

Original user manual

Software

FotoFinder Universe

Original user manual

Please read these original operating instructions carefully before using the device and always keep it easily accessible!



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Softwareversion from 3.5 Date: 26.06.2024





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1 About these operating instructions

1.1 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. 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.

1.2 Related documents

The following associated documents are relevant for the use of the product and these operating instructions:

- EU Declaration of Conformity
- Hardware instructions for use



1.3 Presentation of warning labels

- In the operating instructions, warnings are marked with a signal word panel.
- Warnings are introduced with signal words expressing the extent of the hazard.
- Observe all warnings to avoid accidents, personal injury and damages.
- The following signal words and symbols are used in the operating instructions:



This is the general hazard sign. It warns you of dangers to life and limb. All actions marked with this symbol indicate a personal danger. Follow these warnings implicitly to avoid injury or death.

A DANGER

Death or severe injuries will occur if appropriate cautionary measures are not taken.

A WARNING

Death or severe injuries may occur if appropriate cautionary measures are not taken.

A CAUTION

Indicates a possible hazardous situation, which may lead to minor injuries if not avoided.

ATTENTION

The signal word Attention indicates possible material damage. Non-compliance may lead to damages to the device.

(NOTE

Notes indicate important information that the user must consider when executing an instruction. Notes provide the user with more detailed information on a particular subject.

1.4 Explanation of the symbols



Symbols in the software: Country of origin / Date of manufacture



Product updates available until



Model number



Medical device



Unique Device Identification



Observe User Manual



CE Mark

Manufacturer



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



2 Installation, updates and uninstalling

The Software must be installed by a trained person or a representative of FotoFinder Systems GmbH. This is also applicable for updates, maintenance and deinstallation of the software.

(NOTE

For more information, please contact FotoFinder support: support@fotofinder.de.

2.1 FotoFinder Universe system requirements

In order to operate FotoFinder Universe, certain system requirements must be fulfilled.

The following system requirements apply to operation without network integration:

		Dermoscopy & Screening	Total Body Mapping	Master edition	DSLR: 50+ MP sensor
Ор	erating system		Windows 10 Windows 11		
	Speed	2.50 GHz			
Processor	Cores / Threads*	4 (8 Threads) 6 (12 Threads)			
	Architecture		x86-		
	Memory		16 (GB	
Graphics card	Туре	integrated GPU e.g. Intel® HD Graphics	<u> </u>		
	RAM	1 GB		4 GB*	
Display	Resolution	1920x1080 px		recommended: 3840x2160 px	
ызріау	Size	24"	recommended: 27"		
Hard drive 1 (OS + Universe)	Speed	500 MB/s e.g. M.2 NVMe (M.2 with 4 PCiX Lanes supports max. 6 GBit/s = 600 MB/s)			
(OS : OHIVEISE)	Free space	500 GB	500 GB 250 GB		
Hard drive 2* (Database +	Speed	e.g. SATA Rev	500 N sision 3.x / SATA 6Gbit/s		s = 600 MB/s)
Images)	Free space	./.	4 TB	6 TB	12 TB
Backup drive*	Speed		500 N e.g. USB 3.0 Gen	•	
	Free space	500 GB	4 TB	6 TB	12 TB
	FotoFinder medicam	1x USB 3.0 SN < MC1000-4: +1x USB 2.0			
	FotoFinder leviacam	1x USB 3.0			
USB*	ATBM control unit		1x USB 3.0		
	FotoFinder Laser Liner		1x U		
	FotoFinder PolFlash XE		1x USB 2.0		
	FotoFinder Polflash XE DX		2x US	B 2.0	
	DSLR / DSLM	1x USB 3.0			
Network	Local	recommended: 1 Gbit/s			
	Internet	required fo	r product activation, soft	ware updates and rem	ote support

* = not required for View-Only clients

Fig. 1: Minimum and recommended configuration for single user / client (PC / Notebook)

A WARNING

Malfunction of the application

Correct execution of the application can only be ensured if the system requirements are met. Please pay attention to the system requirements!

2.2 Use in a network

■ It is possible to operate the system in a network with several FotoFinder Universe clients.

(NOTE

For more information, please contact FotoFinder support: support@fotofinder.de.

2.3 Compatibility of software versions

2.3.1 Compatible FotoFinder medical devices

- FotoFinder medicam 800_{HD}
- FotoFinder medicam 1000
- FotoFinder leviacam
- FotoFinder Moleanalyzer pro (6.0.4)
- FotoFinder Moleanalyzer pro (6.0.5)
- FotoFinder Moleanalyzer pro (6.1)

2.3.2 Compatible FotoFinder systems

- FotoFinder bodystudio ATBM (1st generation)
- FotoFinder bodystudio ATBM master
- FotoFinder vexia
- FotoFinder dermoscope desktop
- FotoFinder dermoscope Komponentenlösung
- FotoFinder studio



For further information, please refer to the respective system manuals.



For more information, please contact FotoFinder support: support@fotofinder.de.



3 Safety

3.1 Adherence to the operating instructions

ATTENTION

This manual including the safety instructions refer exclusively to the software. The additional safety instructions described in the separate manuals for FotoFinder systems (hardware and software) are essential and must be followed!

(NOTE

Every person assigned to work with the system must have read and understood these operating instructions and particularly the chapter on *Safety*.

- The knowledge and observation of the applicable contents is a prerequisite for protecting users and patients from hazards and to prevent user errors.

 It is therefore imperative that all safety guidelines are followed to ensure your safety.
- These operating instructions are a component of the system and must always be available near the product. These operating instructions must be read and understood by the personnel and observed during any work with the system. Please contact the manufacturer immediately if contents of these operating instructions are unclear or if you have any questions.
- Apart from the safety guidelines in these operating instructions, please observe the following regulations and provisions:
 - Intended use
 - Appropriate accident prevention regulations
 - Occupational health regulations
 - Generally recognized safety-related regulations
 - Country-specific regulations
 - Attached documentation from third-party manufacturers
- In addition to these user instructions additional safety regulations of your institution or company may have to be observed.
- Additional training is required besides reading these user instructions. The training must be administered by qualified training personnel only.
- The safety instructions of the manufacturer are provided in addition to the general safety regulations of your institution or company. The provided instructions shall not invalidate existing regulations.

3.2 Intended use

FotoFinder Universe is a standalone software intended for:

- acquiring, processing, annotating, comparing and visualizing microscopic and macroscopic images of the human skin by medical professionals and dermatologists
- storing and managing images, patient and user data
- the standardized documentation of the intact skin surface and skin changes over time for preassessment and diagnosis support of skin conditions
- allowing the combination, communication and exchange of data with hardware devices and software manufactured by FotoFinder

3.3 User groups

User group	Demographic data	Expected / Intended qualification, job experience, skills
Dermatologists and general physicians (Primary user group)	 Typical job title: Dermatologist, General 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 2 x 4 h training by FotoFinder employee or distribution company employee
Practice personnel (Primary user group)	 Typical job title: Medical assistant, Nurse Age: in average between 18 and 65 Sex: all sexes Sensory abilities: normal abilities required to fulfil job Cognitive abilities, including memory: normal abilities required to fulfil job 	 Trained and instructed and professionally qualified through a completed apprenticeship in specialized medicine Experience with IT 2 x 4 h training by FotoFinder employee or distribution company employee
Service and Hospital technicians (Secondary user group)	 Typical job title: Service technician, Hospital technician Age: in average between 18 and 65 Sex: all sexes Sensory abilities: normal abilities required to fulfil job Cognitive abilities, including memory: normal abilities required to fulfil job 	 At least 3 years of professional experience in the medical technological sector Experience with IT 2 x 4 h training by FotoFinder employee or distribution company employee
FotoFinder employees (Secondary user group)	 Typical job title: Manager or employees in Sales, Support and IT, Management of company Age: in average between 18 and 65 Sex: all sexes Sensory abilities: normal abilities required to fulfil job Cognitive abilities, including memory: normal abilities required to fulfil job 	 Experience with the product/software Experience with IT Briefing and training by supervising FotoFinder employees



External distribution company employees	Typical job title: Manager or employees in Sales, Support and IT, Management of distribution company	Experience with the product/softwareExperience with ITBriefing and training by
(Secondary user group)	Age: in average between 18 and 65	supervising FotoFinder employees
	Sex: all sexes	
	Sensory abilities: normal abilities required to fulfil job	
	■ Cognitive abilities, including memory: normal abilities required to fulfil job	

3.4 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 3.3 User groups).
- The product is intended for use and operation in a patient environment as per EN 60601-1 only.
- Refer to the respective chapter (cf. chapter 2.1 FotoFinder Universe system requirements) for requirements regarding the physical and technical environment of use.
- There are no additional requirements for the social or clinical environment of use.
- The product is not intended for use by laypersons.

3.5 Requirements to the workstation

The workstation should be set up in a way that medical information is easily visible.

The following conditions should be avoided:

- Direct sunlight
- Reflections on the screen
- Insufficient contrast
- Insufficient screen brightness
- Incorrect color settings

A CAUTION

In order to run the application correctly, FotoFinder Universe must be operated on a workstation with a mouse, keyboard and monitor. The monitor must be set to landscape format. Running the application on a monitor set to portrait format is not supported.

3.6 Patient population

Patients conforming the following criteria can be treated with the software:

Indications

- General persons with skin lesions, moles
- Patients with multiple nevus syndrome
- Patients with general inflammatory skin
- Patients with Psoriasis vulgaris
- Patients with scalp hair disorders

Height:

It is only possible to scan patients with a height of 130 cm – 200 cm (applicable for Total Body Mapping)

Age:

Analysis with Bodyscan is only permitted for adult patients between 18 and 100 years, as it is otherwise not possible to provide correct documentation due to changes in body height

Mental conditions:

No restrictions

Physical conditions:

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

The intended patient population includes patients regardless of demographic factors (e.g. gender, occupation), physical factors (e.g. weight, strength) or social, religious and cultural background. It is possible to document various skin types within FotoFinder Universe.



3.7 Indications and contraindications

Indications

ICD Code	Description
L57	Actinic keratosis
C44	Basal cell carcinoma
L82	Benign lichenoid keratosis
D48	Atypical nevus
D18	Hemangioma
L98	Hemorrhage
L81	Lentigo simplex
C43	Malignant melanoma
D03	Malignant melanoma in situ
D03	Lentigo maligna
C43	Lentigo maligna melanoma
C43	Superficial spreading malignant melanoma
C43	Nodular malignant melanoma
C43	Acrolentiginous malignant melanoma
C43	Amelanotic malignant melanoma
C43	Desmoplastic malignant melanoma
C43	Malignant melanoma, not further classified
D22	Melanocytic nevus
D22	Papillary melanocytic nevus
D22	Acral melanocytic nevus
D22	Blue nevus
D22	Spindle-cell nevus
D22	Spitz nevus
D22	Halo nevus
D22	Melanocytic nevus with congenital part
L81	Naevus spilus
L81	Lentigo simplex
L81	Agminated melanocytic nevus
L81	Irritated seborrheic keratosis
L82	Seborrheic keratosis
L82	Lentigo solaris/senilis
D23	Dermatofibroma
D04.9	Bowen's Disease
L40	Psoriasis
L43	Lichen ruber planus
D36	Benign neoplasm
L85	Keratoakanthoma
C80	Spinocellular Carcinoma
L63	Alopecia areata
L64	Alopecia androgenetica

L66	Scarred alopecia
B35.0	Tinea barbae and tinea capitis
F63.3	Trichotillomania
L21	Seborrhoeic dermatitis
L63.0	Alopecia (capitis) totalis
L63.1	Alopecia universalis
L63.2	Ophiasis
L65.0	Telogen effluvium
L65.1	Anagen effluvium
L65.2	Alopecia mucinosa
L66.0	Pseudopelade
L66.1	Lichen planopilaris
L66.2	Folliculitis decalvans
L66.3	Perifolliculitis capitis abscedens (dissecting cellulitis)
L66.4	Folliculitis ulerythematosa reticulata
L66.9	Cicatricial alopecia, unspecified
L67	Hair colour and hair shaft abnormalities
L67.0	Trichorrhexis nodosa
L93.0	Discoid lupus erythematosus
Q84.0	Congenital alopecia
Q84	Other congenital malformations of integument
Q84.8	Other specified congenital malformations of integument (Aplasia
	cutis congenita)
C44.92	Squamous cell carcinoma

Abb. 2: Indications

Contra-indications:

The system is not intended to support pre-assessment or store images from mucosa, eyes, natural or artificial body orifices or injured skin.

The Total Body Mapping module is only available to persons with a height between 130 cm and 200 cm. The analysis with the Bodyscan is only permitted for patients with an age between 18 and 100 years.

The software does not diagnose a disease. Diagnosis is the responsibility of the medical professional! It provides support for dermatologist to differentiate between the indications mentioned above.



3.8 Clinical Benefits

The software is intended to document the skin surface of a patient over time. This enhances the detection and accuracy of the physician's ability to identify changes and differences of the skin. These differences could be detected as changes in the shape of a mole or lesion.

The standardized capturing and saving of reproducible images improves the comparability of separate images over time.

Therefore, the following clinical benefits apply to the patient / user when using FotoFinder Universe:

- Quick identification of changes due to follow up imaging allows an earlier detection of melanoma.
- Visualization of various skin details (pigmentation, vascular, etc.) enhances the classification of different skin diseases.
- Digital dermoscopy helps to reduce excision rates of benign moles.

Performance characteristics

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

- The software supports the capturing of lesions with a minimum size of 1 mm.
- The software allows micro imaging with a magnification of 20x to 140x.
- The software offers a resolution of 1920 x 1080 pixel.

3.9 Improper use

- Any use other than that described in the chapter on Intended use (cf. chapter 3.2 Intended use) and in this user manual and any use beyond the scope is considered improper use!
- The manufacturer is not liable for any resulting damage. The risk is borne solely by the user / operator.
- The software may only be operated on computers (incl. screen) that meet the minimum system configuration (cf. chapter 2.1 FotoFinder Universe system requirements) requirements.
- The use of the software in a medical context on devices that do not meet these OS specifications is prohibited.

3.10 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.

When using the optional expert system Moleanalyzer pro:

- The physician believes that the accuracy of the Al Score can be claimed and assumes that the score is indicative of the malignancy of the mole.
- The physician requests an Al 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.

3.11 Residual risks

A 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.

Software

- 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.
- Installing additional software on the PC may, in some cases, cause the FotoFinder Universe software to stop working. If you have any questions about compatibility, please contact FotoFinder support.
- Misuse by the user cannot be ruled out completely despite the provision of written user instructions and training.

3.11.1 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 the rapeutic patient data being published along with the name of the patient in the worst case.

3.12 Operator duties

- The instructions for use are an essential part of the product.
- The user must ensure that the instructions for use are read by all persons working with the software. Only trained personnel who have been instructed in the operation of the software are allowed to work with the software.
- The instructions for use must be kept accessible at the operating site of the product at all times.
- The manufacturer is not liable for damage caused by non-compliance with the documentation accompanying the product.



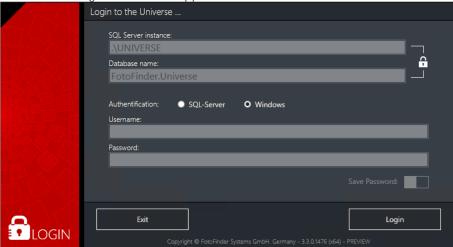
4 Starting the System

4.1 Database login



1. To start the FotoFinder Universe software, simply double click on the desktop shortcut.

The database login window will appear:



2. Establish the connection to the database by clicking on *Login*. If you are working with the optionally available user management, you must first enter the username and password before clicking on *Login*.

The dashboard will appear (cf. chapter 4.2 Dashboard).

4.1.1 View-Only access

Alternatively, the database connection can also be established through a *View-Only access*. This is designed to

- to view / manage / edit the images and
- to review the findings.

In this mode no new images can be captured.



- 1. To start FotoFinder Universe as a *View-Only*, double click on the respective icon on the desktop.
- 2. Add the login credentials as seen above if necessary and click on *Login*.

4.1.2 QuickLogin

Alternatively to the above mentioned starting method, the software can also be started through *QuickLogin*. In this case the login window will be skipped and you will be directed to the dashboard.



The *QuickLogin* function cannot be enabled if the optional User Management is activated (cf. chapter 5 User management (optional)) in Universe.

The QuickLogin can be activated as follows:

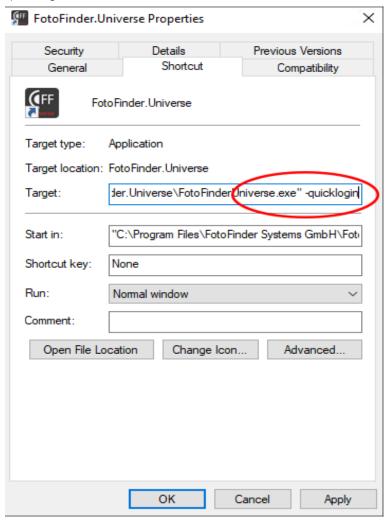


1. Right mouse click on the *FotoFinder.Universe* icon on the desktop. A context menu will appear.

2. Click on Properties.

The subsequent Properties window will appear.

3. In the *Target* field go to the end of the text and add the following extension: (*space*)—quicklogin

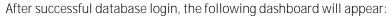


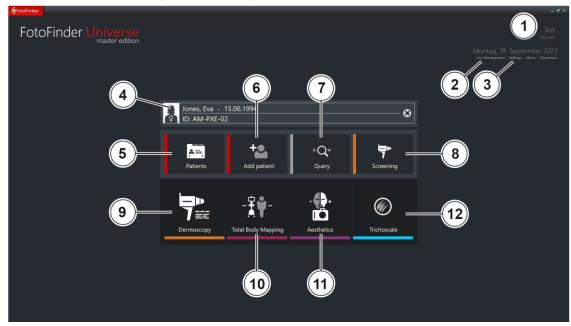
4. Click on *Apply* and then on *OK*.

Afterwards when Universe is started, the login window will be skipped and you will be directed to the dashboard (cf. chapter 4.2 Dashboard).



4.2 Dashboard





This displays the following modules and functions enabled as per your programme license:

- Software information section(cf. chapter 4.2.1 The About section)
- User Management (optional)(cf. chapter 5 User management (optional))
- 3 Settings (cf. chapter 6 Settings)
- 4 Patient selection field (cf. chapter 4.2.2 Patient search field)
- 5 Patient Management (cf. chapter 7 Module Patient administration)
- 6 Add Patient

- 7 Research (cf. chapter 12 Module Query)
- 8 Screening (cf. chapter 11 Module Screening)
- 9 Dermoscopy(cf. chapter 9 Dermoscopy module)
- 10 Total Body Mapping (cf. chapter 8 Total Body Mapping Module)
- 11 Aesthetics (cf. chapter 10 Module)
- 12 Trichoscale
- Patient Management, Add Patient, Research and Screening can be used immediately once the programme has been started.
- To start Dermoscopy, Total Body Mapping or Aesthetics, you first have to select a patient. These buttons are initially disabled.
- Using Trichoscale DX requires the purchase of a separate license.

4.2.1 The About section

On the dashboard in the upper right corner is the additional About section.



Fig. 3: The About section

Next to the *User management* (2) (cf. chapter 5 User management (optional)) and the *Settings* (3) options (cf. chapter 6 Settings) the *About section* can be accessed:

Logged in user account (1)

If you are working with the optional *user management*, you can see at this point which user is currently logged in. Otherwise, this area will stay empty.

Date

About (4)

By clicking on *About* you will get information about the program version used, contact details of the manufacturer and other information.

Disconnect (5)

You can log out from the database by clicking *Disconnect* without having to close or restart the application.



4.2.2 Patient search field

1. Type the last name or first name, date of birth or patient ID into the input field. The matching patients will be displayed in a drop-down list as you type.



Fig. 4: Example of a patient query

2. Select the desired patient directly from the drop-down list by mouse click.

The selected patient is now displayed with name, date of birth and patient ID in the patient selection field. This is however different if the option to anonymize patient data is activated in *Settings* (cf. chapter 7.2.2 Anonymizing the Patient Data). In this case, only the initials of the patient and the patient ID appears in the drop-down list.

3. By clicking on the X on the right side of the input field the selected profile can be cleared.

5 User management (optional)

5.1 Starting User Management

The user management can be started from the FotoFinder Universe dashboard. The corresponding button is located in the upper right corner.

After clicking here the user management window will open.



To control access to data and functions in FotoFinder Universe, user accounts can be set up and permissions assigned. When the user management is enabled, the software can only be started with user name and password.

ATTENTION

The configuration of the user management is at your own risk. Please keep your administrator password and the recovery key (displayed during the configuration) of the user management safe. FotoFinder has no way to restore access to the database or the images if you loose your Administrator password and recovery key! Your photos are encrypted and could not be accessed anymore!

In user management the following actions are available:

- Extensive permission management for individual users and user groups
- Create, edit or delete user groups and user profiles
- Creating and editing USB keys

Generally the following applies:

- All users access the same patient database.
- The requested password strength that is set during initial login applies to all users.
- All actions the individual users can perform in the user management depends on the settings in the permission management (cf. chapter 5.8 Permission management).



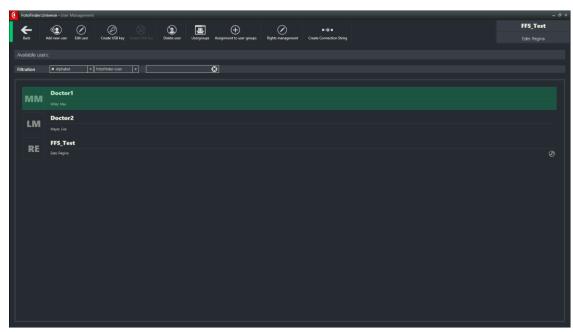


Fig. 5: Example view for the User management

5.2 Concept/Best-Practice

We recommend the following procedure:

The following information must be available:

- Administrator password
- Recovery key (printed out / safely stored)
- List of users for whom a user account should be created

Steps:

- 1. Create the accounts for the users (cf. chapter 5.4 Creating a new user)
- 2. Assign the users to a predefined user group (cf. chapter 5.7.1 Adding a user to a user group). The following user groups are preinstalled and available:

Standard user: Full access to patient data, can change its own password Doctor: Just like the standard user, however cannot change its own

account/password

Nurse: Just like the doctor account it cannot change any software settings,

and additionally cannot delete any patients

View Only user: Like the nurse account, but with only read permissions for the

patient data

IT technician: No access to the patient / user data, however it can change the

software settings

IT admin user: Like the IT technician, and additionally it can make changes to the

users

The permissions of the predefined groups should normally be sufficient. If further restrictions are required, permissions can be withdrawn via the permission management (cf. chapter 5.8 Permission management).



