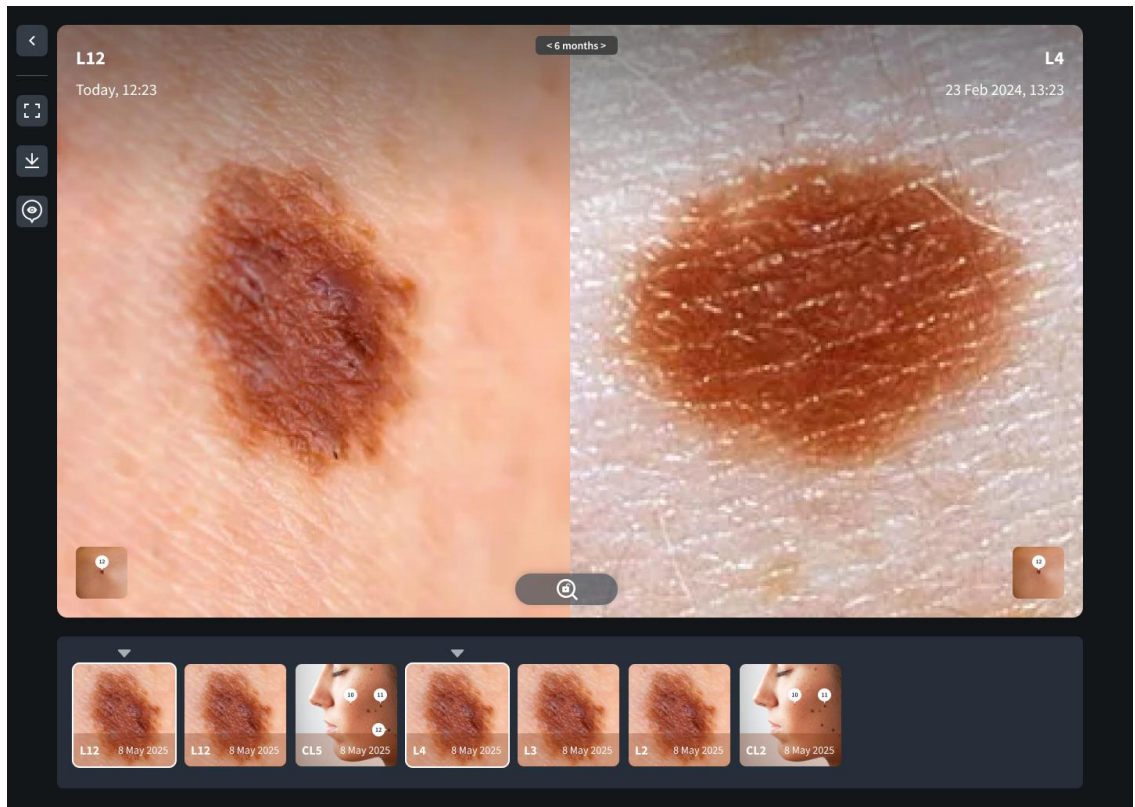


Fig. 12: Example view of image comparison

- You can drag and drop other images from the gallery into one of the two preview windows at the top.
- You can move one of the images individually by clicking and holding down the left mouse button.

Image comparison functions:



The Back arrow takes you back to the patient file.



Full screen mode

The gallery is hidden and the two preview windows are enlarged to cover the entire screen. Click again to close the full-screen view.



Download button



Showing and hiding markers



Zoom Lock

This function is activated by default when calling up the image comparison. This allows you to zoom in and move both captures at the same time. This also enables an objective comparison of the images. Without *Zoom Lock*, you can display both images independently of each other.

### 4.5.3 Subsequently reassigning and saving captures (Merge function)

You can reassign saved captures at a later date. This may be necessary if, for example, an image was incorrectly assigned or several markers with captures were inadvertently created for a lesion.

#### NOTE

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A maximum of 5 images can be merged simultaneously.

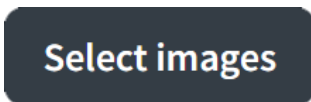
---

#### NOTE

---

Only images of the same capture type can be merged (e.g. overview images with overview images (clinical images) or micro images with micro images).

---



1. Open the patient list.
2. Click on the desired patient in the patient list.  
This opens the patient file.
3. Click on the image selection button.  
The button has now turned red and image selection is active. The images that belong together must be selected.
4. Select the desired images by placing a tick directly in the respective image.
5. Open the functions menu and select *Merge*.  
This opens a dialogue box showing you the possible merges for your selected captures. If you click on one of the options, you can already see in the preview what the merge will do for this selection.
6. If you are happy with the selection, click on *Merge* in the dialogue box at the bottom.  
The captures are now assigned according to your selection.

#### 4.5.4 Downloading images

You can use this function in the detailed view or in the image comparison.



1. Click on the download button on the left-hand side of the screen next to the display and editing tools.

The download starts and its progress is displayed.

### 4.6 AIMEE Score (AI Score)

#### 4.6.1 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

The FotoFinder Hub offers you the option of letting Artificial Intelligence view the lesions after the image has been taken. The system uses a Convolutional Neural Network (CNN) algorithm, the so-called AI Score. The sensitivity and specificity of the algorithm were demonstrated in a clinical study.

#### NOTE

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

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- The AI Score is based on comparisons with images of malignant skin tumours (melanoma, basal cell carcinoma, lentigo maligna, squamous cell carcinoma, actinic keratosis). The score indicates the similarity of a lesion to typical malignant skin tumours.
- The AI Score is not used to assess the malignancy of the examined lesion! It merely provides an initial assessment of whether a lesion is potentially malignant.

#### NOTE

---

The AI Score is based on statistics. The accuracy of the AI Score can therefore not be guaranteed. It is intended as additional support for the doctor.

The AI Score is not a substitute for the doctor's complete clinical diagnosis!

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## 4.6.2 Get AI Score

### NOTE

The number of AI scores you can retrieve each month depends on your Hub subscription plan.

1. Click on the desired patient in the patient overview.  
This opens the patient file.
2. Click on the capture for which you would like to retrieve an AI score.  
This opens the detailed view of the capture.

### NOTE

The lesion must be completely visible in the capture.

 AIMEE Score

3. Tap on the *AIMEE* AI symbol.  
After a short loading process, the AI score is displayed.

### NOTE

Please also note the disclaimer.

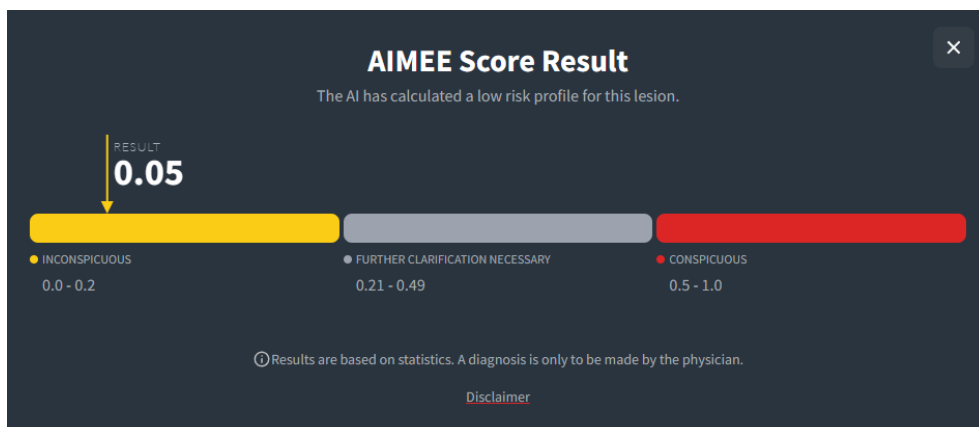
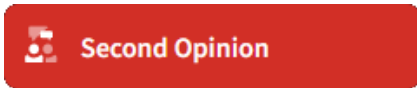


Fig. 13: Example view of the AI Score

## 4.7 Second Opinion

*(Not included in every subscription plan)*

A *Second Opinion* is an additional service available to you for a fee. You can request a Second Opinion from experienced international dermatologists.



Call up the Second Opinion service by clicking on *Second Opinion* in the main menu. This opens an overview. You can choose between two lists:

- *Inbox*: Here you can see all the Second Opinions you have already received.
- *Pending*: Here you can find your requested Second Opinions for which you have not yet received a response.