Permissions that are directly assigned to a user have priority over permissions that may be denied to the user via an assigned group.

5.3 Filtering and sorting tools in user management

Alphabet
 Alphabet
 Alphabet
 Last Modification
 Last Modification

For a better overview, various filters and sorting tools are available in the user management: Sorting tools

You can sort the list of users and user groups (ascending or descending) by

- Alphabetical order or
- Time of Last Changed.

Filtering tools

The filtering tools are available for both users and user groups.



- The FotoFinder user (groups) shows all users (groups) that are created in the FotoFinder Universe software. This includes the preinstalled users (groups) as well.
- The *LDAP user (groups)* shows all users (groups) that were imported in Universe through the LDAP import.
- The *Changed users (groups)* shows all the already modified users and groups.



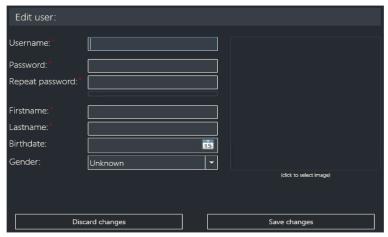


5.4 Creating a new user



1. Click on Add new user.

The *Edit user* window will appear:



- 2. Fill in all the necessary informations. The fields marked with an asterix are mandatory, the user picture is optional.
- 3. With the *Discard changes* button you can erase the added data.
- 4. With clicking on *Save changes* the new user will be saved and now listed at the Available users.

5.5 Editing a user



Click on Edit user to make changes on the selected user.

The same editing window will appear as when creating a new user.

- 2. Make the necessary changes.
- 3. After clicking on *Save changes* the new data will be saved.

5.6 Deleting a user

To delete a user from the user management follow these steps:

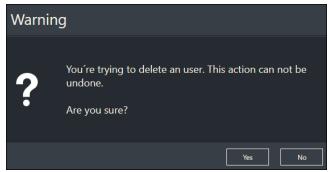
1. Click on the user you wish to delete.

This user will be now highlighted.



2. Click on *Delete user* in the menu bar.

The following dialog box will appear that the action cannot be revoked:



3. Confirm with *Yes*, or click on *No* to cancel this action.

5.7 User groups

The *User groups* allow to have the same permissions set for a group of users.

Please refer to our recommendation for this in the beginning of this chapter (cf. chapter 5.2 Concept / Best-Practice).

Generally the following applies:

- In *Patient management* there are already preinstalled *User groups* available. The already set permissions can be adjusted or deleted here.
- It is also possible to create a new user group with specific permissions.
- Every user can be added to one or more user groups.

5.7.1 Adding a user to a user group

One user can belong to several user groups. You can adjust the individual assignments as follows:

. Click on Assignment to user groups in the menu bar.

The following menu will open:



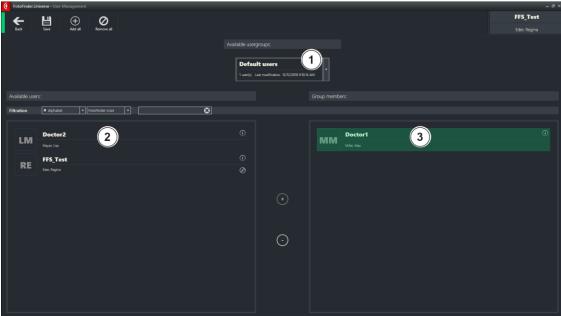


Fig. 6: Example view for the user assignment menu

To change a user assignment:

- 2. Open the drop down menu in the middle at *Available user groups* (1).
- 3. Select here the group where you want to add the user.

On the right side at *Group members* (3) all the already assigned users will be visible. On the left side at *Available users* all users will be shown (2) that are not members of this selected group yet.

4. Click on the user you want to add or remove from the selected group.

The selected user will be highlighted.

5. A user can be added or removed with the and buttons between the two columns. With a click on the plus sign the user will be added to the selected group. With a click on the minus sign the user will be removed from the selected group.





Add or remove all users at once

With the Add all and Remove all buttons all the users of the selected group can be added or removed.





6. Confirm your selection with *Save*.

5.7.2 Adding and editing a new user group

Typically the preinstalled user groups should be sufficient. In case an additional user group is required, with the following steps can a new group be created:



Click on the *User groups* icon in the menu bar to open the editing window:

5.7.2.1 Adding a new group



1. Click on *Add new group*.

On the right side a new window will appear where you can add the name of the group.

2. Add the group name and save it.

The new group will be now visible in the list.

5.7.2.2 Deleting a user group

1. Mark the user group you wish to delete.

The group will be highlighted.



- 2. Click on the *Delete group* icon in the menu bar.
- 3. Confirm the following message with *Yes*.

The group will be deleted.

5.7.2.3 Editing a user group

1. Mark the desired user group you wish to edit.

The group will be highlighted.



- 2. Click on *Edit group* icon in the menu bar.
- 3. On the right side the editing window will open where you can make the required changes.
- 4. Confirm your changes with Save.



5.8 Permission management

In the permission management you will have a full overview over all active permissions. You can also control here all individual user and user group permissions.



1. Click on the *Permission management* icon.

The following window will appear:

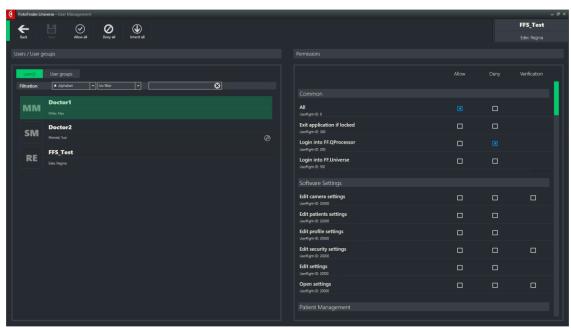


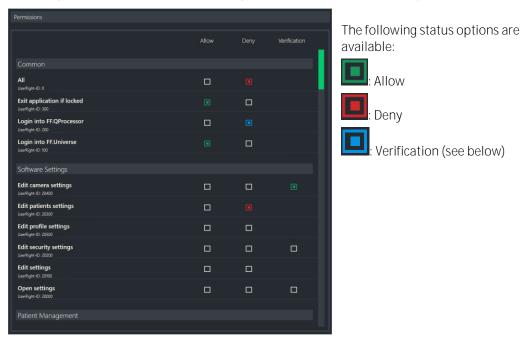
Fig. 7: Example view of the permission management



- 2. Select on the left side if you want to work on individual (user) or group permissions.
- 3. From the list below select the user/group you wish to edit.

The selected user/group will be highlighted.

On the right side of the screen the list of rights / permissions will be displayed:



4. Adjust the permissions as required.

5 User management (optional)



The following buttons are also available for quick changes:

With clicking on *Allow all*, all points will be set to allowed. You still can set the permissions individually.



With clicking on *Deny all*, all points will be denied. You still can set the permissions individually.



With clicking on *Inherit all*, all the permissions will be copied from the other users of the same group. These permissions are displayed with blue on the right side. Allowed permissions will only be the ones that have the allowed status.



5. Confirm your changes with *Save*.

Generally the following applies:

- If a user is in more groups added, it will only have the permissions that are in every group allowed for the user.
- If any permissions are denied for a group, the same permission can still be allowed for any individual users in the same group.



Any permission that is allowed for a user has priority over permissions that are set for the group where the user is.



5.9 USB Key

With a USB Key you can log in safe and fast without always having to type in a Password. Your login data will be stored on a USB Stick or SD Card. To set this please follow these steps:

(NOTE

Only the active user can set a USB Key. It is not possible to set this for another user.

(NOTE

Please keep your administrator password and recovery key safe at all times.
FotoFinder has no way to restore access to the database or images if all access data is lost. If the key is lost, you won't be able to access the data again!

5.9.1 Creating a USB Key



- 1. Plug in a USB stick or SD card.
- 2. Click on Create USB Key.
- 3. In the appearing window select the drive you wish to use.
- 4. Confirm your selection with clicking on OK.



The USB Key will be created on the drive and can immediately be used to log in to the database. In the user management a small key symbol will be shown at any user where a USB Key is created.

5.9.2 Deleting a USB Key



Every user can also delete their own USB Key as well. In addition, users within the *Administrators* group can also delete other users USB keys.

1. Click on *Delete USB Key*.

This user now will only be able to log in with typing in the password.



6 Settings

You can adjust the settings of your program on the Dashboard (cf. chapter 4.2.1 The About section) itself. The *Settings* button is located in the upper right corner.

Clicking on it will open a menu in which you can manage various settings. The most important ones are described in the following sections.

6.1 General

In the General section, you can make the following settings (mark the checkboxes at the corresponding functions):

6.1.1 Customer data

This section is described separately (cf. chapter 6.8 Adjust user information).

6.1.2 Patient List

- The software can for example, automatically assign a new ID when creating a new patient.
- Anonymizing patient data: In the Patient List and when searching on the dashboard, the Software will only be display the initials of your patients. The full name is still displayed when the application is open.
- Specify the unit system with which you want to measure (cm/inch).

6.1.3 Safety

Lock settings with a password: To ensure that selected settings are not changed inadvertently you can enter a password under Security. Settings can then only be changed by entering this password. For additional information, please contact FotoFinder Support at support@fotofinder.de



6.2 Image Capture Devices

In the section *Capture devices*, you can control different parameters for the connected cameras, for example the white balance.

(NOTE

Please note that changes to the camera settings can have a negative effect on the comparability of new images with the images already available.

6.2.1 General

Here you can adjust the settings for the image display:

- If required, enable or disable the 4: 3 mode for new capturings.
- By default the micro images are set to start in polarized mode. Disable this here if necessary.

Device names

If you used the renaming option you can reset the device name here.

6.2.2 medicam

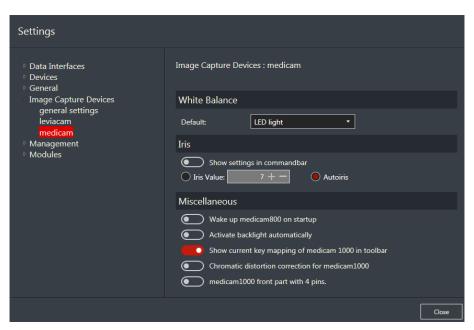


Fig. 8

White balance

Here you can specify a standard value, which can be changed during the capturing process. Select the type of illumination in accordance with the lighting condition in your practice.

Iris

Select the iris settings in accordance with the lighting condition in your practice.

Miscellaneous



Activate or deactivate the display of medicam key allocations in the Software.

Fig. 9



6.3 Data Interfaces

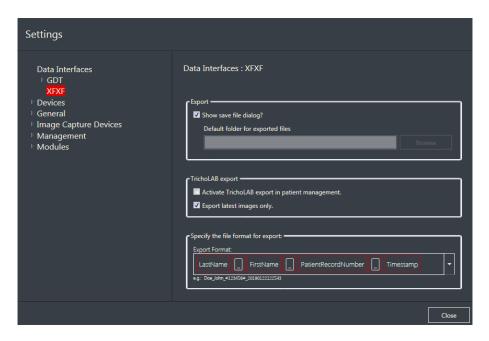
6.3.1 GDT

Here you can adjust the settings for the GDT connection. For this you will need the data of your GDT system.

Please contact FotoFinder Support for individual consultation and integration.

6.3.2 XFXF

Here you can adjust the settings for exporting data (for example, setting a default storage folder).



Export

You can skip the save dialog for XFXF exports by removing the check mark in the dialog box for entering the storage path. Exports are then directly saved in the storage folder you selected here. If you leave the checkmark here, the last used storage location will be suggested. The system remembers this and also differentiates according to the individual export functions, such as Image Export, FXF Export, etc. The location can be changed each time you save / export.

TrichoLAB Export

The TrichoLAB Export provides you with an export function for hair analysis via TrichoLAB. Please note that this requires the installation of the TrichoLAB sync Software.

Please adjust the following settings:

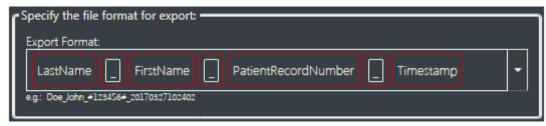
- 1. Remove the tick for *Show save file dialog*.
- 2. Tick Activate TrichoLAB export in patient management.
- 3. Optional tick: Export latest images only

Do not enter a password during the TrichoLab export process.



Specify the file format for export

Here you can specify how file names are recommended by the Software for export. The file name is comprised of various data fields.



- 1. If you want to add a certain field, click on the arrow on the far right and select the required field from the displayed drop-down list.
- 2. Click and hold the left mouse button to change the order of fields in the selection.
- 3. You can delete the field again by right-clicking on a field and then selecting *Delete*.
- 4. The field *Customize* provides a text field for free text. If you click into the field, a cursor appears and you can enter your text.

A sample is displayed below the field selection and shows the current order of your fields.

6.4 Devices

6.4.1 Automatic Tower

You can find some functional settings for the ATBM Tower under *Devices*.

- Camera profile: Here you can preselect a camera profile as default, e.g. *PolFlash XE*. The selected camera profile is preset in the capturing process, but can be changed at any time.
- Countdown: Before starting a Total Body Mapping or Body Photography, there is a countdown rate before the camera starts moving for safety reasons. By default, this countdown lasts for 3 seconds. This countdown can be changed or deactivated completely by setting it to 0.
- Service position: The service position describes one of three possible positions of the camera slide on the tower (top, middle, bottom).

The service position is used for better accessibility of the camera slide including the devices mounted on it (e.g. camera, PolFlash XE, cable) for maintenance.

Select the desired service position from the drop-down list.

You have two options for moving the camera slide to the service position:

- Through the *Settings*: Click on the *Service position* icon on the right side of the drop-down list.

service position

Or:



- Enable in the *Settings* the option *Show service position in live view.* As a result, the corresponding button will also be displayed in the Total Body Mapping module in live image. Click on the Service Position button to move to this position.
- Parking position: The digital camera can automatically go to a parking position at eye height when the program is closed. This prevents the camera from sliding down and possibly causing damage in the camera. To set this check the appropriate checkbox. When you exit the program, a window will appear which must be confirmed. Afterwards, the camera will automatically move to the parking position.

6.5 Modules

6.5.1 Dermoscopy

Here you can specify the pre-settings of the Dermoscopy module.

6.5.1.1 General

- Hide/Show the Screening button on the menu bar.
- Select the reference image to be shown when creating a new micro image.
- Micro image comparison: Select the combination with which image should the latest micro image be compared (first, second or second to last).
- Micro image comparison: Select whether the overview image should be displayed automatically in the absence of a comparison image.
- Specify whether a micro image is to be displayed on full screen immediately after capturing or only in the preview window
- Activate or deactivate the highlighting of overview images without markers in the gallery (SmartGallery).
- Use *Filter and sort gallery* to adjust the standard filter value in the image gallery (SmartGallery).



Use *Medicam Zoom* to specify a standard enlargement for micro images. This is then automatically set during the capturing process of baseline images.

If you mark *Reset to standard zoom value* this will cause a reset to the standard value after the capture of every micro image. If not, the manually selected zoom level will be maintained during the capturing process.

For follow-up images, the same zoom level as in the baseline images will be set by default, to ensure an optimal image comparability.

6.5.1.2 Image Viewer

- Here you can activate or deactivate the possibility to attach file attachments for images (cf. chapter 8.1.6 Saving file attachments).
- Enable or disable the automatic synchronization of micro image appearance (cf. chapter 9.7.3 Imaging Tools)
- Enable or disable the Ghost button for micro images here (cf. chapter 9.5 Micro capturing (images and videos)).
- Select if the Zoom percentage should be displayed in the Image Viewer or not.
- Enable or disable the grayscale button for micro images.

6.5.1.3 Localization

By default, for an image abbreviations are used for localization such as "HF" (Head Front)

Change the localization descriptions by clicking on *Enable user-defined localization descriptions*. Enter the required descriptions in the appearing table.

6.5.1.4 PuppetControl

For each overview image, the corresponding localization must be chosen on the localization puppet. By default, the puppet appears automatically when saving if you have not yet selected a localization.

- Adjust the time of the automatic appearance.
- The virtual patient can be displayed with or without clothing. Adjust this if necessary

6.5.1.5 Reporting

- Check *Extended printer options* in order for the extended printer menu to appear when creating a report.
- Select whether
 - markers
 - overlay graphics und
 - measurement ranges (with or without grid)

should be included in the printed report. Check the respective field as required.

- You can select a standard output for the reports: PDF, Preview or Printer. This option allows you to select the type of any subsequent reports. This can be edited in the extended printer menu.
- If necessary, adjust the *Marker scaling* here. This changes the size of the markers in the reports. You can also leave this setting on *Default*.
- By clicking on *Browse* you can select a standard destination folder to save the reports to.
- Define file format for export and reports: You can set here the title format of the reports and exported images.



6.5.1.6 Schematic Localization

If you use schematic images instead of overview images, different localizations to the ones used in the selection via PuppetControl are used.

Adjust the default descriptions. Click on *Activate user-defined localization descriptions* and edit the values in the appearing table.

6.5.1.7 Screenshots

When creating a screenshot with *Copy to Clipboard* from image comparison, further information is made available together with the image.

- Select these details here.
- Adjust the image size of the rendered screenshot.

6.5.1.8 Videos

Here are the settings available for the Video recordings:

- Recording
- Export
- Watermarks

6.5.1.9 Wi-Fi

You can also capture macro and micro images with a digital camera via Wi-Fi SD card.

Activate the checkbox *Activate Wi-Fi* and specify the folder to where the WLAN SD card imports the images. When taking overview or micro images in the Wi-Fi mode, the images are then imported to the Universe software from this designated folder. Deactivate the use of sub-folders in the Wi-Fi SD card menu.



The connection to the Wi-Fi SD card and the computer must be established outside of the Universe software with the help of the Wi-Fi card's third-party software. Additionally, a wireless network must exist so the Wi-Fi SD card can import images to the FotoFinder PC.

The eyefi mobi and Toshiba Wi-Fi SD cards are supported and recommended.



6.5.2 Total Body Mapping

Here you can adjust the Total Body Mapping module's default settings.

6.5.2.1 Image Viewer

Gerneral

Here you can activate or deactivate the possibility to attach file attachments for images (cf. chapter 8.1.6 Saving file attachments).

Image cropping

For Total Body Mapping, you capture four images from every side of the body that are automatically assembled into one full body image.

- Set how the combined image is supposed to be displayed with the original images. You can choose how the photos are displayed:
 - cropped images



- original images with marked overlay (transparent overlay)
- Activate the *Display mode* function in order to switch between the various display mods within the mode.



Activate Display alignment to re-align compared TBM images at the push of a button.

6.5.2.2 Bodyscan

Choose if the images should be normalized for the Bodyscan.

6.5.2.3 Reporting

- Check *Extended printer options* and the extended printer menu will appear when creating the report.
- Select whether
 - markers
 - overlay graphics and
 - measurement ranges

are to be included in the report or print-out. Check a respective field as required.

- If required, select a standard output for your reports: you can select between PDF, Preview or Printer. This lets you preselect the type of output during the creation of subsequent reports. This can be edited in the extended printer menu.
- By clicking on *Browse* you can select a standard folder for reports from this module.
- Specify the file name format for exports and reports: Here you can specify how file names are recommended by the Software for exported images and reports (cf. chapter 6.3 Data Interfaces).



6.5.2.4 PuppetControl

■ The virtual patient can be displayed with or without clothing. Adjust this if necessary

6.5.3 Query

6.5.3.1 Reporting

If desired, you can define the file name and format for exports and reports from this module (cf. chapter 6.3 Data Interfaces).



6.6 Management

On the Administration tab, you can manage a list of possible treatments, diagnoses and studies and change the associated settings for the dermoscope and aesthetics modules.

The list will then appear as a drop-down menu with the image data on the user interface.

- You can add more entries by clicking on *New*.
- You can deactivate individual list entries by using the mouse to uncheck behind the appropriate name. By clicking the mouse again, you can check it again and reactivate the entry.
- After clicking on a previously stored entry, you can change the name with *Rename*. Please note that this change will also affect existing images in which this entry was already used.

€NOTE

If you want to combine several (up to five simultaneous) existing entries, e.g. because the same treatment was created with different spelling, you can easily combine them as follows:

1. Select the appropriate entries by clicking the mouse and holding the Ctrl button.

The selected lines are highlighted in red.

- 2. Click on *Rename* and allocate a name.
- 3. Confirm by clicking on OK.

The entries are now combined.

Confirm all changes with *Save*. Click on *Close* to return to the Dashboard.

6.6.1 Treatments

(Treatments only relevant for the aesthetics module)

Checking *Editable list of recommended treatments in Aesthetics* will result in the following: You can either choose a treatment from the previously created list or freely enter a treatment directly in the user interface. New entries are automatically moved to the treatment drop-down menu.

6.6.2 Diagnoses

You can import a saved csv file by using the *CSV Import* button.

Leaving the checkbox empty at *Use fixed templates for diagnoses in Dermoscopy/Aesthetics* will result in the following for the specific module: You can either choose a diagnosis to tag a photo from the previously created list or freely enter a diagnosis directly in the user interface. New entries are automatically moved to the diagnosis drop-down menu. The system does not suggest any diagnosis.

6.6.3 Studies

Leaving the checkbox empty at *Use fixed templates for studies in Dermoscopy/Aesthetics* will result in the following for the specific module: You can either choose a study from the previously created list or freely enter a study directly in the user interface. New entries are automatically moved to the study drop-down menu.



6.7 Audit Control

Since Universe Software Version 2.0.35.0 it is possible to record changes and procedures by each user. This record is activated by default.

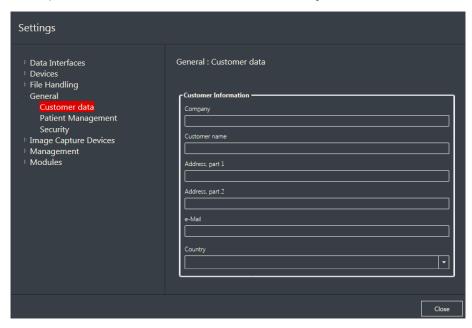
Please get in touch with your local FotoFinder contact person if you need further information.

6.8 Adjust user information

During the installation process you filled in your user information for the print layout. This data is now displayed in the header.

You can edit these data as follows:

- 1. Click on Settings at the top right of the start screen.
- 2. Open the menu *General Customer Data* and edit your data there.



3. Exit the menu by clicking on *Close*.

Your data are now edited.

Alternatively, you can edit the company name, address and email as follows:

- 1. Press the Windows key.
- 2. Enter SetCustomerInfo.
- 3. Confirm with Enter,

which opens a window in which you can update the data.

4. Save the data and exit the program with *Accept*.



When creating a report, these data will now be inserted automatically.



7 Module Patient administration



You can perform the following actions in the Patient List module:

- create new patient profiles
- edit or delete existing patient profiles
- export or import patient data with all associated images (cf. chapter 13 Import and Export)

7.1 Add patient



1. To create a new patient profile, click on the button *Add Patient* on the left in the patient management section or



on the button Add Patient on the dashboard.

This opens the input mask:

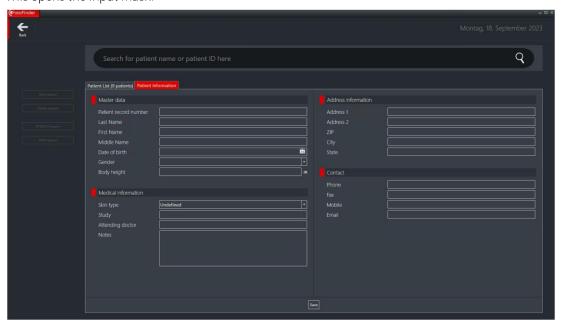


Fig. 10: Add Patient input mask

2. Enter the required patient data. Mandatory and optional fields are available for this purpose.

(NOTE

- Fields marked with an asterisk are mandatory!
- Body height is not a mandatory field in the master data. However, its specification is mandatory for Automatic Total Body Mapping. If you do not specify anything here, the software will ask for the patient's height as soon as you start the creation process for the first time
- The format of the patient number is not specified. It can be individually created by the user. Both numbers and letters or a combination of both are allowed. Under Settings → General you can set up automatic creation of the patient number by selecting the field Generate new patient IDs automatically (cf. chapter 6.1 General).

Save

3. To confirm the data, click on Save.

A new patient was added to the database and you are returned to the dashboard.

7.2 Editing Patient Records

7.2.1 Opening a Patient Profile

You can select an existing patient profile by either searching in the search mask on the Dashboard itself, or by searching in the Patient List module.

(NOTE

The most recently selected patient record remains active in the search field of the Dashboard. Click on the closing symbol X on the right side to clear this selection and to start a new search.

7.2.1.1 Searching with a search option

1. Insert at least the first character of the patient record number, the last name or the first name or the complete date of birth into the search field on the upper edge of the screen.

During the input of the characters, possible results will already be displayed in the hit list:



2. Click to select the required patient profile from the hit list.

7.2.1.2 Searching for first names and surnames

You can also search for surnames and first names simultaneously:

1. Enter these in the search field. The first characters suffice.



2. Click to select the required patient profile from the hit list.

7.2.1.3 Feature for patients with several first names or surnames

Please note the following when entering a search for a patient has several first names or surnames (e.g. "Tina Mary"):

For instance, when entering "Tina Mary", the Software will only recognize the patient if you also add a comma (,). The Software can then detect that the search refers to one and the same field (in this case; the first name).

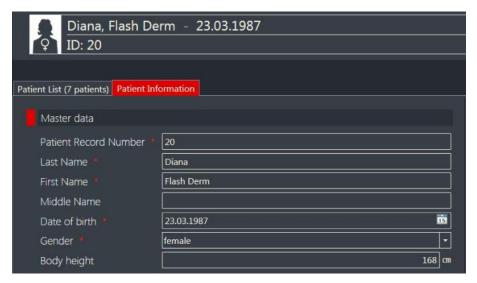


7.2.2 Anonymizing the Patient Data

The patient names are by default anonymized so that it is not displayed while treating a third party. However, you can still select anonymized patient names via the search field. You can turn anonymizing off in Settings (cf. chapter 6.1 General).

7.2.3 Updating and Deleting Patient Information

- 1. Select the required patient profile.
- 2. Click on the Patient data tab.
- 3. Edit or complete the patient data and contact details.
- 4. Click on Save.



Delete patient

If you want to delete a profile, select the appropriate profile from the database first and then click on *Delete Patient*.





After confirmation, the patient profile and all related images will be removed irrevocably!

8 Total Body Mapping Module

Total Body Mapping (TBM) is the module used in combination with the ATBM Tower. Use this module to create and then evaluate whole-body images.

Create a patient profile or select an existing profile.



2. Click on *Total Body Mapping* on the dashboard.

8.1 The Desktop

The user interface of the module consists of six sections:



Fig. 11

- 1 Menu Bar
- 2 Patient Data Field
- 3 Timeline

- 4 Body Map
- 5 Preview Window
- 6 SmartGallery



To give the preview window more space, you can reduce or hide the display of the image segments and the SmartGallery:

1. Click on the hide symbol in the shown spot (see arrow markings on the next figure) in order to reduce the size.

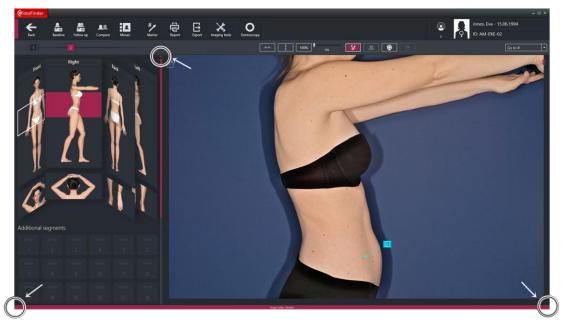


Fig. 12: User interface with enlarged preview window

2. Click on the symbol a second time to enlarge the window again.

8.1.1 Menu Bar

You can see the Menu Bar on the upper edge of the screen.





Imaging tools

Dermoscopy

Back: you are returned to the previous screen. When you click this button in the overview, you will leave the module and return to the Dashboard.

Baseline: You start Total Body Photography on patients for whom prior reference images are not yet available, or if you want to create a new baseline for the patient. Please refer to the notes in the separate chapter for more information.

Follow Up: You start the capturing process of images for patients for whom prior references are already available.

The Compare function: You directly compare images from one position but different sessions.

Mosaic: Viewer to see multiple pictures on a single screen.

Marker: You insert an arrow and mark a skin feature.

Report: You create a report. The print is specifically designed to match Total Body Mapping.

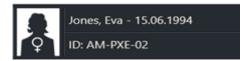
Export: You export the image displayed in the preview.

Imaging tools: Open the tools to mark, measure and anonymise images.

Dermoscopy: You directly change over to the Dermoscopy module.



8.1.2 Patient Data Field



The Patient Data Field is displayed on the right side of the screen with the name and patient number of the current patient. The number of images already captured of this patient is specified next to the patient number in brackets.

8.1.3 Timeline

The timeline is located in the upper left section of the screen. Use this timeline to select baseline and follow-up images in chronological sequence.

A baseline here are characterized by a slightly larger square than the follow-up images.



The currently selected session is marked with color.



Fig. 13

If you move the cursor over the mark of an individual session, the information related to the session will appear.

You will see

- the name of the capturing session
- the date of capture
- the number of images
- the height of the patient and
- the image segments for which images were captured (displayed in color; those without images are gray).

You will also find the *Delete session* button below.

8.1.4 Body Map

On the left hand side of the screen, body puppets guide you through the various capturing segments.

- Positions with existing baseline images are shown in color.
- Gray body parts are not yet photographed.
- The current image, which is also shown in the preview window, is highlighted in color.

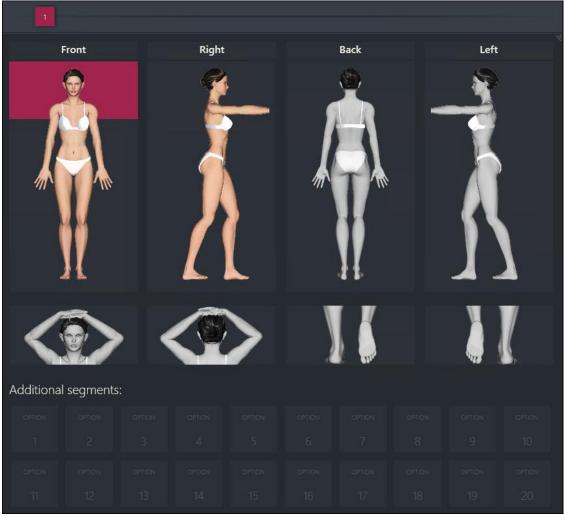


Fig. 14

Each body map is divided into four segments:

- Head and shoulders
- Torso
- Upper legs
- Lower Legs



The Total Body Mapping software automatically prompts for 20 standard poses to document the majority of the skin surface. To capture additional body areas which are not visible on the standard views, up to 20 additional positions can be photographed.

Click on any segment to select it. The selected area is then highlighted and the selected image will appear in the preview window.

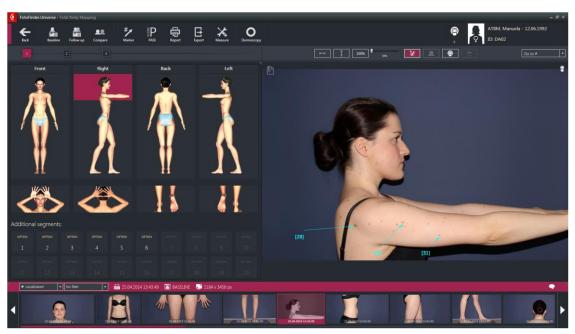


Fig. 15

8.1.5 Preview Window

The preview window is located on the right hand side of the screen. Here you can see the image of the current imaging session and the currently active segment or the live image during the capturing processes.

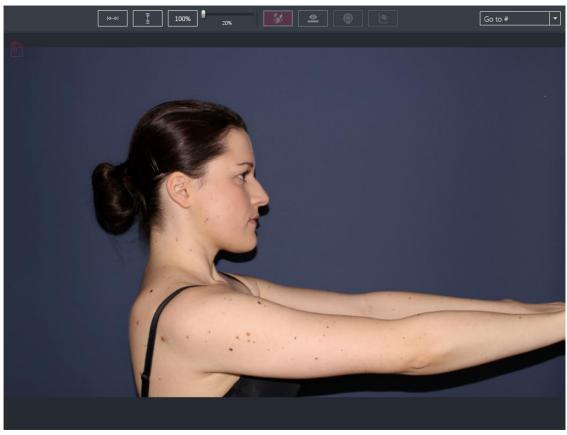


Fig. 16

8.1.5.1 Magnifier function

If you right-click and hold the mouse button in the displayed preview image, a magnifier appears which allows you to enlarge an image section. Adjust the size of the magnifier with the mouse wheel while you keep the right mouse button pressed.

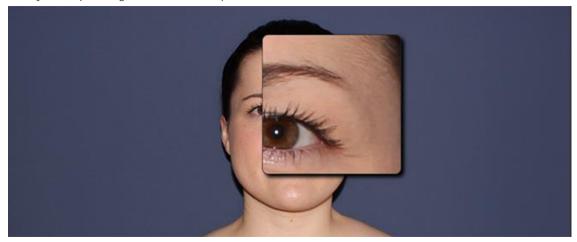


Fig. 17: Magnifier function



8.1.5.2 Imaging Tools

Above the image you see the following menu bar for the image display:



•

With this button you can enlarge the image to the width of the preview window.

With this button you can adapt the image to the height of the preview window.

With this button you can display the full resolution of the picture.

With the help of the slider or by turning the mouse wheel you can zoom in or out on a photo. You can pan the image by holding the left mouse button after you zoomed in.

With this button you can hide or display Markers.

With this button you can show or hide overlayed graphic items.

With this button you can show or hide Bodyscan circles .

This is only possible for images created in the Total Body Mapping module.

8.1.5.3 *Go to #* function



With the *Go to #* button you can select images of a special marker. Select the number of the appropriate marker in the drop-down-menu.

Only the markers that were set in Total Body Mapping images are displayed. To see all markers please go to the Dermoscopy module.

Use the *Dermoscopy* button to quickly call up any associated micro images.

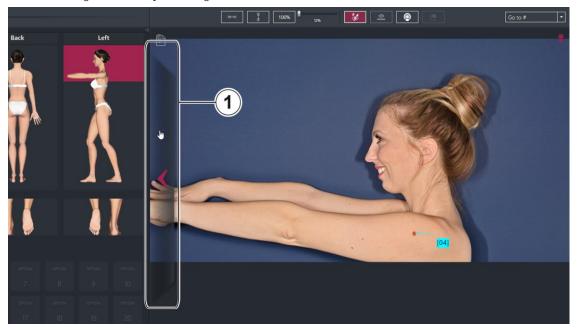
8.1.5.4 Changing the segments in the preview window

If you want to change the displayed segments in the preview window, there are two options available:

Change using navigation arrows:

- 1. Move the cursor to the sides, or to the upper or lower edge of the preview window. This displays a bar with a navigation arrow.
- 2. Click on this arrow.

The view changes to the adjacent segment in this direction.



1 Navigation arrow

Change via direct selection on the puppet:

1. Left-click onto the required puppet segment on the left side of the user interface. The view changes to the selected segment.



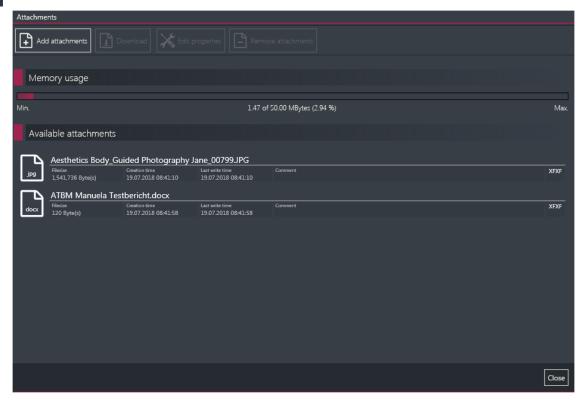
8.1.6 Saving file attachments

You can save file attachments for every photo.

This function can be activated and deactivated in the settings (modules / ... / image viewer) (cf. chapter 6.5.1.2 Image Viewer).



1. Click on the paperclip icon in the upper left corner of the preview window. The Add attachments window will open.



2. Via Add Attachments you can select files that you want to save as an attachment here.

Once you selected an existing attachment, you can also perform the following actions here:

- Download: The attachment can also be stored outside of Universe.
- Edit properties: You can change the files name, enter a comment and choose whether to include the attachment in an XFXF export.
- Remove selection: The file can be removed again as an attachment.
- 3. With Close this menu and window will be closed.



You can see if there is any attachment if the paper clip is colored. This color variates depending on which module are you using (Dermoscopy, Total Body Mapping or Aesthetics).

8.1.7 SmartGallery

The SmartGallery is located on the lower edge of the user interface. This is where you can see miniature views of all the images of a session in the sequence of capture.



Fig. 18: SmartGallery

- If you click on one of the images in the SmartGallery, it is marked with a red frame and displayed in large format in the preview window.
- Information on the capturing session (date, name, image size) is located above the SmartGallery.
- You can use the right and left arrows to scroll through the images in both directions. Alternatively, you can use the mouse wheel to do the same, if you place the cursor in the SmartGallery.

8.1.8 Image comments

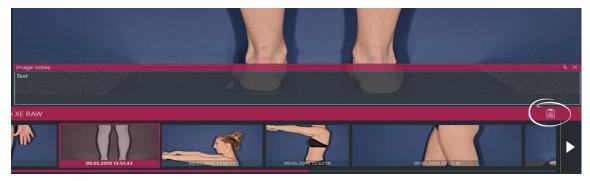


Fig. 19: Field for image comments

You can save image comments for each image.

1. Click on the small clipboard at the top right in the SmartGallery.

This opens the image comments field.

- 2. Make your entries here.
- These remarks are also displayed in the Dermoscopy module in the image information.
- You can also tell if there are already comments on the image by the slight pulsation of the clipboard icon (permanent colour change from white to purple).
- With the pin in the upper right corner you can fix this input window in place. It then remains open until you click on the pin again.



8.2 Creating images

The CamControl technology is used to connect the camera to the computer and control it using the software. This facilitates standardised capture of high-resolution digital images.

- 1. Make sure that the camera is connected correctly (see hardware instructions).
- 2. The camera should generally remain switched on at all times, even after completing operation. If, however, it is off, switch the camera from OFF to ON on the master switch at the top of the camera.

Otherwise, the connection between the software and camera cannot be established and you will receive an error message.

(NOTE

All settings, such as exposure, flash etc., are automatically saved in the profile via the CamControl function and optimised for the respective use.

- 3. Make sure that the menu wheel on the camera is set to M ("manual") before you switch to the capture mode. Otherwise, you will receive an error message.
- 4. Switch on the Laser Liner and check the alignment of the mat using the laser line marking on the mat designated for the purpose.

€NOTE

The patient should be completely unclothed apart from a single-colour, preferably black, close-fitting slip and, if applicable, brassiere. The patient's hair must not cover parts of the face etc. and should be tied up.

8.2.1 Baseline images with the ATBM

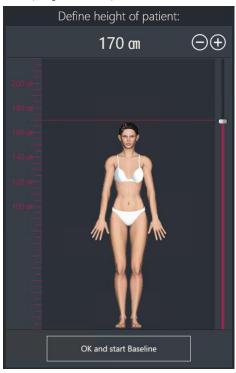
(NOTE

Please observe the requirements to the capturing environment and background in the hardware manual.

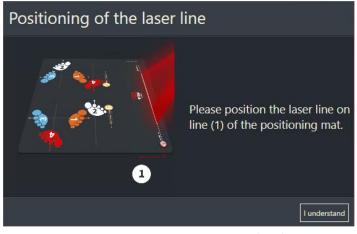


1. In the Total Body Mapping module, click on *Baseline*.

If you did not enter the patient's height in the patient file, the software will now request this information (only for ATBM):



- 2. Use the slider or the +/- signs to enter the body height in centimetres. This information can later be edited in the master data in Patient Management. Confirm with *OK and start baseline*.
- 3. The software now indicates the correct laser line positioning. For all captures, ensure that the laser line is accurately aligned with the positioning mat.



You can deactivate this information window in the settings (cf. 6).



4. Click on *I understand* to continue.

This starts the capturing process:



Fig. 20: Menu display during baseline

In accordance with the patient's height you entered, the camera moves to the first capture position after a short countdown.

If desired, you can select a different body view by clicking on the schematic manikin in the centre of the screen and create images for this purpose.

€NOTE

The system is only designed to capture images for heights between 130 and 200 cm.

The area relevant for the capture is highlighted as a segment of the body manikin and a live preview is displayed on the right in the preview window.

- 5. Position the patient in the posture specified by the body manikin in the software. Also use the positioning poster to instruct the patient.
- 6. A selection for the camera profile (e.g. *PolFlash XE*) is available in the menu bar. This can be adjusted as required. By default, the camera profile stored in the *Settings* is preset in the creation process (cf. 6).
- 7. If you have different cameras connected to your system, you can change the camera selection in the menu bar. You can also rename them as desired.



Option: Autofocus preview

The live preview image displayed is only intended as an aid to correct patient positioning. It does not show the full capturing quality of the camera. If the preview display is blurry, you can use the

Autofocus Preview button to initiate a new automatic focus. The camera will always focus before capturing an image.



8. As soon as you have positioned the patient accordingly, start the capture series by clicking on *Capture*.

The Total Body Mapping module now automatically creates four images of the respective segments on one side of the body (from head to toe). The camera automatically moves through the different segments and captures an image at the specified positions.

Option: SingleStep



The button is underlined in purple as soon as it is clicked.

SingleStep lets you capture each segment individually. For example, you can check the patient position and the capture in general for each segment individually.

After each capture with SingleStep, the menu provides the options





Repeat. The current image is discarded.

Continue: The programme jumps to the next capture position.

The left side of the screen now displays an overview image automatically stitched from four individual images. the transitions between the individual images can be adjusted and moved (cf. FotoFinder SmartMatch Technology (image cropping)).



If the image does not meet your expectations, click on Discard.



Restart the process



9. Click Save to secure the image.

The software now calls up the other side of the body automatically.

10. Follow the same principle for all other captures.

The system uses the manikin to show you how to position the patient. Once all twenty standard segments have been captured, a pop-up window confirms that the capturing sequence is complete and you can choose to record more segments.

Focus errors

If the camera is unable to focus correctly during capture, it will issue an error message. You are given two options:

Repeat: Discards only the current image.

Discard: Discards all images from this side of the body.

Option: Emergency STOP!



If you want to interrupt the automatic capturing process at any stage, click on *Emergency STOP!* The camera will stop immediately and all images of this segment will be discarded. Further photos can only be made after clicking *Back* and restarting the capturing process.



FotoFinder SmartMatch Technology (image cropping)

Before saving the four images of one side of the body, you can manually adjust and move the transitions between the individual images.



Fig. 21: Manual correction of image cropping after baseline capture

- 1. Click and hold the left mouse button to move the red lines (1) between the individual images.
- 2. Release the mouse button as soon as the body is correctly displayed in the full body image.

In the settings (cf. chapter 6.5.2 Total Body Mapping), you can specify

- how to display the view of the overlapping areas in the user interface at a later stage and
- have additional buttons displayed to change the view in the user interface.

Reset Smart Matching

If you want to restore the original capturing view, you can discard your manual changes by clicking on *Reset Smart Matching*.

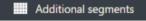
€NOTE

The Software will adopt the manual adjustments from *SmartMatch* for every follow-up Session for this patient.

8 Total Body Mapping Module

Additional segments

Should you need to add further images to the specified positions, there are a total of twenty special positions available.



- 1. Click on the *Additional segments* button below the large segment puppet in capturing mode.
- 2. Use the arrows to align the camera.
- 3. Click on one of the 1 20 special positions (e.g. Option 1).