### 4.7.1 Requesting a Second Opinion

1. Open the patient file of the respective patient.
2. Select the micro image to be examined and click on it.

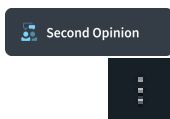
#### NOTE

You can also select several captures via *Image selection* (cf. chapter 4.3.4.1 Image selection button and functions menu). Please note that credits will be deducted for each analysed capture.

3. Click on *Second Opinion*.

You can find this button

- in single image view: on the right-hand side of the screen
- when selecting several images: in the functions menu.



This opens the request screen. The selected captures and the patient data are displayed in a new screen:

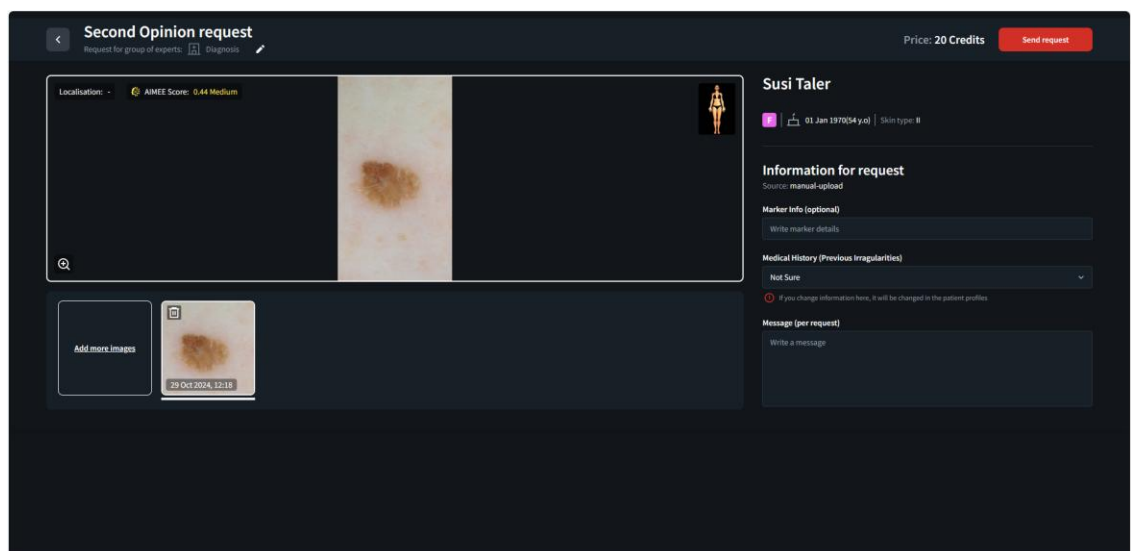


Fig. 14: Example view of requesting a Second Opinion

4. Optionally, enter further information to the right of the image.
5. Click on *Send request* at the top right.

You will receive a response within 12 to 48 hours. It usually takes fewer than 24 hours.

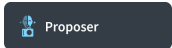
## 4.7.2 Opening Second Opinion

1. In the main menu, click on *Second Opinion*.

This opens the overview for the Second Opinion service.

2. Select the *Inbox* tab.
3. Open the received Second Opinion by clicking on the respective line.

## 4.8 Proposer



The Proposer is available as an additional application for images in the *Aesthetics* section. You can use it to clearly propose specific recommended products and actions to your patients. An extensive product and treatment database as well as various drawing and marking tools are also part of the Proposer.

Detailed instructions can be found in the separate FotoFinder aesthetics manual.

## 4.9 Transactions

### Transactions

You will find a list of your actions in the Hub in the *Transactions* section.

These include, for example:

- AI score requests
- Second Opinion requests or
- Voucher redemptions

It is possible to filter specific bookings.

The list can be exported as a PDF file or as a CSV file.

## 4.10 Settings



Another submenu is located in the Settings section:

### 4.10.1 My Account

Here you can find data for your user profile. You can also edit the data.

### 4.10.2 My Clinic

- Personnel  
Users with administrator rights can add further users here.
- Devices  
Here you can add devices to your Hub account and remove devices from the Hub.
- General information  
Here you can find the stored information about your clinic and your region. You can also define headers for your reports and save a clinic/practice logo for the reports.