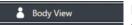
The live image appears and the selected field will be marked in color.

Start capturing.

Saved images are then displayed as thumbnails in the respective special position field.



For follow-up images of a special position, the camera will automatically move into the position of the baseline image.



By clicking on the *Body view* button, you can exit the special position area and return to the standard capturing segments.

5. Click on *Back* to return to the user interface and to exit the capturing mode.



8.2.2 Creating a new Baseline

If necessary, a new baseline can be created. This might be necessary if:

- The patient's body or weight drastically changed
- the original baseline is incomplete or no longer comparable
- additional images of further body parts are necessary or the previous baseline is not comparable.

Previous sessions will still be saved but will no longer be used as the reference baseline in case of a new follow-up session. New follow-ups can only be created for the latest baseline session.

(NOTE

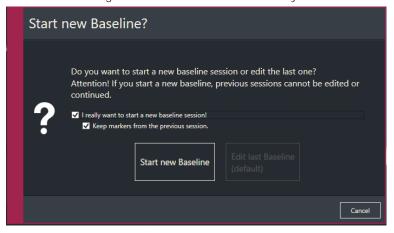
The FotoFinder Bodyscan can only be performed within a baseline and the belonging follow-up session.

You can create a new baseline by following these steps:

Pareline

1. Click on *Baseline* in the Total Body Mapping module.

The software recognizes if a baseline session already exists and will show the following window:



- 2. Mark the checkbox at I really want to start a new baseline session!
- 3. If the markers from the previous baseline sessions should be taken over then mark the checkbox at *Keep markers from previous session* too.
- 4. Click on Start new Baseline.

Alternatively you can

- Edit last Baseline (default) to make adjustments to the original baseline, or
- Cancel to close this window.
- 5. Enter the height of the patient in the following window. You can add this with the help of the +/- symbols or on the slide bar.
- 6. Click on OK and start Baseline.

The following steps are identical to a normal baseline session.

8.2.3 Follow-up images



Standardized follow-up images allow a comparison over time.

1. Start the capturing process for a patient by clicking on *Follow up*.

In case not all 20 default positions were fully documented during the baseline session, a message will appear.

- 2. You can choose to either complete the baseline session or immediately proceed to the follow-up session.
- 3. Watch out for the selected camera profile (e.g. *PolFlash XE*). For the best comparison the same profile has to be selected as the profile of the baseline. By default the camera profile set in the *Settings* will be used by the software (cf. chapter 6.4.1 Automatic Tower).

After having initiated the follow-up session, the Ghost function places the baseline image and the live image on top of one another. This helps to see how to position the patient to have an ideal comparison.



Use the slider above the preview image to adjust the transparency of the baseline image.

If required, you can select a different body part by clicking on the localization puppet and creating appropriate images, but only if a baseline image already exists. You can recognize this as soon as the localization puppet is displayed in color and is not gray.

In the preview window on the right side, you will now see a live image and the relevant body part will be highlighted in purple on the virtual patient.

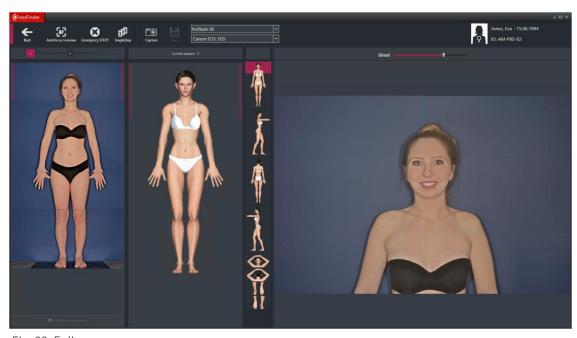
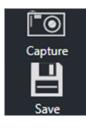


Fig. 22: Follow-up



- 4. Click on *Capture* after positioning the patient correctly.
- 5. Then click on *Save* if you are satisfied with the image.



If you are not satisfied with the image, click on Undo.



Restart the capturing process.

Option: SingleStep (only for ATBM)



You can use the *SingleStep* function to compare individual segments with the Ghost function. This function is described separately .

Once you have saved the image, the program will automatically take you to the next position.

6. Continue with the next follow-up images until all positions are done.



7. When you are finished with the capturing, you can return to the patient user interface by clicking on *Back*.

(NOTE

All stitching coordinates of a body position will be saved from the baseline session.

To create consistent follow up photos make sure that you use:

- an even background
- consistent patient positioning
- even illumination
- matching camera profile (e.g. PolFlash XE)

8.2.4 Polarized Bodymapping

Your ATBM system allows you to create polarized total body images. Follow these instructions:

Foto	Finder bodystudio ATBM master	FotoFinder bodystudio ATBM (1. Generation)
1.	In the Settings at <i>Devices I Automatic Tower</i> set the camera profile to <i>PoIFIash XE RAW</i> or PoIFIash XE.	1. In the Settings at <i>Devicesl Automatic Tower</i> set the camera profile to <i>AutomaticTowerPolarization</i> (from <i>AutomaticTowerDualFlash)</i> .
		€ NOTE
		Make sure that your system is equipped with a PolFlash (not BodyFlash). In case of any questions, please contact your local FotoFinder representative. You can find the label with the model description on the bottom of the flash.
2.	The PolFlash XE will automatically change to polarized.	Place the polarization filter - Polfilter body in front of the camera on to the PolFlash.
3.	Continue with the imaging as usual.	
4.	If you wish to return to making non-polarized images, please keep these points in mind:	
	set the camera profile back to PolFlash XE RAW NonPOL or PolFlash XE NonPOL.	set the camera profile back to AutomaticTowerDualFlash and
		■ take the filter - Polfilter body off the flash.

(NOTE

The ATBM procedure can be used for the examination of Psoriasis patients as well. The FotoFinder PASIscan* supports a computer-aided evaluation of the PASI Score.

For more detailed information, please contact your local FotoFinder distributor or FotoFinder representative.



8.3 Working with the images

8.3.1 Compare



You can use the compare function to compare the images of one position from different capturing sessions.

1. To start, click on the *Compare* button.

If you hold the mouse cursor above a square in the timeline of the displayed image you will be shown a small preview window with capturing information.

2. Click on the timeline to select the desired shooting sessions. The selected timeframes are purple, the remaining one are white.



Fig. 23 You can now compare two images.

8.3.2 Image display tools



In the image comparison besides the image display tools of the preview window you have the following button:



Use this button to change the function of the cursor:

With holding down the mouse button you can move / change either only the enlarged image, or individually the markers.

- More about the markers in the Total Body Mapping module can be found in the separate chapter (cf. chapter 8.6 Connection with the Dermoscopy module).
- By turning the mouse wheel you can select any magnification factor.

To move the magnified image section, follow these steps:

- 1. Click in the image.
- 2. Hold down the left mouse button.
- 3. Move the cursor.
- The magnifier tool is also available in image comparison (cf. chapter 8.1.5 Preview Window). If the magnifiers in the two images are not located in the same position (e.g. because the capturing positions were not identical), you can move one magnifier and therefore adjust the positions:
 - 1. Press the Ctrl button on your keyboard and the right mouse button at the same time. This takes you to Offset mode and you only move the magnifier which is currently selected by the cursor.
 - 2. Release the Ctrl button as soon as both magnifiers are in the same position.

Zoom Lock (SmartZoom)



The Zoom Lock function is set as default if you select the compare section. This function allows you to zoom in and move both images simultaneously. This also enables an objective comparison of the images.

Without Zoom Lock both images can be displayed independently.

1. Click on the Zoom Lock button again.

Zoom Lock is deactivated and a second zoom control is displayed.



In image comparison the *Merge marker* function is also available.

If several markers have been created for the same lesion, they can be merged to one marker number using the *Merge marker* function

(cf. chapter 9.4.3 Merging markers).



Navigation

In comparison mode you always compare the same segments with one another. A change in segments is therefore always performed simultaneously for both images. There are several options for navigating between segments in comparison mode.

If you move the cursor onto one of the tabs on the left and right edge of the screen, a slide-in display of the capturing segments will appear, where you can select the required body sections.



Fig. 24

■ Use the navigation arrows on the edge of the preview images also available in image comparison.

Bodyscan

In the image comparison you can view Bodyscan circles (cf. chapter 8.3.3 Bodyscan ATBM).



You can repeat the scan at any time by clicking on *Scan patient*.

8.3.3 Bodyscan ATBM

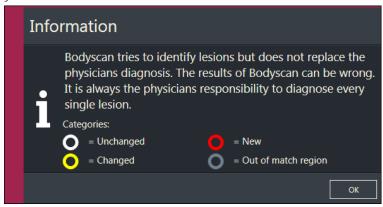


Bodyscan ATBM is an software modul for detecting new and changed lesions and is integrated in the Total Body Mapping module. It automatically analyzes whether new lesions have appeared on the patient since the last examination or whether previously existing lesions have changed. With the help of a complex algorithm, the current images are compared with the images of the last examination and any changes will be marked.



Fig. 25: Bodyscan results

Every time you call up this display after restarting the program, the following overview will appear for your information:





The *Out of match region* is used to classify lesions which were not assignable during the image comparison (e.g. when the patient position deviates too severely and lesions are located on the edge of the images). However, these lesions marked in gray should be examined and visually compared by a dermatologist.



(NOTE

Analysis with Bodyscan is permitted only for fully grown patients to ensure the comparability of the images. The best possible standardization of the images increases the quality of the results. Please note that dense body hair may affect the result, as the Bodyscan is a visual procedure. The classification of the Bodyscan results is based on statistical analyses and does not replace professional medical diagnosis. The diagnosis is the responsibility of the doctor.

The results of the Bodyscan can be displayed as follows:

- in the preview window of the desktop
- in full screen mode
- in image comparison
- in the Dermoscopy module

8.3.3.1 Performing a Bodyscan



In Image Comparison, the following buttons are available for the Bodyscan:

With Rescan complete, the system start a Bodyscan for all of the patient's images. The Bodyscan is automatically performed in the background for new images.



During the scan, a counter is displayed on the right in the menu bar. It tells you how many images needs to be still scanned.

The Prioritize button is located to the left of the counter. You can use this button to prioritize the images currently displayed in image comparison.



By pressing *Rescan localization*, the system starts a Bodyscan only for the two currently displayed images.

8.3.3.2 Bodyscan views



If the Bodyscan button is deactivated, the Bodyscan markings are not displayed on the image.



If you click the icon once, all circles are displayed.



If you click the icon twice, only yellow and red circles are displayed.

The small Bodyscan symbol in the corner of each image in image comparison indicates that Bodyscan was completed.

- A red symbol indicates the presence of yellow and red circles.
- A white symbol indicates the presence of white circles only.



Fig. 26: Bodyscan symbol

or

8.3.4 Image editing

Image editing provides the following options:

- Analysing the image with measuring tools
- Insertion of marks and text
- Anonymising the patient with black bars
- Displaying the Bodyscan results

There are two options to access image editing:



■ In the menu bar, click on Edit Image,

■ Double-click on an image in the preview window.

This opens the image editing window.



Fig. 27: Example view of image editing

- 1 Image Viewer Tools
- 2 Drawing and measuring tools
- 3 Navigation arrow (one of four possible)

(NOTE

Please note that a photo is a two-dimensional representation of a three-dimensional body. The values can therefore not be determined with exact precision.

Navigation

There are various options available for navigating between the individual images:

The SlideGallery bar is located below the displayed image. With the help of this tool you can comfortably scroll through the positions or jump to the desired position with one click.



This can be hidden or displayed as required by clicking on the Hide symbol in the upper left and right corner of the SlideGallery.



Moving the mouse cursor to either sides the lateral edge will display a bar with a navigation arrow. By clicking on it, the view will change to the adjacent segment in this direction (cf. chapter 8.1.5.4 Changing the segments in the preview window).

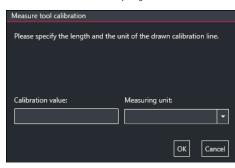
8.3.4.1 Calibration

Before measurements are possible in the displayed image, you first have to calibrate the image.



- 1. Start the calibration process by pressing the *CAL* button in the menu bar on the right of the displayed image.
- 2. Click once to create a starting point in the image and then draw a line with the mouse button pushed down.

A context menu is displayed.



- 3. Add the known length of the line and the appropriate measuring unit.
- 4. Confirm your entry.

Calibration is now complete. Now you can measure distances, surfaces and angles in the image.

8.3.4.2 Drawing and measurement tools





Edit/Move:

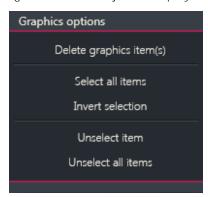
Moving inserted objects

Move the cursor over the object until the arrow turns into a cross-hair. Move the object by pressing and holding the left mouse button.

Changing the size of the inserted objects Click to mark the required object. Small squares now appear along the edges/corner points. Click and hold the left mouse button to move the squares and change the size.

Context menu

Right-click on an object to display a context menu.



Here you can

- Delete graphics item(s)
- Select all graphics items
- Reverse the selection
 - Deselect the graphics item
- Deselect all graphics items









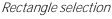












Click and hold the left mouse button to insert a rectangle and mark several draw objects simultaneously to edit them all after changing to the *Edit/Move* tool.

Line tool

Click and hold the left mouse button to insert lines.

Arrow

Click and hold the left mouse button to insert arrows.

Rectangle (empty)

Click and hold the left mouse button to insert an empty rectangle.

Rectangle (filled)

Click and hold the left mouse button to insert a filled rectangle.

Ellipse (empty)

Click and hold the left mouse button to insert an empty ellipse.

Ellipse (filled)

Click and hold the left mouse button to insert a filled ellipse.

Anonymization functions Black Bar and Ellipse

By clicking and holding the left mouse button, you can insert a black bar or ellipse to hide certain areas or to deidentify your patient.

Text tools

After selecting the text tool, left-click on the image. A text input and formatting window will appear.

Use this tool to measure angles between 0 - 180 degrees.

- 1. Click on a point on one side of the angle.
- 2. Click on the apex.
- 3. Click on a point on another side of the angle.









The software calculates the size of the angle.

Measure distance

Use this tool to measure the length of a distance.

- 1. Click and drag the mouse in the required direction.
- 2. Release the cursor once you have reached the end point.

The software calculates the distance between the two points.

Area measurement

Use this tool to measure any area.

- 1. Click on each consecutive corner point on the edge of the area you want to measure.
- 2. Then click on the first set point again.

The software calculates the area which is delineated by the connecting lines between the set points. *Diameter*

Use this tool to calculate the diameter of a circular area.

- 1. Click into the center of the required circle.
- 2. Click and hold the mouse button to drag the circle to the required size.

The software calculates the circle's diameter.

Color Selection

The color buttons allow you to select a color in which the new measurement objects are drawn into the image. The current color can be seen in the larger bar above. By left-clicking on this, you can also open an additional menu.



Line thickness

Here you can select the line width for the drawn objects.

8.3.4.3 Anonymization

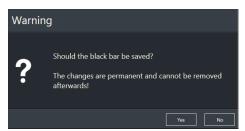
If you want to deidentify patients or want to blacken parts of the image for any other reason, use the *Black Bar* function.



- 1. Click the *Black Bar* button in the right menu bar of the measuring function in the preview window.
- 2. Hold the right mouse button down to drag the black rectangle from one corner to the opposite one.



3. To save, click on the disc symbol in the menu bar above the image.



4. Click *Yes* to confirm the security message.



Once an black bar is saved it can no longer be removed.

8.3.4.4 Deleting images

It is not possible to delete individual images in the module Total Body Mapping. Alternatively, the following options are available:

- Delete complete sessions:
 - 1. Move the cursor over the number of the corresponding session in the timeline until the info window for the imaging session appears (cf. chapter 8.1.3 Timeline).
 - 2. Click on *Delete session* and confirm the following message.

If a baseline has been deleted, the first follow-up session automatically becomes the baseline. Please note that this action cannot be undone!

- If necessary, the entire patient profile can be deleted (cf. chapter 7.2.3 Updating and Deleting Patient Information).
- Alternatively, information that is no longer required in individual images can be permanently overdrawn with the anonymizing function and thus deleted. (cf. chapter 8.3.4.3 Anonymization). Please note that this action cannot be undone! The overdrawn content of the image will be irrevocably overwritten.
- If the image content is only to be temporarily overdrawn, you can use for example the Rectangle drawing tool (filled) (cf. chapter 8.3.4.2 Drawing and measurement tools)



8.4 Mosaic View (exclusive for ATBM master Edition)

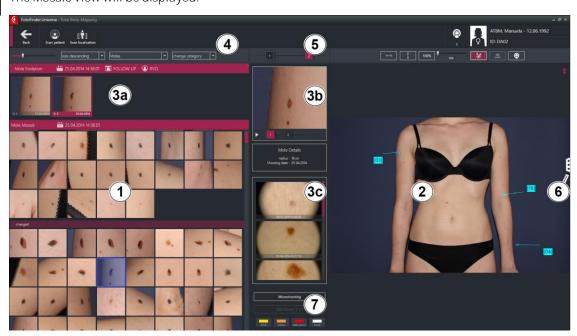
After performing the FotoFinder Bodyscan (cf. chapter 8.3.3 Bodyscan ATBM) the Mosaic View can be used for the lesions. This feature is exclusively only available for the ATBM master. The function is for the rapid detection and comparison of lesions. The lesions of the Bodyscan are displayed in a grid, which allows a simple comparison of shapes and sizes.

€NOTE

The classification of the Bodyscan results are based on statistical analysis and do not replace a medical diagnosis. The diagnosis is the responsibility of the doctor.



1. To start, click on the *Mosaic* icon in the menu bar. The Mosaic View will be displayed:



Mosaic (1)

In the lower left half of the screen (1) you can see all detected tiles of the Bodyscan.

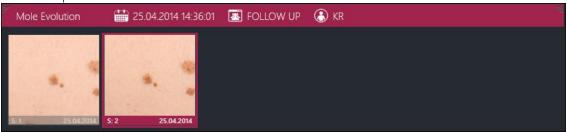
Overview image (2)

If you click on one of the tiles, the corresponding overview image (2) appears on the right. There, the selected tile is marked with a small blue circle.

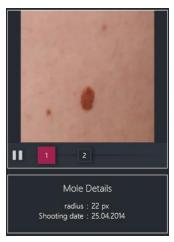
8 Total Body Mapping Module

Mole Evolution (3a) and (3b)

The development of the selected lesion will be shown in this section:



Each capturing session is listed individually (3a).



In addition, an evolution course is displayed in the middle section of the screen (3b).

The view of the lesion changes here through the individual imaging sessions and thus indicates the change over time.

With clicking on the Pause icon you can pause the replay and with another click now on the Play icon you can resume.

Below the replay further information are shown, e.g. capture date.

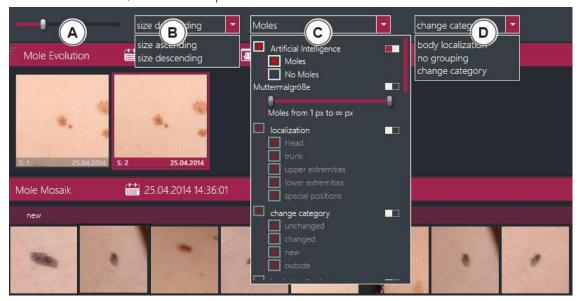
Existing micro image (3c)

If a marker with micro images already exists for the selected lesion, these will be displayed in the center of the screen (3c). By clicking on the micro image you can also enlarge it in the preview window.



Sorting, filtering and grouping options (4)

For a better overview, there are multiple tools available:



A Zoom control

Here the zoom factor can be freely adjusted.

B Sorting options

Here the sorting can be set, based on size (ascending or descending).

C Filter function

Here a selection of the criteria can be set that the lesions must meet in order to be displayed. Inactive filters are grayed out, active filters are marked with a colored checkbox.



The Mosaic view works with Artificial Intelligence, which provides even more accurate results compared to rule-based lesion detection. To refine the results displayed here, the *Artificial Intelligence* filter is already active by default and set to *Moles*.

D Grouping function

Based on Localization or the status of change (new, changed, not changed, other) the images can be further grouped.

Selecting the imaging session on the Timeline (5)



A timeline is also available here (cf. chapter 8.1.3 Timeline). You can quickly and easily switch to another recording session with a mouse click.

Selecting Localization (6)



- 1. Move the mouse over the tab on the right edge of the image to call up the localization menu:
- 2. Select the desired body region by mouse click.

Adding a Marker (7)

1. Select in the Mosaic grid view on the left or in the preview image the corresponding tile with a mouse click.



2. In the lower part of the screen, click on the *Add marker* icon.

The tile is then marked on the overview image with a marker and automatically assigned with a marker number.

- 3. To classify the tile click on the corresponding field (*Normal, Suspicious*, ...) in the classification menu.
 - You can also click directly on the desired classification instead of step 2. to create and classify a marker in just one step.
- 4. Right-click on the marker number to open a context menu to. e.g. continue directly with the micro image capture or delete the marker again. Detailed information about markers can be found in the separate chapter (cf. chapter 8.6.1 Marker).



8.5 Reports



With the *Report* button in the menu bar of the TBM module 's user interface or the image comparison, you can create various types of reports in pdf format.

ATBM Single

The photos during a session are selected without the associated micro images.

ATBM Full

The selected markers and micro images associated with the photos of a session are also selected. ATBM Image compare

You can start this report function from the image comparison screen. The photos currently selected from the two sessions are selected for the report.

8.6 Connection with the Dermoscopy module

With the *Dermoscopy* module you can take images with a Dermoscopy camera.

- You can capture dermoscopic images of lesions and track changes.
- The results of the Bodyscan are transferred to the Dermoscopy module where they can be displayed or hidden just as in the TBM module.



With the *Dermoscopy* button in the menu bar of the user interface you can change directly into the Dermoscopy module. The image currently displayed in the TBM module is then also shown in the preview window of the Dermoscopy module, where you can continue using it immediately. If you click *Back* in the Dermoscopy module, you will return to the TBM module.



You can start some important functions of the Dermoscopy module directly from the TBM module.

8.6.1 Marker



Use this tool to mark a skin feature.

You can start the *Marker* tool in the TBM module by clicking on the *Marker* button. You can find this button in the following menu bars:

- On the Desktop
- In full image display
- In image comparison

The image displayed in the preview window of the image is framed red in the marker mode. You can now place markers with arrows on the photo.

- 1. Move the cursor over the area you want to mark.
- 2. Press and hold the left mouse button and move the mouse to draw an arrow in the required length.
- Release the mouse button.

A marker is added and automatically numbered.



8.6.1.1 Context menu

Right-click on the number of a marker to open the context menu.



Fig. 28

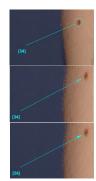
- With *Micro image* you can start the micro image capturing process.
- With *Micro image compare* you can compare two existing micro images at the marker position.
- With *Delete marker* you can remove a marker and all associated micro images.
- With *Deactivate marker* you do not delete the marker. It is then displayed as deactivated.
- The four colored buttons in the middle allow you to classify the skin feature.

8.6.1.2 Markers in Follow-ups (Ghost Marker)

The software automatically copies existing markers (Origin Markers) into follow-up sessions. This prevents the creation of markers with different numbers for the same skin feature. You will see the marker in all follow-up sessions.

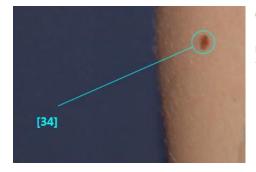
Here is an overview of the different marker labels:

Ghost Marker that has not yet been confirmed: Marker tip is round.



Ghost Marker, which was confirmed: Almost like an Origin Marker, but the tip is not filled.

Original Marker: Marker head is filled.

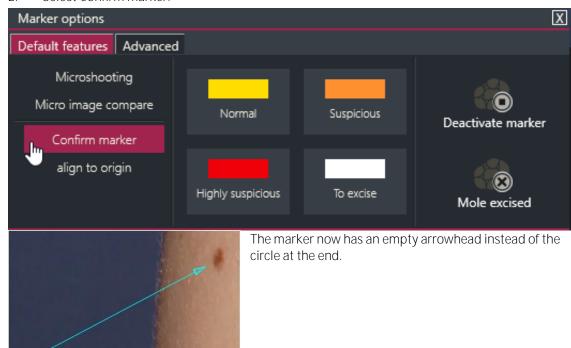


Once you create a follow-up image, any markers from previous sessions will be displayed there as well. You will recognize these automatically adopted Ghost Markers on the circle at the end instead of a pointed tip.

Confirming markers

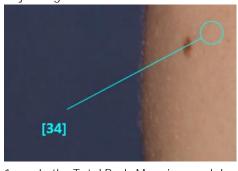
If you are satisfied with the automatic placement of the marker in the following shot, you can confirm the marker:

- 1. Open the context menu with the marker options by right-clicking on the marker number.
- 2. Select Confirm marker.



Adjusting markers

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If for example the orientation of the following shot does not exactly match that of the previous one, the Ghost Markers are not inserted exactly at the lesion. In this case, you can move Ghost Markers:

- 1. In the Total Body Mapping module, open the image comparison with the two overview images.
- 2. The tool required to do this has to be selected. It will be highlighted in purple.
- 3. If you want to move the marker, click with the left mouse button and hold it pressed down on the desired marker and move it.
- 4. If you want to change the angle of a marker, click on the end of the arrow (not on the number) and drag it to the desired direction and length.

The marker now has an empty arrowhead instead of the circle and is considered confirmed.



Auto aligning markers

If you have not manually aligned your Ghost Markers in the follow-up image, you can also use the *Auto-align markers* feature. The prerequisite is a Bodyscan performed, as this function aligns the markers in all follow-up images.



8.6.2 Capturing micro images

You can start capturing micro images directly from the Total Body Mapping module.

- 1. In the preview window or in image comparison, right-click on the marker of the required lesion.
- 2. Select the *Microshooting* option in the appearing context menu.

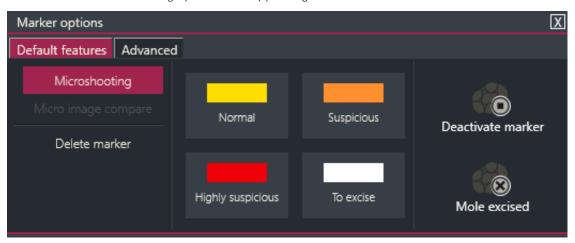


Fig. 29

The software starts the capturing mode of micro images in the Dermoscopy module (cf. chapter 9.5 Micro capturing (images and videos)).

3. Click on *Back* to return to the TBM module.

8.6.3 Display micro images

You can view dermatoscopic micro images directly in the TBM module. You can recognise markers with existing micro images by the fact that the numbering at the end of the marker arrow is in color. To open the micro images, proceed as follows:

1. Left-click on the number highlighted in color.

A thumbnail preview of all micro images associated with this marker position will open.

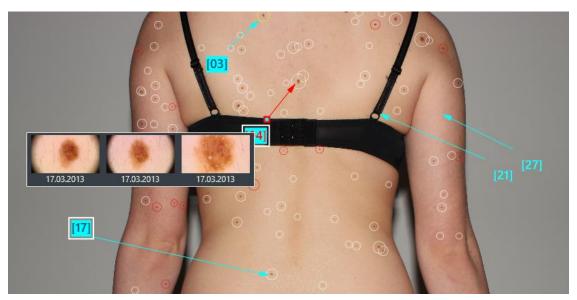
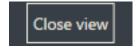


Fig. 30

2. Click on one of the thumbnails to display the respective micro image instead of the overview image in full screen.

You can now view the image in detail.

3. Double-click on the enlarged micro image to return to the previous view.



Alternatively, you can return to the overview image via the *Close view* button.



8.6.4 Micro image compare

You can compare two micro images of one marker position from the TBM module.

- 1. Right-click on the number of the required marker position.
- 2. Select the *Micro image compare* option in the appearing context menu.



Fig. 31

The software starts the image comparison of micro images in the Dermoscopy module at the selected marker position (cf. chapter 9.7.4.2 Comparing micro images).

3. Click on *Back* to return to the last view in the TBM module.

$9_{\, \text{Dermoscopy module}}$

9 Dermoscopy module

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Dermoscopy

To start, click on the *Dermoscopy* button.

9.1 The Desktop

The Dermoscopy user interface consists of seven sections:

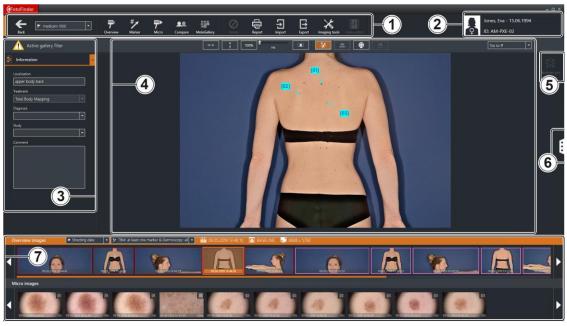


Fig. 32: Example view of the Dermoscopy module's user interface

- 1 Menu bar
- 2 Patient data field
- 3 Image data field
- 4 Preview window

- 5 Optional expert systems (not available in all countries)
- 6 Tabs for the localisation menu / classification menu
- 7 SmartGallery



9.1.1 Menu bar

The menu bar is located on the top edge of the screen.



The functions of the buttons are listed below.

Back: This returns you to the previous screen.

Back

Open the camera selection via the small triangle on the right.



Screening: This takes you to the Screening module (cf. chapter 11 Module Screening). You can choose to hide or show this button under Settings (cf. chapter 6.5.1 Dermoscopy).

This button changes depending on camera selection:

Overview. Create overview images.

Schematic. Select the localization on the basis of a schematic manikin.



MoleGallery

Marker: Draw arrows in overview images to indicate the location of individual lesions and assign microimages.

Micro: Start capturing microimages. To do so, you first need an overview image with markers.

Image comparison: This takes you to image comparison to compare images of one patient.

MoleGallery. The MoleGallery displays all markers with the relevant overview image and the previous reference images in one overview page and offers additional functions.

Delete: You can delete the marked (orange framed) image. Before final deletion, you must confirm the function.

Report: Create a report with a patient's relevant images.

Import: Import overview images from your hard drive or external storage media (cf. chapter 13.1 Importing images).

Export: Export images to local or external storage media such as CDs, USB stick, hard drive, etc.

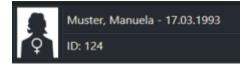
Image editing: Open the tools to mark, measure and anonymise images (cf. chapter 9.7.5 Image editing).

Videoeditor: The Videoeditor lets you edit videos (cf. chapter 9.8.1 The Video editor).

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$9_{\, \text{Dermoscopy module}}$

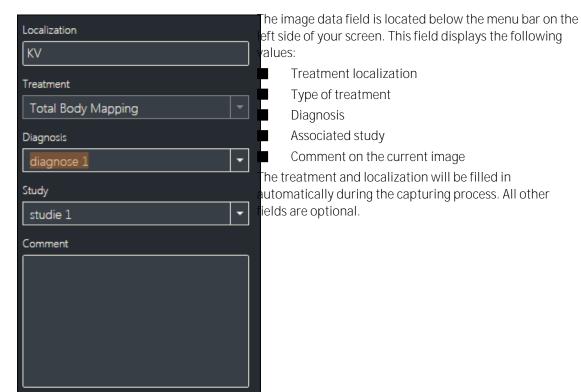
9.1.2 Patient Data Field



The most important patient data are displayed in a field on the top right next to the menu bar:

- Name
- Date Of Birth
- Patient Record Number

9.1.3 Image Data Field





9.1.4 Preview Window

The Preview Window is located in the middle of the screen. Here you can freely enlarge selected overview or micro images. You can select the image's enlargement individually by turning the mouse wheel. You can also move the slide bar above the image. You can change the displayed section by clicking and holding the left mouse button to shift the image.



Fig. 33

9.1.4.1 Magnifier function

If you right-click and hold the mouse button in the displayed preview image (overview or micro image), a magnifier appears which allows you to enlarge image sections. Adjust the size of the magnifier with the mouse wheel.



Fig. 34

9 Dermoscopy module

9.1.4.2 Imaging Tools

Above the image you see the following menu bar for the image display:



With this button you can enlarge the image to the width of the preview window.

With this button you can adapt the image to the height of the preview window.

With this button you can display the full resolution of the picture.



With the help of the slider or by turning the mouse wheel you can zoom in or out on a photo. You can pan the image by holding the left mouse button after you zoomed in.

With this button you can hide or display Markers.

With this button you can show or hide overlayed graphic items.



With this button you can show or hide Bodyscan circles.

This is only possible for images created in the Total Body Mapping module.



Use this button to fade in a scale in the preview window (not possible for uncalibrated images). By right-clicking on this button, an additional menu will appear where you can individually set the line thickness as well as the text and line color.



With this button you can show or hide the results of the Bodyscan function integrated in the Total Body Mapping module in two steps.



During the first step, you can mark all detected lesions with white, yellow or red circles. Here, the red and yellow circles mark the new or changed lesions in the more recent image. To simplify visual comparison, the changed lesion are also marked yellow in the prior image.



During the second step, you can mark only the new or changed lesions in the new image with yellow or red circles.



9.1.4.3 Marker



With the *Go to #* button you can jump to the images of a specific marker. Select the number of the appropriate marker in the drop-down menu.

(NOTE

More about the marker functions can be found in the chapter Markers (cf. chapter 9.4 Marker).

The following points apply to the marker view:



The numbered arrows (Markers) on an overview image point to the marked lesions.



If the number of a marker is highlighted with a color, at least one micro image exists for this position.



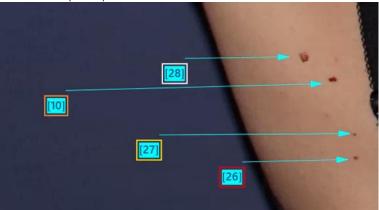
The currently selected marker is displayed in red.



Disabled markers appear as light gray arrows with the numbers crossed out with red. Disabled markers can be enabled again (cf. chapter 9.4.2.6 Deactivating a marker).



- Deleted markers appear as light gray arrows with the numbers crossed out with white. Deleted markers can also be reactivated (cf. chapter 9.4.2.7 Set markers as deleted).
- Classified markers appear with a coloured frame around the number (cf. chapter 9.1.6 Localization and Classification):
 - Normal (yellow)
 - Conspicuous (orange)
 - Highly conspicuous (red)
 - To excise (white)



9 Dermoscopy module

9.1.5 Optional expert systems

Click on the respective button to start the optional expert system.

(NOTE

The software application Moleanalyzer pro is described in detail in a separate manual.

€NOTE

The software application of TrichoLAB is available in a separate manual for TrichoLAB Suite.



9.1.6 Localization and Classification

If you move the cursor to one of the tabs on the right or left side of the screen, a menu with additional information on the currently selected image will appear. If you move the cursor away from the displayed menu it will disappear again.



The tab on the right side of the screen displays a schematic view of the patient. The localization of the image in the preview window is highlighted in color. There are two different localization puppets for Total Body Mapping and Dermoscopy.

Localization in the Dermoscopy module is editable (e.g. when the wrong arm was selected). Click to deselect.



The tab on the left is only visible if the image in the preview window is a micro image. A menu will appear where the displayed micro image can be classified. You can fixate this menu with the pin in the top right corner. You can classify several micro images without having to open the menu again each time.

$9_{\, \text{Dermoscopy module}}$

9.1.7 SmartGallery

The gallery on the lower part of the screen displays all the overview and micro images of the selected patient.

Micro images belonging to the respective (orange framed) overview image are displayed in the second line.



Fig. 35

Overview images

The field Overview images displays all of a patient's overview images.

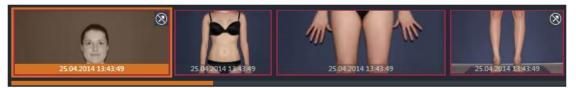


Fig. 36

- The active image is displayed with an orange frame.
- You can scroll through the images with the arrows on the right and left of the overview images. Alternatively, you can use the mouse wheel to do so. In this case, the mouse cursor must be in the SmartGallery.
- Click on any thumbnail to select it. The selected image is displayed in the preview window

The screening date and time, image type as well as the resolution of the selected image are displayed above the gallery:





The crossed-out arrow on the thumbnail of an overview screen indicates that there is no marker in this overview.

You can enable/disable the display of this icon in the settings (cf. chapter 6.5.2 Total Body Mapping)

(NOTE

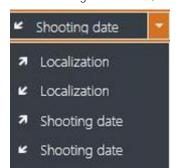
The color of the overview image frame indicates the image type:

- Dark purple: TBM baseline session
- Pink: TBM follow-up session
- Blue: Overview image from the Dermoscopy module

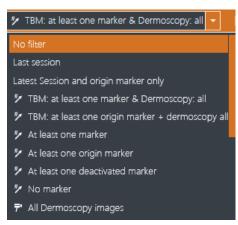


Sorting and Filtering Overview Images

By default, all overview images of a patient are displayed in the gallery sorted by image capturing date. To make navigation easier, the SmartGallery offers additional options for sorting and filtering images



With the help of the drop-down menu above the overview images, you can sort the images by localization or capturing date in ascending or descending order.



An additional drop-down menu is located on the right. Here you can specify the criteria an image needs to fulfill in order to be displayed in the gallery.

9 Dermoscopy module

Micro images

Micro images are displayed on the lowest screen section.



- As a default setting, all micro images for the current (orange framed) overview image are displayed. As soon as you left-click to choose a marker in the preview window, this will appear in red and only the corresponding images will be displayed in the micro gallery.
- If the marker has already been classified, the marker number in the gallery is framed with the corresponding color.

By clicking on one of the micro images in the gallery, this micro image will be displayed in the preview window. By double-clicking in the preview window you can see the image in full screen.



Fig. 37

The bar above the micro images displays information on the capturing date and time, treatment,

image type and resolution. It also displays the zoom factor used during the capture of micro images. In addition you can see whether the micro image was captured with polarized or non polarized lighting.



9.1.8 MoleGallery



Start the MoleGallery by selecting the MoleGallery button of the Dermoscopy module. The MoleGallery displays all markers with the relevant overview image and the previous reference images. The MoleGallery also offers different filtering and sorting functions and additional tools.



Fig. 38: Example view of the MoleGallery

- 1 Menu bar
- 2 Number of capturing sessions for the marker
- 3 Marker (overview image)
- Today (displays the current day's microimages, if any have already been taken).

Here you can

- start a follow-up capture
- label the marker as *Deactivated*
- label the marker as Excised
- 5 show previous recording sessions, sorted chronologically in descending order side by side



Fig. 39: Information symbol for additional images

If more than one microimage is saved for a marker during a capturing session, you will find the adjacent icon on the preview image in the MoleGallery.

$9_{\, \text{Dermoscopy module}}$

9.1.8.1 Sorting function

The MoleGallery offers display sorting options. You can sort according to

- the number of capturing sessions or
- the marker number.

sortiert werden.



1. To sort, click on the sorting symbol in the column heading.



The rows are sorted according to the selected column. You can also recognize this by the changed sorting symbol with red arrow and red corner.

2. Click on the same sorting symbol again if you want to change the sorting sequence (in ascending or descending order).

9.1.8.2 Menu bar

Filter functions

Different filters are available in the menu bar.

- Active filters, recognisable by an orange bar underneath the button.
- The number in the upper right corner of the respective button shows the number of markers that match the filter criterion.



All: No filter. All markers are displayed.

Missing. Only those markers are displayed for which a subsequent capture has not yet been

created and saved in the current capturing session.

Excised: Only markers marked as excised are displayed.

Deactivated Only markers marked as deactivated are displayed.

Follow-ups



1. Click on *Follow-ups*. These buttons are located in the menu bar or in the *Today* column at the respective marker.



This starts the capturing mode. The capturing mode is described in detail at a different point of these operating instructions (cf. chapter 9.5 Micro capturing (images and videos)).

2. You can create follow-ups for all markers one after the other. If required, you can also skip markers or select another sequence in capturing mode.

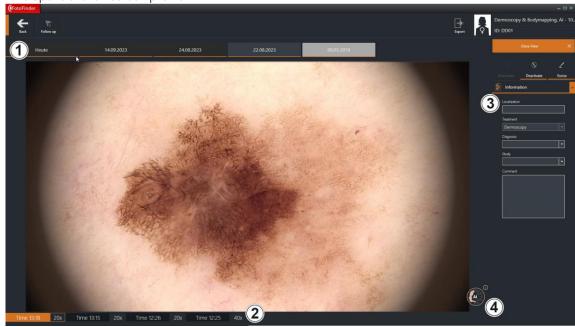


9.1.8.3 Call up microimages of a marker

You can view the saved microimages of a marker in full screen.

1. In the MoleGallery, select a marker and click on a micro-preview-image of this marker.

This opens the full screen preview:



1 Above the preview image you can see all the dates on which capturing session took place.

Meaning of the date colours stored here:

Black: no microimage available

Dark grey: at least one microimage available

Light grey: at least one microimage available and currently displayed in the preview

window

- Click on a date to open a certain capturing session.
- 2 Under the preview image you can see the number of microimages saved for this marker during the selected capturing session. The time and zoom value are also displayed.
 - Click on this detailed information to open the respective microimage.
- On the right you will find the image information that can also be seen in the user interface of the Dermoscopy module.
- The button for retrieving an AIMEE score is available at the bottom right of the preview image (cf. chapter 9.7.1 AIMEE AI Assistant).

$9_{\, \text{Dermoscopy module}}$

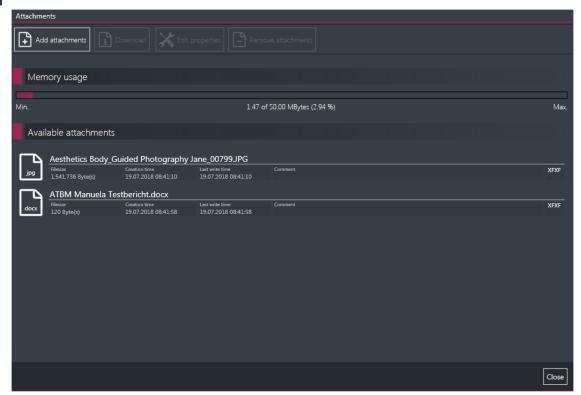
9.1.9 Saving file attachments

You can save file attachments for every photo.

This function can be activated and deactivated in the settings (modules / ... / image viewer) (cf. chapter 6.5.1.2 Image Viewer).



1. Click on the paperclip icon in the upper left corner of the preview window. The Add attachments window will open.



2. Via Add Attachments you can select files that you want to save as an attachment here.

Once you selected an existing attachment, you can also perform the following actions here:

- Download: The attachment can also be stored outside of Universe.
- Edit properties: You can change the files name, enter a comment and choose whether to include the attachment in an XFXF export.
- Remove selection: The file can be removed again as an attachment.
- 3. With Close this menu and window will be closed.

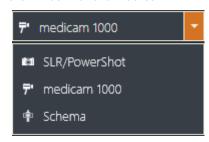


You can see if there is any attachment if the paper clip is colored. This color variates depending on which module are you using (Dermoscopy, Total Body Mapping or Aesthetics).



9.2 Overview images

In overview images, you can save the exact position of a lesion which is to be microscopically examined with the medicam.



You therefore need an overview image assigned with markers for every microscopic image. You can create this overview image in various ways:

- with the medicam or the leviacam without the dermoscopy lens
- with a digital camera connected to the computer
- as a schematic template



The standardized overview images of the entire body taken in the *Total Body Mapping* module can also be used as overview images for dermoscopy.

▲ WARNING! Magnetic field

Magnets can influence the function of pacemakers and defibrillator implants.

Never place the leviacam without levialens directly next to pacemakers or implanted cardioverter defibrillators (ICDs), and ensure a sufficient distance.

9.2.1 Overview images with the medicam or the leviacam

For Overview images with the medicam or the leviacam please consider the following:

- Make sure that the room is bright and well illuminated.
- Do not capture images in front of a window as this could result in overexposed images.
- Hold the camera still while capturing. Use the distance holder to help you when capturing close-ups with the medicam.
- 1. Remove the micro lens from the medicam or the leviacam.

A CAUTION

Please pay attention to the following when using the medicam without a lens attached: A small low voltage electrical charge could be transmitted if the contact pins inside the lens bayonet ring are touched by the patient or user. Therefore, do not touch the contact pins during use!