### 4.10.3 My Devices

Here you can add devices to your Hub account and remove devices from the Hub.

### 4.10.4 Assessments

This allows you to pre-define lists of

- treatments
- studies
- diagnoses

and then select them from a list when capturing images.

### 4.10.5 Security

Here you can change your password. Updating your password will disconnect all linked devices.

### 4.10.6 Messages

Here you can activate an e-mail notification for feedback on Second Opinion requests.

### 4.10.7 Invoicing

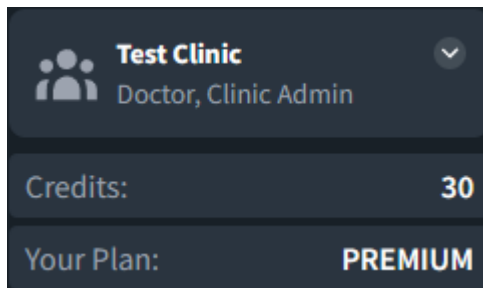
Here you can

- Call up invoices
- Redeem your activation code
- Change your subscription plan and find information on the individual plans
- View the memory space used
- View your current credits balance and purchase more credits.

You will also see a credits history that lists the credits and their use. Functions that you have already been able to use free of charge because they are included in your subscription plan are also displayed here.

## 4.11 User data and account information

This information is displayed at the bottom left.

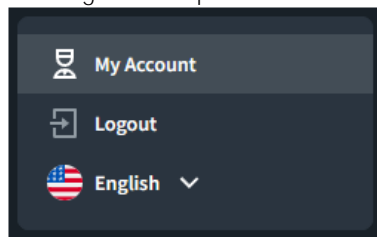


*Fig. 15: Example view of user data and account information*

The area is divided into three sections:

User data

Clicking on this opens an additional submenu:



- My Account  
Here you can find data for your user profile. You can also edit the data.
- Logout
- Language selection

Credits

Displays the current credits balance

Your Subscription

Displays the booked FotoFinder Hub subscription plan

## 4.12 About FotoFinder

 You will find this software area at the bottom left of the Hub home page.

Here you can view

- the privacy policy
- the service conditions
- the software information area with, for example,
  - the manufacturer's contact details
  - Details about the software version

Explanation of symbols:



CE mark



Manufacturer



Country of origin/date of manufacture



Serial number/software version



Medical device



Indicates the Swiss representative:

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



Unique Device Identification



Electronic user manual

eIFU indicator



UK conformity assessed

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



Homepage

## 5 Appendix



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### EU - KONFORMITÄTSERKLÄRUNG EU - DECLARATION OF CONFORMITY

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Hersteller / <i>Manufacturer:</i>	FotoFinder Systems GmbH
Adresse / <i>address:</i>	Industriestraße 12 84364 Bad Birnbach Deutschland/Germany
Single Registration Number (SRN):	DE-MF-000007084
Benannte Stelle / <i>Notified Body</i>	TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 München / Munich Germany
Zertifikations-Nr. / <i>Certificate No.</i>	G10 115802 0002

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

FotoFinder Hub  
Version: 2025.3

**Zweckbestimmung / *Intended Use:***

FotoFinder Hub is a cloud-based image storage platform for mobile dermatoscopes. The purpose of FotoFinder Hub is to store and display images, patient information and analysis results. FotoFinder Hub is intended for the documentation of microscopic and macroscopic images of the intact human skin and to visualize skin changes over time. The FotoFinder Hub is not intended to provide a diagnosis, as it is the responsibility of the physician. FotoFinder Hub is intended to communicate with other FotoFinder software and exchange data. The FotoFinder Hub is intended to administer subscription and user management.

der Risikoklasse / <i>of risk class:</i>	IIa (Annex VIII MDR)
Basis UDI-DI / <i>Basic UDI-DI:</i>	426015845HUB001ZS

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

Konformitätsbewertungsverfahren / <i>Conformity assessment</i>	(EU) 2017/745, Annex IX Chapters I & III
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Diese Erklärung ist gültig, bis sie durch eine neue Version ersetzt wird / *This declaration is valid until superseded by a new version.*

Bad Birnbach, 28.01.2026



Susi Rumreich, PRRC