3. Click on *Overview* to start the capturing.

Now you are in the imaging mode.

(NOTE

The camera will automatically exit the live view after 5 minutes of inactivity. If necessary, start the capturing again by clicking on the icon above.

The imaging mode will start after a short initialization. Here it is possible to change between image or video recording with the Switch button.



The LED ring light turns on automatically.





Select the zoom level using the respective buttons.

leviacam: zoom not possible.

During the capturing process, you can choose between five white balance settings in the menu bar.

Select the color profile depending on the environmental and light conditions. Use the same color profile for follow-up images.



6. Now press the camera's release button or click on the *Photo* icon.

Ieviacam: Please note that capturing an image with activated autofocus (cf. chapter 6.2 Image Capture Devices) may take a few seconds. Keep the device still during this period. If the autofocus is



deactivated, focus the image using the arrow button before capturing the image. If the image is blurry or if you are not satisfied with the image, you can reactivate the Live view by clicking on the *Live image* icon. The captured image will be deleted.

This will also work using the appropriate button on the back panel of the camera:

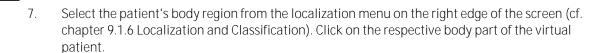


Ieviacam



You can enter additional information in the image data field on the left side of the screen:

- Diagnosis
- Associated study
- Comments





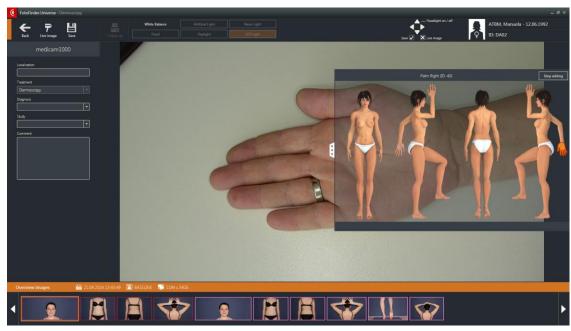
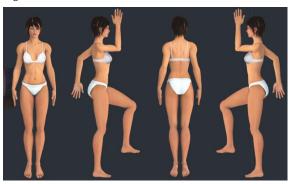
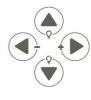


Fig. 40: Localization menu



When moving the cursor over a localization, this will be highlighted. By clicking on one sections it will be marked red and automatically entered in the *Localization* field.



The localization puppet also appears when the release button is pressed again. You can use the arrow buttons to browse through the displayed body regions on the localization puppet and select the appropriate one using the release button.

When using the medicam, it is also possible do this with the corresponding button of the camera:



In this way, the image is also saved and stored in the SmartGallery.



- 8. If you have not already done so, save the image with one of the following methods:
 - Press the release button a second time.
 - Click on the Save button.

After the image is saved, the camera switches back to the live view and you can immediately take the next overview image.



Use the Follow-up function to create a follow-up image for an already existing overview image.

When starting this function by clicking on *Follow-up* in the menu bar, the preview window will be divided in the middle. The already existing overview image will be displayed on the left side. You can select the required image of the patient from the field on the bottom of the screen.

When using the medicam or leviacam, you can browse in the SmartGallery with the buttons on the back panel and select an image:

medicam:







$9_{\, \text{Dermoscopy module}}$

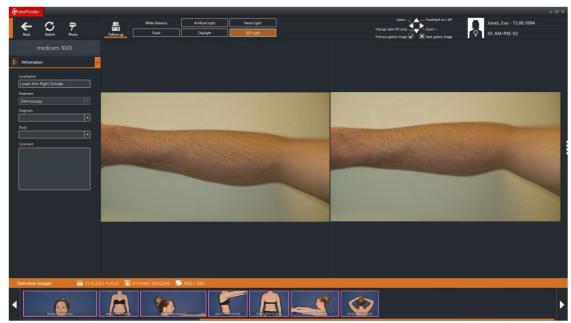
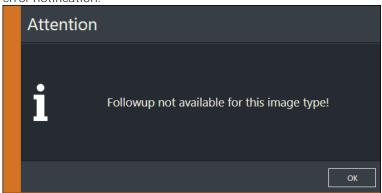


Fig. 41

Please note that you can only capture follow-up images for images that were also captured in the dermoscopy module. Imported images are an exception. Selecting a different image will result in an error notification:



You can optimize comparability between baseline and follow-up images by proceeding as follows:

- 1. Position the camera so that both images display the same sections.
- 2. Configure the lighting values so that both images correlate in the following points:
 - Image section
 - Capturing angle
 - Lighting
 - Color

Use the *Back* button to end the capturing and return to the user interface of the Dermoscopy module.



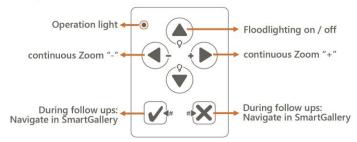
€NOTE

The image data field now automatically displays the capture date and time, treatment and localization.



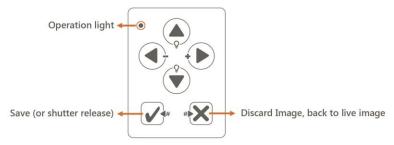
An overview of the medicam 1000 panel functions relevant for overview images is provided below:

1. Overview Images



1a. Overview Images - Frozen Image

Floodlighting automatically on



1b. Overview Images - select localization

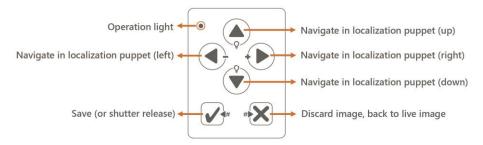


Fig. 42: medicam 1000 panel functions for overview images

9.2.1.1 White Balance for the medicam 1000

Environmental and light conditions in overview images may vary considerably. In order to adjust your medicam 1000 to the current ambient lighting, you can adjust the white balance.

For white balance in the Dermoscopy module, proceed as follows:



- 1. Remove the micro lens from the medicam.
- 2. In the menu bar, select the medicam.



3. Click on Overview to start the imaging mode.

Now you are in the imaging mode.

- 4. Hold the camera over a white surface.
- 5. Click on *Fixed*.

The camera color settings are now aligned to the current ambient light conditions.



9.2.2 Overview images with a digital camera

In order to capture overview images with a digital camera connected to the system, proceed as follows:



. Select *SLR/Powershot* in the drop-down menu.



2. Start the capturing process with the *Overview* button You are now in capturing mode.

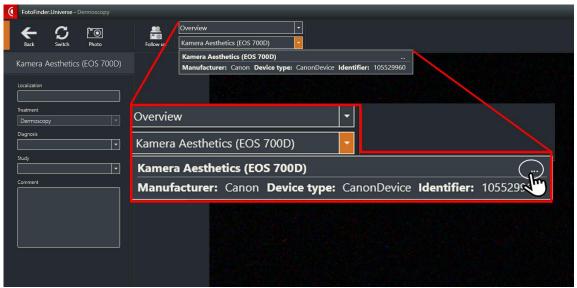
- 3. The default capturing profile is *Overview*. You can change this if necessary to adjust the camera settings to your needs.
- 4. If several SLR cameras are connected, the camera selection can be changed in the drop-down menu in the menu bar.

The further procedure is similar to the use of the medicam.

9.2.2.1 Renaming connected digital cameras

Several different digital cameras can be connected to your system. As a user to be able to differentiate between these cameras during the capturing process, these cameras can be individually renamed.

- 1. Start the capturing process.
- 2. Open the camera selection drop down menu.
- 3. Click on the "..." at the end of the row (see on screenshot below)



4. A cursor appears behind the current camera name. Overwrite this as desired and confirm with *Enter*.

Reset camera names

You can reset the camera names to the original if you follow these steps:

- 1. From the main Dashboard go to Settings | Image Capture Devices | general settings.
- 2. Click on Reset at Reset all custom device names.
- 3. Quit the *Settings* with clicking on *Close*.



9.2.3 Overview images via Wi-Fi



Overview images can also be imported with a digital camera via Wi-Fi SD card.

- 1. Select *Wi-Fi* from the drop-down menu.
- 2. Click on the *Overview* button.

In Wi-Fi mode, you can take several overview images without having to confirm anything in the software.

After the capturing process, you can insert localizations using the tab on the right edge of the screen (cf. chapter 9.1.6 Localization and Classification).

More information is contained in the chapter Settings (cf. chapter 6 Settings).

$9_{\, \text{Dermoscopy module}}$

9.2.4 Overview images with the scheme

Instead of clinical overview images you can also use the virtual patient's corresponding detail.

- 1. Select *Scheme* from the drop-down menu.
- 2. Click *Scheme* now.

You can now select different localizations.

3. Select the appropriate body part from the most suitable perspective by clicking on it. The selected schematic body area will now appear enlarged on the right. In the image information area on the left you can add further details, e.g. Diagnosis, Study or Comments.

4. Click on Save.

The selected schematic display is saved as an overview image.

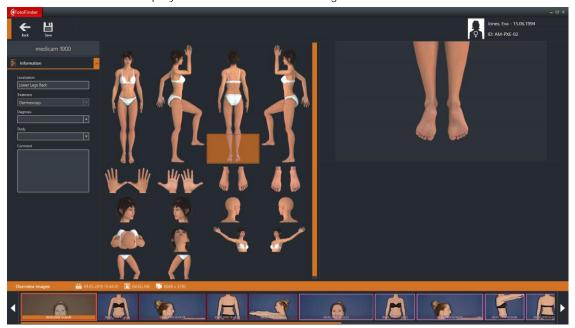


Fig. 43



9.3 Overview video

The FotoFinder Universe software offers the possibility besides imaging to create and save videos as well.

These videos can be recorded in the *Dermoscopy* and *Aesthetics* modules. In the *Dermoscopy* module it is possible to create a video for overview and micro recordings as well.

For good results please always keep in mind all the instructions applied for normal image capturing (cf. chapter 9.2.1 Overview images with the medicam or the leviacam).

- 1. Take the microscopic lens off of your medicam or leviacam.
- 2. Select from the drop down menu your medicam or leviacam.







The camera will quit the Live view mode after 5 minutes of inactivity. You can start the imaging again by clicking on the Overview button again.

The LED ring lights will automatically turn on.

After a short initialization the imaging mode will start. You can switch here between Image capture or Video recording.



4. Position your imaging device.



5. Click on *Record*, or press the release button on the grip to start the video recording.



Fig. 44: Example view for active video recording

During the recording:



the length of the recording shows in the upper right corner. The blinking red dot indicates that the recording is in progress.





- you can adjust the zoom factor on the medicam with the respective buttons.
- the *Pause* and *Stop* buttons are active:



You can pause the recording with the *Break* button. You can restart the recording any time with clicking on *Record* again.



When finished, click on Stop.

You can specify the maximum length of videos in the settings. (cf. chapter 6.5.1.8 Videos).

Right after the recording the video will be automatically played back.



You can enter additional information in the image data field on the left-hand side of the screen:

- Diagnosis
- related Studies
- Comments



- Click on Save when you are satisfied with the recording.
 Otherwise click on Live image to be able to start a new recording or on Back to quit the capturing mode.
- 7. The localization menu will open automatically after you click on *Save*. Here select the body part on the virtual patient (cf. chapter 9.1.6 Localization and Classification).

For editing options please see in *Videoeditor* (cf. chapter 9.8.1 The Video editor).



9.4 Marker

Markers indicate the positions on the overview images where lesions are to be examined with dermatoscopy. Before a micro image can be created, a marker has to be drawn. Additional markers can be set in newly captured or already existing overview images at any time.

(NOTE

- Without drawing a marker it is not possible to capture and save a micro image.
- Every micro image has to be ordered to a marker on an overview image.
- The same lesion should always be captured under the same marker.

(NOTE

An overview of the possible marker views can be found earlier in this manual (cf. chapter 9.1.4.3 Marker).

MoleHistory

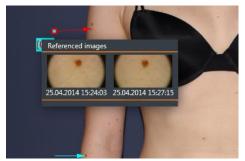


Fig. 45: MoleHistory

To visualize the evolution of existing micro images for a specific marker (*MoleHistory*), click directly on the marker number with the left mouse button. Click on any of the preview images to see it in full screen mode.

9.4.1 Set marker

For labeling, please proceed as follows:



1. Click on the *Marker* button.

This is located in the menu bar of the user interface of the dermoscopy module as well as in the full screen view of the selected overview image.

When the marker function is activated the button and the preview images or both marked with an orange frame.

- 2. Click and hold the mouse button to draw a line away from the required lesion in the overview image.
- 3. Release the mouse button when the line has the required length and alignment.

The line is saved and automatically given a number.

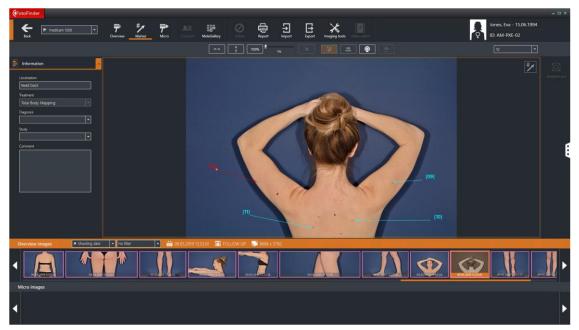


Fig. 46: Set marker

- 4. Mark the whole overview image in this manner.
- 5. As soon as all areas are marked, switch off the marker function by clicking on the *Marker* button again.



A patient's marking is consecutive, i. e. each number is assigned only once.



9.4.2 Marker Context Menu

Right-clicking the number of a marker displays a context menu with various marker options.



Fig. 47: Marker Context Menu

9.4.2.1 Importing a micro image

You can import micro images from your harddrive or external storage media.

9.4.2.2 Micro image compare

You can compare two micro images (cf. chapter 9.7.4.2 Comparing micro images).

9.4.2.3 Delete marker

You can delete incorrectly placed or no longer needed markers.

- 1. In the image, right-click on the number of the appropriate marker.
- 2. In the appearing context menu, select *Delete marker*.



By deleting a marker all micro images in this position are also deleted.

9.4.2.4 Print micro image review

If micro images have been captured for this marker, the function *Print micro image review* will also be active. Selecting this will directly create a review with the appropriate overview image and all available micro images (cf. chapter 9.9 Reports).

9.4.2.5 Classify Marker

You can classify markers using four different marker tags. Depending on the lesion, you can label the markers as follows:

■ Normal (yellow) ■ Highly conspicuous (red)

Conspicuous (orange) To excise (white)

Select the required classification in the appearing context menu.

If a micro image in the Dermoscopy module is displayed in the preview window or in full screen mode, you can classify this position by using the tab menu on the left side of the screen.

In addition, a classification menu is available in the Dermoscopy Micro Image compare menu bar. The selected classification applies to all capturing sessions.

9.4.2.6 Deactivating a marker

If a marker should be skipped in all future examinations, but the marker itself should not be deleted, this can also be disabled:

1. Right click with the mouse directly on the marker number.



2. From the appearing menu select *Disable*. This icon is also available in Micro compare.



The marker number on the overview image will be displayed with a red X crossed out.



With the same steps the marker can be enabled again. For this in the appearing menu click on *Enable*.





You can also find this function in the MoleGallery in the Today column.

9.4.2.7 Set markers as deleted

If a lesion has been excised, the belonging marker can be set to *deleted*. With all follow-up examination this marker position will be skipped without the micro images being deleted.

1. Right click with the mouse directly on the marker number.



2. From the appearing menu select *Excised*. This icon is also available in Micro compare.



The marker number on the overview image will be displayed with a white X crossed out.



With the same steps the marker can be reactivated again. For this in the appearing menu click on *Reactivate.*





You can also find this function in the MoleGallery in the Today column.



9.4.3 Merging markers

If several markers have been created for the same lesion, these can be merged to one marker number using the *Merge marker* function:

- 1. Start the image compare feature in Dermoscopy or Total Body Mapping.
- 2. Select the overview image with the markers you wish to merge.
- 3. Select the two markers with pressed down Ctrl key on your keyboard and left mouse click. The selected markers will be red.





Click on Merge marker.

The following window will appear:



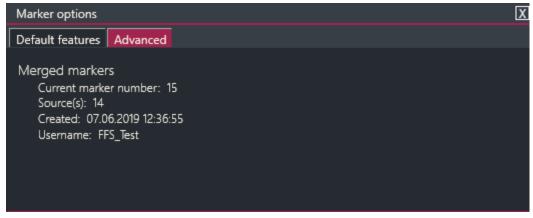
5. By default the software will offer to take the marker number from the left and merge it into the marker number on the right.

With clicking on *Change direction* you can change this to the other way around. If you would prefer creating a new marker number, check the checkbox at *Merge into new marker number:* ...

6. Confirm with *Yes* to finalize the marker merge.

In this example the remaining marker has been assigned number 15. All existing micro images of both markers are stored at this new number now.

You can also find information about the performed marker merges in the marker context menu in the *Advanced* tab:



9.5 Micro capturing (images and videos)

Once you have marked a lesion in an overview image with a marker, you can use the medicam or the leviacam to create high resolution illuminated micro images (incl. videos).

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.Details on the proper cleaning steps can be found in another chapter.
- 1. Place the micro lens onto the medicam or leviacam.



- 2. In the menu bar, select medicam or leviacam.
- 3. In the SmartGallery, select an overview image for which you would like to capture micro images.

You have two options to change over to the micro image capturing mode:

4. Right-click to select the appropriate marker position on the overview image. This opens the context menu.

5. In the appearing context menu, select *Micro image*.

or.



6. Click on *Micro* in the menu bar.

This will open the micro image window.



The camera will automatically exit the live view after 5 minutes of inactivity. If necessary, start the capturing again by clicking on the icon above.



Here you can also choose between markers using the adjacent buttons.

This will also work using the appropriate buttons on the back of the camera:









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The program now shows you the interface for micro image capturing.

Fig. 48: Screen view for micro image capturing

- Live imageAt the top left you can see the current live image and if activated the Ghost function.
- 2 Reference image

 Next to it is the last recorded reference image. In case there are no reference images, the corresponding window will be empty.
- Marker positionThe lower left corner shows the marker position in detail.
- 4 Overview

On the bottom right is the overview picture with the active marker (colored red). With ATBM or Aesthetics images you will always see here the baseline overview image with the Origin Markers, not a follow-up image. The orange bar above the image can be used to display the other overview images for this marker (baseline, follow-ups). The new micro images will be stored at the last Ghost Marker, even if this may not yet be aligned (cf. chapter 8.6.1.2 Markers in Follow-ups (Ghost Marker)).

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- 7. The lens light turns on automatically.
- 8. For non-polarized images use an immersion fluid.

 For polarized images with the medicam and the D-Scope IV lens, or with the leviacam there is no need for an immersion fluid.
- 9. Place the microscopic lens on the skin.

medicam 1000 in combination with the D-Scope IV:

You can switch from polarized to non-polarized images during the capturing process. Press the corresponding button on the medicam:



leviacam: You also do not need immersion fluid when capturing polarized images with the leviacam. In this case, switch the light over to polarized:





10. Only for medicam: Use the *Zoom level* button to select the required magnification.

Alternatively, you can set the magnification factor using the zoom buttons on the camera's back panel (zoom change is also possible during a video recording). If there are already micro images for this position, the camera automatically adjusts to the same values as in the reference image.

The leviacam captures micro images with a 20x zoom factor.

The following procedure differs depending on whether you want to create a micro image or a micro video:

9.5.1 Further steps at micro image captures



For later segmentation in Moleanalyzer pro, you require images with 20x, 30x or 40x magnification. For analysis with AI Score you require images with 20x magnification.

This magnification factor is also required for hair analysis with Trichoscale® pro.

The medicam will Autofocus right away. With the leviacam you can adjust the settings for the Autofocus. (cf. chapter 6.2 Image Capture Devices).

Micro Ghost

To have access to this features it must be enabled first in Settings at Dermoscopy. (cf. chapter 6.5.1.2 Image Viewer).



If there is already a reference image then you can use the Ghost function to improve the comparison. Here the reference image will be layered over the live image. The intensity of the transparency can be set with the slide bar on the right side of the live image. You can also turn the Ghost feature off for the active image with the button on the left side of the slide bar.

The bar above the reference image allows you to select another image as the reference image if there are others available.



You can switch here between Image capture or Video recording.





11. Press the release button on the camera handle or click on the *Photo* icon.

The image will immediately be frozen and displayed in full screen.

Alternatively you can also specify that the displayed image is only shown in Field 1 (cf. chapter 6.5.1 Dermoscopy).



If the picture is blurry or you are not satisfied with the image you can reactivate the *Live View* and with that delete this image.

This you can do with the respective buttons on the back panel of your imaging device too:



leviacam:

12. If necessary, the captured lesions can be immediately categorized. Click on the classification menu above the Micro image.



This also works through the respective buttons on the back panel of your imaging device:



Around the selected class a red frame will appear.



- 13. You can save the image in the following ways:
 - Press the release button on your camera twice.
 - Click in the software on Save.



With the *Previous* and *Next* buttons you can jump to the next marker. You can also select the desired marker number from the drop down menu at *Go to #*.

If all markers of an overview image have been called up, the system automatically jumps to the chronologically next overview picture.

Micro images via Wi-Fi You can also create micro images via Wi-Fi.



- 1. In the menu bar, select Wi-Fi.
- 2. Select the *Micro* button to import images. In this mode, the software automatically jumps to the next marker without you having to confirm anything in the software.

3. Save the image.

The software jumps to the next marker.

4. Repeat the last steps to take further images.



When clicking *Back* you are returned to the dashboard of the Dermoscopy module. If you have not yet saved the last captured micro image, the system will now prompt you to do so.



9.5.2 Additional steps with Micro videos

The first steps to capture micro videos are described earlier in this chapter (cf. chapter 9.5 Micro capturing (images and videos)).

With the Switch feature you can change between image capturing and video recording.





Click on *Record* or press the release button on the grip of your camera to start the video recording.

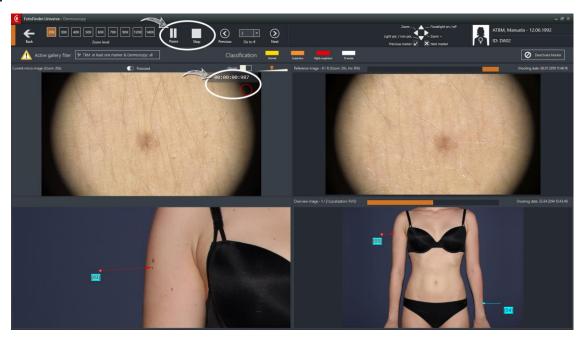


Fig. 49: Example view for active recording in Micro video recording mode

During the recording



the length of the recording shows in the upper right corner. The blinking red dot indicates that the recording is in progress.





you can adjust the zoom factor on the medicam with the respective buttons.



the Pause and Stop buttons are active:



You can pause the recording with the *Pause* button. You can restart the recording any time with clicking on Record again.

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When finished, click on Stop.

You can specify the maximum length of videos in the settings (cf. chapter 6.5.1.8 Videos).



Right after the recording the video will be automatically played back.

Click on Save when you are satisfied with the recording.
 Otherwise click on Live image to be able to start a new recording or on Back to quit the capturing mode.

The saved video will be displayed in the SmartGallery.

For editing options please see in *Videoeditor* (cf. chapter 9.8.1 The Video editor).



An overview of the medicam 1000 panel functions relevant for micro images is provided below:

1. Micro imaging micro illumination automatically on Operation light Zoom "-" Only with D-Scope IV: Lightchange polarized/non polarized Previous marker Next marker

1a. Micro imaging - frozen image

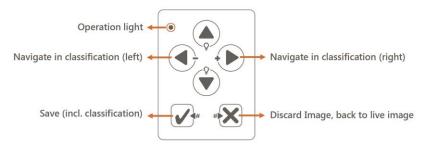


Fig. 50: medicam 1000 panel functions for micro images

9.6 Micro images with the D-Scope III



Fig. 51: D-Scope III



1. For D-Scope III images, start the micro image mode.

- 2. Attach the D-Scope III to your medicam. Proceed as follows:
 - 1. Remove the standard lens. Open the bayonet fastener by rotating it slightly to the left.
 - 2. Attach the D-Scope III. Ensure that the small red dot is at the top and then insert the two pins into the appropriate recesses in the medicam. The D-Scope III will click into place by rotating it slightly to the right.



3. Open the context menu by right-clicking the mouse in the preview. Select *Dscope III mode*. This disables the medicam autofocus and you can use the D-Scope III to manually set the focus level in the image. Enlargements are possible up to zoom factor 400.

- 4. Use immersion liquid on the skin.
- 5. Place the medicam directly onto the patient's skin.
- 6. To capture an image, activate the release button on the camera 's handle. Keep the camera very still and adjust the focus ring manually to focus.

The subsequent process follows in accordance with normal micro image capturing (cf. chapter 9.5 Micro capturing (images and videos)).

Ending D-Scope III recordings:

- 1. End the D-Scope III mode by unchecking in the context menu.
- 2. Remove the D-Scope III from your medicam and replace the standard lens.



9.7 Working with the images

9.7.1 AIMEE AI Assistant

AIMEE is a virtual AI assistant for the initial assessment of skin lesions.

(NOTE

The use of AIMEE requires a FotoFinder Moleanalyzer pro license.

The AIMEE Score serves as preview of the FotoFinder Moleanalyzer pro result. For a more accurate analysis, please continue to use the expert tool!

€NOTE

An AIMEE score can only be requested for microimages with a magnification of 20x.

1. Open a microimage.



The AIMEE button is shown in the lower right preview window.



2. For further information, click on the small i button next to the AIMEE button.

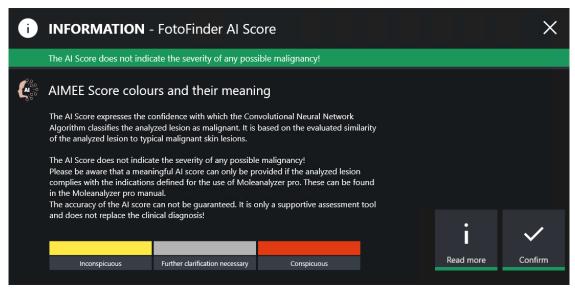


Fig. 52: Information window for the FotoFinder AI-Score

Click Confirm to close the window.
 Click on Further information to access the FotoFinder website and to find out more about this topic.

The information window for the FotoFinder Al score is displayed during every AIMEE score retrieval. You can deactivate this automatic display in *Settings* under *Modules*.

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4. Click on the AIMEE button to request the AIMEE score.

The AIMEE score is displayed as a bar value:



Fig. 53: Example view of AIMEE score with the result in the grey area "requires further clarification"

Depending on the result, the AIMEE button is provided a different colour:



Green: Inconspicuous



Grey: Inconspicuous, requires further clarification



Red: Conspicuous, requires highly vigilant observation



Observe the information in the separate Moleanalyzer pro manual!

The software has no diagnostic function. A diagnosis and decision for treatment are the responsibility of the physician. Segmentation and parameter accuracy cannot be expected or claimed. The AI score is based on statistics.



9.7.2 Compare



The *Compare* function allows you to compare both overview images and micro images.

- 1. Select an image you want to compare with other images by clicking on it.
- 2. Click on the *Compare* button in the menu bar of the Dermoscopy module's user interface.

9.7.3 Imaging Tools





With this button you can enlarge the image to the width of the preview window.

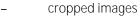
With this button you can adapt the image to the height of the preview window.

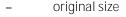
With this button you can display every pixel of the image with one pixel at a time.

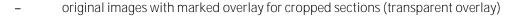
With the help of the slide bar or by turning the mouse wheel the enlargement of the image display can be set individually. You can shift the image by clicking and holding the left mouse button.

For Total Body Mapping, you capture four images from every side of the body (in the Total Body Mapping module), which are then automatically assembled into one full body image. Use this button to alternate between different display modes:











This button changes depending on the current selection.

With this button you can fade inserted image markings (e.g. Marker) in and out.

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With this button you can fade inserted measurement tools in and out.



Use this button to synchronize the brightness and color of the two micro images. This symbol will appear as a watermark in the top right corner of the synchronized image. The other image is synchronized when you press the button again. A third click will return both images to their original form. These adjustment are not saved.



Use this button to fade in a scale in the preview window (not possible for uncalibrated images). By right-clicking on this button, an additional menu will appear where you can individually set the line thickness as well as the text and line color.

With this button you can switch to grayscale view in the micro image comparison. This button only appears if you have activated it in the settings (cf. chapter 6.5.1.2 Image Viewer).

You can select the image's enlargement freely by turning the mouse wheel.

To move around in the zoomed in image, proceed as follows:

- 1. Click on the image.
- 2. Click and hold the left mouse button.
- 3. Move the cursor.

- The magnifier tool is also available in image comparison (cf. chapter 9.1.4.1 Magnifier function). If the magnifiers in the two images are not located in the same position (e.g. because the capturing positions were not identical), you can move one magnifier and therefore adjust the positions:
 - 1. Press the Ctrl button on your keyboard and the right mouse button at the same time. This takes you to Offset mode and you only move the magnifier which is currently selected by the cursor.
 - 2. Release the Ctrl button as soon as both magnifiers are in the same position.

9.7.4 Zoom Lock (SmartZoom)



The Zoom Lock function is set as default if you select the compare section. This function allows you to zoom in and move both images simultaneously. This also enables an objective comparison of the images.

Use the button at the top of the screen to zoom into the displayed images simultaneously. Without *Zoom Lock* both images can be displayed independently.

1. Click on the Zoom Lock button again.

Zoom Lock is deactivated and a second zoom control is displayed with the image display tools.

Copying into clipboard



Using the *Into Clipboard* button you can insert compare images directly in other programs, e.g. Word or Power Point. In this case an accurate screenshot is created with all current settings.

- 1. Select the required images, enlargements and sections.
- 2. Click on the *Into Clipboard* button.
- 3. Right-click into the target document.
- 4. Select Paste.



Fig. 54
Information on image type, date and time of capturing is located above the images.



9.7.4.1 Comparing overview images

In this section you can view and compare all of the patient's overview images taken so far.

- 1. Select the required overview image for image comparison.
- 2. When the desired overview image is displayed in the preview window, click on *Compare*.
- Use the scroll bar located below the images to call up the required overview image.
- Older images are further to the left, the latest one is on the far right.

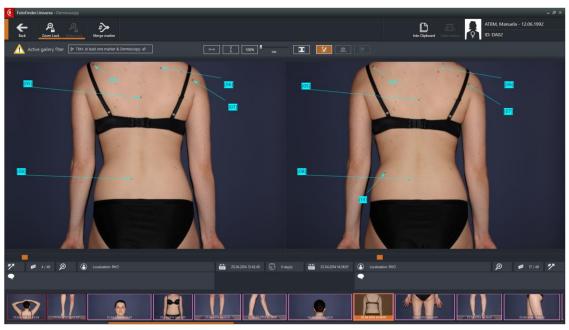


Fig. 55

The following information is displayed below the overview images:

- the total number of images taken so far
- where the selected image chronologically stands
- the date of capture

Click on *Back* to return to the overview of the Dermoscopy module.

Comparing micro images 9.7.4.2

- Select a micro image in the desired position so that it is displayed in the preview window.
- 2. Click on the Compare button.

Alternatively, you can also right-click on the marker number in the overview image. This will open the marker context menu. Select Micro image compare.

The following user interface will open:

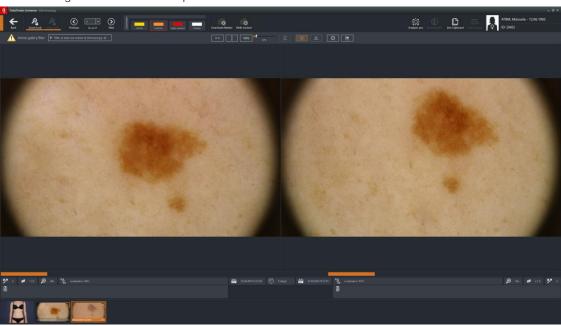


Fig. 56

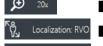
You can now compare all lesion images in the two sections of the screen. The following options are available to select an image:

- Use the slide bar under the preview images to browse between older or more recent images.
- Drag and drop the required micro image from the gallery field on the lower screen to the required preview position.

Under the two displayed micro images the following image settings are shown:

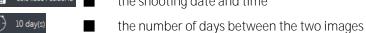


- the marker position (the number of the marker)
- where the selected image chronologically stands
- the total number of images



- Information about the used zoomfactor
- the shooting date and time

the localization







The lower left corner of the screen displays the corresponding overview image. If you move the cursor over this thumbnail the overview image will be shown enlarged and the currently selected marker position will be highlighted with red.

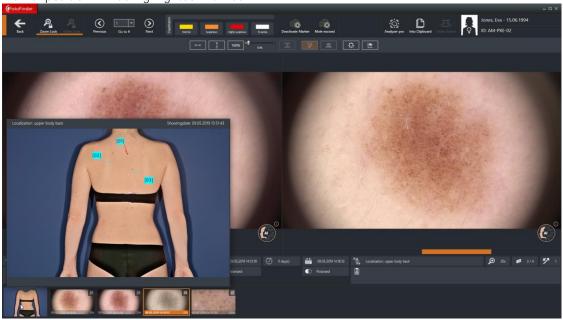


Fig. 57

You can also have the overview image displayed in the left preview window.

Left-click once on the reduced overview image.
 Instead of a micro image, the overview image is now displayed in the left preview window:

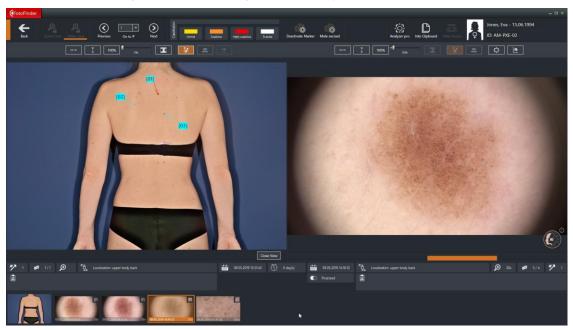


Fig. 58

2. Left-click again on the reduced overview image or alternatively, on *Close view* to return to the original view with two micro images.



In the menu bar the following icons are also available Deactivate marker and



Lesion excised.

Whether one of these buttons are already selected (possibly here in micro compare or in the Marker context menu) can be determined if the respective icon is underlined with orange.

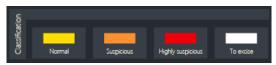
More details regarding these functions can be found in the sub chapters (cf. chapter 9.4.2.6 Deactivating a marker)/

(cf. chapter 9.4.2.7 Set markers as deleted).



be selected for comparison without having to leave the *Compare* function.

Fig. 59: Marker selection fields



Using the *Classification* categories at the top part of the screen, the currently selected lesion can also be classified.

With the *Previous, Go to #* and *Next* buttons other micro images can

Fig. 60: Classification icons



Optional and not available in all countries:

Not With the help of the Moleanalyzer pro in image comparison two micro images can be simultaneously analyzed.



You can only compare micro images that are saved under the same marker.



You can also compare micro images created with different camera generations (medicam 500_{HD}, medicam 800_{HD} and medicam 1000). The software will automatically adjust the display.



9.7.5 Image editing

Image editing provides the following options:

- Analysing the image with measuring tools
- Insertion of marks and text
- Anonymising the patient with black bars
- Displaying the AIMEE score (cf. chapter 9.7.1 AIMEE AI Assistant)

There are two options to access image editing:



In the menu bar, click on *Edit Image*,

or

■ Double-click on an image in the preview window.

This opens the image editing window.

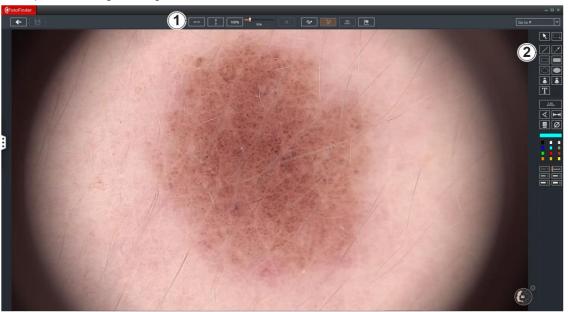


Fig. 61: Example view of image editing

1 Image Viewer Tools

2 Drawing and measuring tools



Please note that a photo is a two-dimensional representation of a three-dimensional body. The values can therefore not be determined with exact precision.

9.7.5.1 Calibration

For micro images captured with a standard zoom (20x – 140x), the image is already calibrated and you can start measuring directly.

Overview images or micro images using a different zoom setting need to be calibrated first before you can start measuring.

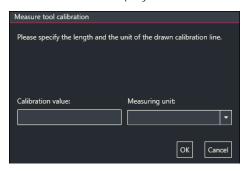
€NOTE

If you already place an object of known size onto the captured image, e.g. a rule, this well help you in the calibration process.



- 1. Start the calibration process by pressing the *CAL* button in the menu bar on the right of the displayed image.
- 2. Click once to create a starting point in the image and then draw a line with the mouse button pushed down.

A context menu is displayed.



- 3. Add the known length of the line and the appropriate measuring unit.
- 4. Confirm your entry.

Calibration is now complete. Now you can measure distances, surfaces and angles in the image.

9.7.5.2 Drawing and measurement tools

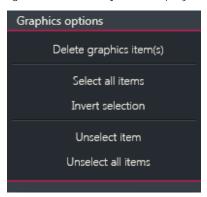
The drawing and measurement tools are located on the right-hand side of the screen.



Edit/Move:

- Moving inserted objects
 - Move the cursor over the object until the arrow turns into a cross-hair. Move the object by pressing and holding the left mouse button.
- Changing the size of the inserted objects
 Click to mark the required object. Small squares now appear along the edges/corner points.
 Click and hold the left mouse button to move the squares and change the size.
- Context menu

 Right-click on an object to display a context menu.



Here you can

- Delete graphics item(s)
- Select all graphics items
- Reverse the selection
- Deselect the graphics item
- Deselect all graphics items



























Rectangle selection

Click and hold the left mouse button to insert a rectangle and mark several draw objects simultaneously to edit them all after changing to the Edit/Move tool.

Click and hold the left mouse button to insert lines.

Arrow

Click and hold the left mouse button to insert arrows.

Rectangle (empty)

Click and hold the left mouse button to insert an empty rectangle.

Rectangle (filled)

Click and hold the left mouse button to insert a filled rectangle.

Ellipse (empty)

Click and hold the left mouse button to insert an empty ellipse.

Ellipse (filled)

Click and hold the left mouse button to insert a filled ellipse.

Anonymization functions Black Bar and Ellipse

By clicking and holding the left mouse button, you can insert a black bar or ellipse to hide certain areas or to deidentify your patient.

After selecting the text tool, left-click on the image. A text input and formatting window will appear.

Angle

Use this tool to measure angles between 0 - 180 degrees.

- 1. Click on a point on one side of the angle.
- 2. Click on the apex.
- 3. Click on a point on another side of the angle.

The software calculates the size of the angle.

Measure distance

Use this tool to measure the length of a distance.

- 1. Click and drag the mouse in the required direction.
- Release the cursor once you have reached the end point.

The software calculates the distance between the two points.

Area measurement

Use this tool to measure any area.

- Click on each consecutive corner point on the edge of the area you want to measure. 1.
- Then click on the first set point again.

The software calculates the area which is delineated by the connecting lines between the set points. Diameter

Use this tool to calculate the diameter of a circular area.

- Click into the center of the required circle. 1.
- 2. Click and hold the mouse button to drag the circle to the required size.

The software calculates the circle's diameter.

Color Selection

The color buttons allow you to select a color in which the new measurement objects are drawn into the image. The current color can be seen in the larger bar above. By left-clicking on this, you can also open an additional menu.





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Line thickness

Here you can select the line width for the drawn objects.

9.7.5.3 Anonymization

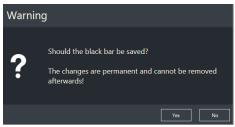
If you want to deidentify patients or want to blacken parts of the image for any other reason, use the *Black Bar* function.



- 1. Click the *Black Bar* button in the right menu bar of the measuring function in the preview window.
- 2. Hold the right mouse button down to drag the black rectangle from one corner to the opposite one.



3. To save, click on the disc symbol in the menu bar above the image.



4. Click *Yes* to confirm the security message.



Once an black bar is saved it can no longer be removed.



9.8 Working with Videos

9.8.1 The Video editor

The recorded videos can be edited (e.g. cropped) in the video editor and markers can be here embedded.

1. In the SmartGallery select the desired video.



2. Click on *Video editor* in the menu bar to start the editor.



Fig. 62: Example view for the video editor

In the lower middle section the following buttons are available:



Start

Pause and

Stop.



In the lower right corner underneath the preview window you can find the total length of the video, in the lower left corner the timeline where you are in the video. The orange bar will too indicate where you are in the video.



On the bottom left you can adjust the playback speed of the video, e.g. 1.5 times.

9 Dermoscopy module

9.8.1.1 Cropping the videos

In the video editor you have the possibility to crop the video so you only see a selected part. Proceed as follows:



1. Click on the crop icon left from the timeline bar.

2. With the mouse button held down, drag the mouse on the bar from the desired start and end points of the video



When you are dragging with your mouse the orange timeline bar, the corresponding position of the video will be displayed above in the preview window

3. When finished, click again on the crop icon.

Now only the selected part of the video is visible. The cropped off part is inactive but can be redisplayed at any time by clicking the cut icon again and moving the start and end points.

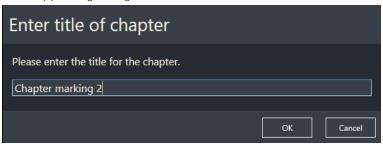
9.8.1.2 Working with chapter Markers

In the Video editor there is an option to insert chapter markers. This way you can jump faster to any desired point in the video. Follow these steps:

1. In the video editor start the video and press pause at the desired point.



- 2. Click on the + symbol on the lower right corner.
- 3. In the appearing dialog window add a name for the marker and confirm it with OK.





4. Now you can jump directly to this point in the video by selecting this marker from the drop-down menu in the lower right corner.

9.8.2 Video Lock



The Video Lock feature is enabled by default (marked with orange) when you are using the image comparison with two videos. With this feature activated both videos will be played simultaneously.

Without the *Video Lock* you can play both videos independently. To deactivate the *Video Lock* just click on this icon once.



9.8.3 Video fusion

You can export videos from the image comparison section out of Universe and save them as one video so that they are displayed in one file next to each other.

1. Open two videos in *Image compare*.



- 2. Click on the *Video Fusion* icon.
- 3. In the following window select a location to save it to and confirm with OK.

The video file (*avi* file format) will be saved. The length of the merged file will be the length of the shorter video. The additional part of the longer video will not be saved here.



Fig. 63: Example view for an exported merged video file.

9.8.4 Inserting watermarks

You can insert a watermark (e.g. practice logo) into videos exported from Universe. Further details can be found in Settings (cf. chapter 6.5.1.8 Videos).

$9_{\, \text{Dermoscopy module}}$

9.9 Reports



The *Report* button in the menu bar of the Dermoscopy module 's user interface allows you to create various types of reports in pdf format.

Under *Settings* you can specify the folder to where the reports should be saved or activate the extended printing options.

Once you have started the Report function, a menu will appear offering three options for creating reports:

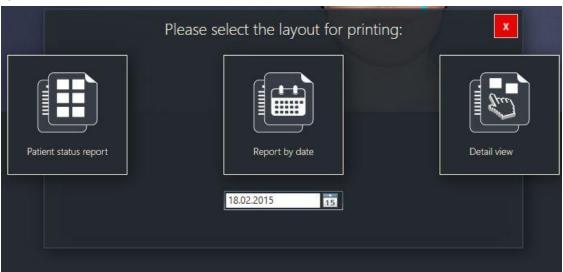


Fig. 64

Patient status report

- All overview images with associated micro images are printed with these associated micro images (first and last session).
- Comments will be included.

Report by date

- All images captured on the specified date will be printed.
- Overview images without existing micro images are also printed.



Detailed print view

You can select the images to be included in the report.

1. To select the images just pull the required overview and micro images into the clipboard in the middle of the screen.

If an overview image is added, all associated micro images are also added.

(NOTE

If you just want certain micro images of an overview image, simply pull those micro images upward. The corresponding overview image will therefore also be selected.



Fig. 65

For review the following print layouts are available (see upper right column):

- *Dermoscopy*. Every micro image on the right side is connected to an overview image with the relevant marker on the left.
- Micro Review: The overview image is only printed once per page for all associated micro images. This report may also be created by selecting the print option in the context menu of a specific marker (right mouse click: Print micro image review).
- Surgery. Each selected micro image is displayed individually with the respective overview image on one page. This report can be used for the clear presentation of naevi to be removed.
- Overview: The selected overview images are included in the report without micro images.
- 2. Click *Print now* to create the report.

10 Module aesthetics

€NOTE

The FotoFinder aesthetics module is used together with the respective FotoFinder hardware for the photo documentation of aesthetic treatments. However, since it does not fall under the scope of the medical device regulation (EU) 2017/745, it is not described further in this manual. Users receive the instructions for use for aesthetic imaging in a separate user manual.



11 Module Screening

Screening Mode in FotoFinder Universe in combination with the medicam 1000 or the leviacam is used to take a quick photo without saving the image to a patient record.

To start, click on the *Screening* button on the Dashboard.



11.1 The Desktop

This screen is displayed when the camera is switched on. The user interface consists of two sections:

- Menu bai
- Full-screen display of the camera image

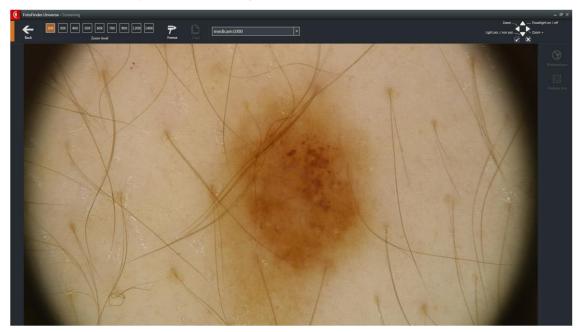


Fig. 66

11.2 Menu Bar

The menu bar is located on the top edge of the screen.



The functions of the buttons are listed below. *Back:* This returns you to the previous screen.



Image: Freeze the live image. Alternatively, press the release button of the medicam or leviacam once.

Live image (the button only appears when the recording button has been activated): Activate the live image. Alternatively, you can activate the recording button again if an image is frozen.

The displayed key has the same function when using medicam 1000:





Copy: Copy a frozen image to the FotoFinder clipboard. You can then assign it to a marker.

When using the medicam 1000 or the leviacam, this will also work via the respective button on the rear:

medicam 1000:



leviacam:





With the switch area *Magnification factor* you can select the desired magnification.

Alternatively, you can also adjust the magnification factor via the zoom buttons (+ and -) on the medicam.

The leviacam has no zoom option. The images are captured automatically with 20x magnification.

€NOTE

If the Moleanalyzer pro expert system is available, a micro image can be analyzed, even without having to save the image first.

For the segmentation in Moleanalyzer pro a micro image with 20, 30 or 40x magnification is needed. For an analysis with Al Score in Moleanalyzer pro a micro image with 20x magnification is necessary.



Moleanalyzer pro: The application can be started from here. This enables the additional analysis of a micro image.



11.3 A screening process

1. Start the Screening mode.

The lights will turn on automatically.

- 2. Moisten the skin with an immersion fluid. For polarized images with the D-Scope IV there is no need for immersion fluid.
- 3. Place the camera on the skin.



- 4. Select the desired *zoom factor* (not possible with leviacam).
- 5. Press the release button to freeze the live image.

You can now comfortably examine the lesion.



Pressing the release button again activates the live image.
 With medicam you can also activate the live image again with the corresponding button on the back panel of the camera.

11.4 Saving images

It is not possible to directly save images in the Screening Mode. However, images taken in the Screening Mode can be copied to the clipboard and assigned to a marker in *Dermoscopy* later.

1. To do so, copy the frozen image by clicking on *Copy* in the FotoFinder clipboard.

When using medicam 1000 or the leviacam, you can also do this with the respective key on the rear: medicam 1000: leviacam:



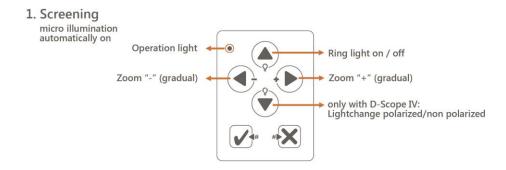


- 2. Exit the Screening mode.
- 3. Select a patient.
- 4. In *Dermoscopy*, open the overview image you want the micro image to be assigned to.
- 5. In the overview image, right-click on the appropriate marker.
- 6. Then select *Insert image* in the following context menu.

The micro image now also appears in the SmartGallery as soon as you have marked the overview image.

11.5 Overview of panel functions of the medicam® 1000

An overview of the medicam 1000 panel functions relevant in the Screening module is provided below:



1a. Screening - frozen image

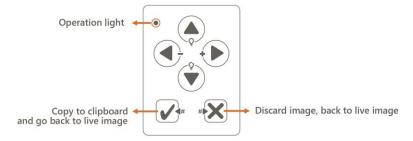


Fig. 67



12 Module Query



FotoFinder Universe offers the opportunity to systematically search your database for images with the help of different search criteria.

Start the module from the Dashboard.

Have a look at the following user interface:

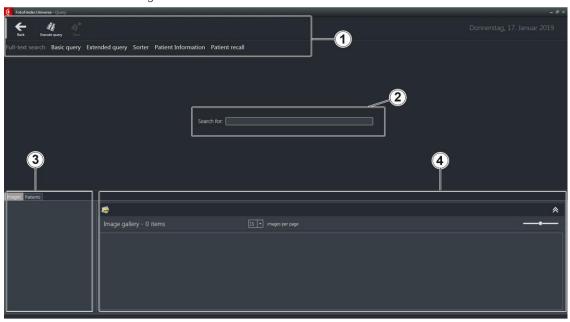


Fig. 68

1 Menu Bar

3

4 Results preview section

Results filter

2 Entry Mode for search criteria / sorter The upper menu bar contains the following standard functions:

Back: you are returned to the Dashboard.





Execute query: You start a defined query after you have specified all associated parameters.



New. You start a new query. The previous search will be discarded if it has not been saved.

Fields for various queries are located below the standard functions.

- Full-text search
- Basic query
- Extended query
- 1. Enter your search criteria into the input field.
- 2. Start the query with Execute query.

The matching data records appear in the results preview. The results are displayed together with the patient's name, patient ID, image capturing date and localization.



The results filter allows you to use additional criteria to group or filter results. The selection options are displayed as drop-down fields on the *Images* tab.

The *Patients* tab allows you to find more information on the patients visible on the images of the result preview. Use *Print* to make this list available in PDF of xls.



12.1 Full-text search

In the Full-text search you can enter a certain term, e.g. "Manuela" or "melanoma".

- 1. Enter the search term in the search field.
- 2. Click on Execute query.

All images whose data record contains the entered term will be displayed in the results preview.

12.2 Basic query

An input screen is displayed for the Basic query.

Enter all criteria applicable for the images, which are filtered by the software.

If you use the values Date of birth and Capturing date, you can search for images taken *before* or *after* a date or *in-between* two certain points of time.

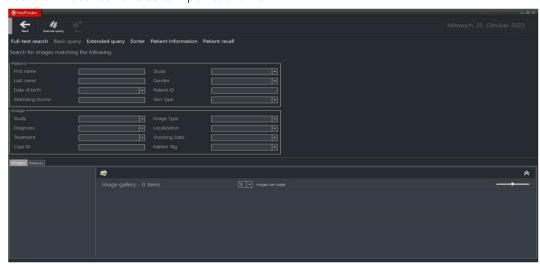


Fig. 69: Basic query

12.3 Extended query

By clicking on *Extended query* several features you can use during the query will be displayed automatically in the upper menu:



This contains a number of possible filter criteria to help you narrow down the results. You can then select the properties you want the researched images to have for every selected parameter.

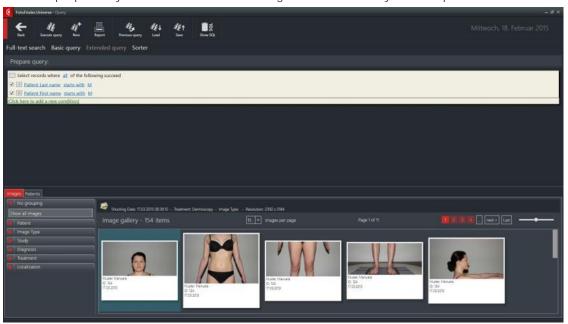


Fig. 70

Sample query:

You are searching for dermoscopic micro images of lesions on the left hands of men younger than 50.

- 1. First, select a new filter. To do so, click on [Click here to add a new filter].
- 2. Now choose a corresponding parameter using the mouse:
 - Patient → Gender is equal to → male
- 3. Narrow down the age with the following steps:
 - Patient data \rightarrow Date of birth is before (precise date) \rightarrow e.g. 01.12.1965
- 4. Search for the localization with the following steps:
 - Image → Localization *contains* → left hand

(NOTE

At the beginning of each query, you define whether all, at least one or none of the query filters have to be met. The more parameters you add, the higher the hit accuracy is.





The functions of the additional buttons are listed below:

Report: After a completed query, you export the found images to a pdf file. You can also print out the images on a connected printer.

Last query. After several queries, you repeat the one before the current query.

Save: You save your query. The data will be saved as an .ffq file in Universe's query folder.

Load: You access saved queries. A new window will open and you will be able to delete the files using the right mouse button.

Display SQL: You view the SQL code of the query.

12.4 Sort function

- 1. Click on Sort.
- 2. Press and hold the left mouse button to drag the required images up into the Sorter. The system will copy the images.



The buttons for editing the selected images are located on the right side.









Import: Imports all selected images from the last sorted arrangement in the current sorter.

Delete sorter. You can delete the images in the Sorter by clicking on this button.

Export: Exports all current sorted images as single JPEG to the selected storage location.

Print: You can print out the images as pdf files.



12.5 Patient information

After a query has been executed in the Research module, you can call up the respective patient data via the Patient Information tab and also switch between patients there.

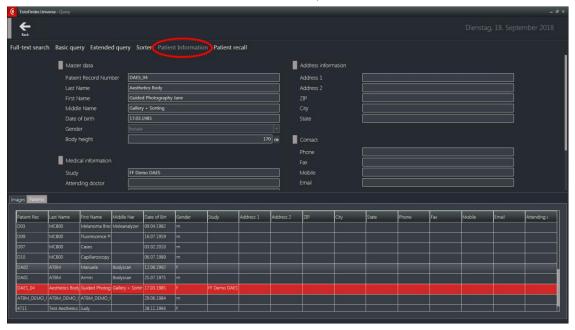


Fig. 71

- 1. Run a query and then click on Patient Information.
- 2. Select a patient.

The currently selected patient is highlighted in red in the result list at the bottom and the associated data is displayed at the top.

3. By clicking on another patient or using the arrow keys on your keyboard, you can change your patient selection.



The selected patient remains active when you exit the Query module. This will allow you to subsequently edit the patient data or take images directly by selecting the appropriate modules.

12.6 Patient Recall

Patients who do not have images taken for a certain period of time can be filtered out using the Patient Recall feature.

- 1. Click on Patient Recall in the menu bar.
- 2. The main criterion of the search is the date of the last visit. As a result, only patients whose last images were before or on this date are shown.

13 Import and Export

13.1 Importing images

You can import overview images and micro images from the hard drive or an external storage medium.

13.1.1 Importing overview images in the Dermoscopy module



1. To import overview images click the *Import* button in the menu bar of the Dermoscopy module.

The image import window appears.

- 2. Select the image you want to import; you can also select multiple images.
- 3. Click Open.

This opens the import menu:

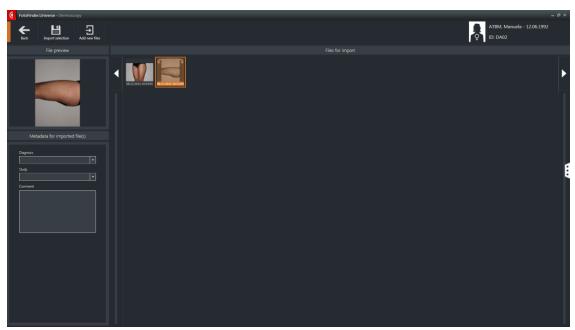


Fig. 72: Import menu

- 4. The program will recognize if you specified image alignment/rotation during image capture. However, you can also rotate images manually:
 - 1. Move the cursor over the small preview image.

Rotation arrows will appear at the top corners of the image for rotation in clockwise or anticlockwise direction.

- 2. Click on the appropriate arrow until the image is suitably aligned.
- 5. Localize the images you want to import on the localization puppet:
 - 1. Click on the small preview image.

The selected image now has an orange frame and the right edge of the screen will display a tab.

- 2. Moving the cursor over this tab will display the localization puppet.
- 3. Click to select the displayed body region.
- 6. If required, enter information under Diagnosis, Study and Comment.







7. With the *Add new files* button you can add additional images to your selection if required.



8. You can unselect images by clicking on them and then pressing the keyboard's *Del(ete)* button.

9. Click on *Import selection* when you have finished processing the images.

The images will now be shown as overview images in the user interface and marked blue as imported images.

13.1.2 Importing micro images in the Dermoscopy module

- 1. If you want to import a microscopic image, first right-click on the respective marker in an overview image.
- 2. In the displayed menu, click on *Import micro image*.

The Import Images window will appear on the screen.

- 3. Select the required image.
- 4. Click Open.
- 5. The program will recognize if you specified image alignment/rotation during image capture and will ask you for the required alignment.

The imported image will appear now in the micro image section.

13.2 Exporting images

13.2.1 Exporting from the Total Body Mapping Module



The export function allows you to export individual images to the local hard drive or other external devices such as a USB flash drive, external hard drive, etc.

- 1. Select the required image in the gallery.
- 2. Click on Export.

Now the window *Export images* will open. Here you can edit the file name, file type where to save the image.

Click on Save.

13.2.2 Exporting from the Dermoscopy module

The export function allows you to export individual images to the local hard drive or other external devices such as a USB flash drive, external hard drive, etc.



1. Click on *Export* in the menu bar of the *Dermoscopy module*. This will open the image selection window.

2. Select the required images from the gallery by clicking and holding the left mouse button to drag them into the selection area in the center of the screen.

The selected images are grayed out in the gallery at the bottom.





If you click on *Select All*, all images will be moved to the selection area. However, this is only possible if you have not selected a filter in the SmartGallery.

You can unselect unwanted images by

- dragging them back into the gallery by clicking and holding the left mouse button or
- clicking on them individually and then pressing the *Delete* key on the keyboard.



If you want to unselect several overview or micro images simultaneously, you can quickly select them as follows:

- Select all images:
 - 1. Click to select an image you want to delete.
 - 2. Press Ctrl + A on the keyboard

All images are now selected and highlighted with an orange frame.

- Selecting several images in a row:
 - 1. Click to select the first image you want to delete.
 - 2. Press and hold the *Shift* key on the keyboard.
 - 3. Click to select the last image you want to delete.

Both marked images and all those in between are now selected

- Selecting several images not directly in a row:
 - 1. Press and hold the *Ctrl* key on the keyboard.
 - 2. Click to select all required images.

All the images you have selected while holding the *Ctr*/key are now marked.

If you click on *Unselect All*, all images will be removed from the selection area.



You can also use the menu bar to select whether the

- markers
- overlay graphics and
- measurement range

are to be displayed in the exported images. In this case, use the mouse to check the appropriate box. You can already preset these three items in the *Settings* tab (cf. chapter 6.5.1.5 Reporting).

When you have finished selecting your images, you can export and save them. (cf. chapter 13.2.3 Exporting and saving images).

13.2.3 Exporting and saving images

After selecting your image for export, proceed as follows:

- 1. Select the destination by clicking on the ... button in front of *Export folder* on the left above the selection frame.
 - The export folder also remains saved for the next export.
- 2. Select the required file format from the drop-down menu at *Export as* on the right above the selection frame.



3. Start the exporting process by clicking on *Export*.

Your selected images are now saved to the export file.

13.3 Import and Export from FXF/XFXF Data

You can use this function to exchange complete profile data records (patient data and associated images) between different FotoFinder installations and save these to various storage media (CD, USB flash drive, etc.).

Start the import and export of fxf data records from the Patient administration module. Available Data exchange formats:

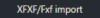
FXF:

- FotoFinder Exchange Format
- used until Universe version 2.0.41

XFXF:

- remodelled FotoFinder Exchange Format
- used from Universe version 3.0.0.0

13.3.1 Import of XFXF- or FXF data records



- . Click on XFXF/FXF Import.
- 2. In the appearing window select the location where the file is located.
- 3. Click on Open.



If you chose an encryption for the exported files you have to enter a password now.

The Import Wizard displays a list of all the images contained in the file.

Import Assistant with FXF file:

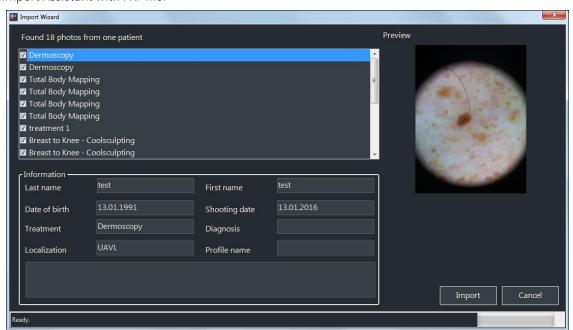


Fig. 73



Import Assistant with XFXF file:

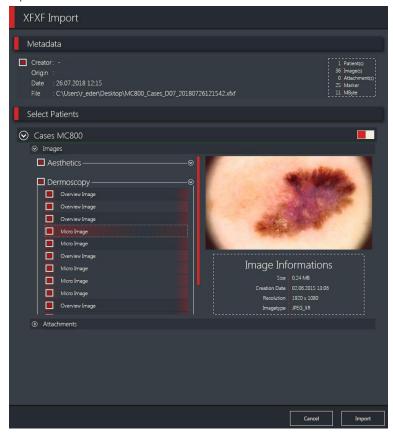


Fig. 74

- 4. Individual images can be removed from the import by removing the checkmark in front of the entry.
- 5. To start the process, click on *Import*.

You will receive a message once the import is finished.

13.3.2 Exporting XFXF files

- 1. Select the corresponding patient with a left mouse click in the patient list.
 You can select multiple patients with holding down the Ctrl key while clicking with the left mouse button. If the desired patients in the list are right after each other, you can click on the first patient and hold down the Shift key and directly click on the last desired patient. All patient profiles in between will be selected.
 - The selected patients are highlighted with red.
- 2. Click on the XFXF Export button.

The export wizard opens.



Fig. 75

- 3. Additional options: Select with a mouse click whether
 - the BodyScan results or
 - the attachments

Should be exported.

- 4. Security: Enable this if you wish to encrypt the file. You can decide between
 - Default Encryption or
 - Password
- 5. Content:
 - If desired, you can deselect individual modules (Aesthetics, Dermoscopy, Total Body Mapping), images and attachments for each patient by clicking next to them in the check boxes, if you do not want to export them.

For Total Body Mapping sessions only follow-up sessions can be deselected, no baselines.

- You can also deselect whole patient profiles here by setting the slide bar on the right side from the patient profile name.
- 6. Click on Export.
- 7. In the appearing window select the location where you want to save your file and then click on *Save*.

The export can take a few minutes. Once it's finished a notification will appear. Please confirm this message by clicking on *OK*.



13.4 DICOM Image Export



With DICOM image export and patient data generated with the FotoFinder system get archived and are compatible with other medical imaging systems.

Image data records can be exported on a per-patient basis. Reference test program was the DICOM viewer MicroDicom*.

You can conduct the following functions:

- Export of complete patient records
- Export of Dermoscopy and Total Body Mapping images
- Export of overview and micro images
- Export of markers
- Collocation of data according to capturing sessions
- Localization of the imported images on the virtual patient
- Hierarchical file and folder organization
- Creation of a DICOMDIR directory
- Choice between uncompressed or compressed JPEG images
- Support of image frames

Further functions, not depending on the DICOM standard:

- ZIP compression and storage
- Encryption of exported data
- Configuration of rendering options for markers



The DICOM image export requires a license and is not installed by default.

1. Start DICOM image export from the Patient administration module with the *Export to DICOM* button.

This button is only available if you select a patient with associated images from the list. "Empty" patients without previous images cannot be exported.

2. Configure the process with the following dialog:

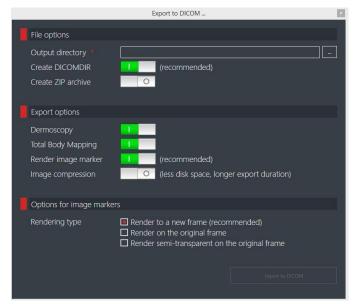


Fig. 76

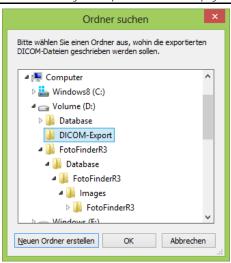
13.4.1 File options

In the file options, you can set the output files and folders. The only mandatory field of the dialog is the output folder.

Output directory

(NOTE

Data can only be exported to an empty folder! You must therefore create a new folder first.



1. Select the output directory by clicking the button [...].

A dialog appears where you select a folder on any random storage medium supported by the operation system. You can also select a network path here.

- 2. Select the newly created folders as target destination.
- 3. Click on OK.

Fig. 77

Create DICOMDIR

DICOMDIR-files contain a hierarchical overview and directory. They can be read by any DICOM-Viewer (external program) that needs to be installed on your computer.

The manufacturer recommends the selection of this option.

Create ZIP archive

If you activate this option, the software will also use the exported files to create a compressed ZIP archive. This is recommendable if you plan on forwarding the data. You can choose from the following additional options:

ZIP options

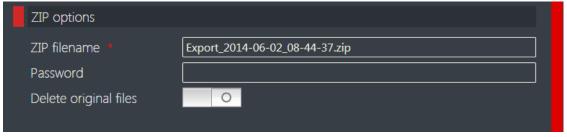


Fig. 78

Specify a file name for the ZIP archive in the text field. The ZIP folder will be created in the Output directory that you have chosen above.



Password

If you enter a password, the created ZIP folder will be encrypted. To unpack the file at a later stage, you need to enter this password again, as otherwise the files will remain illegible. If the text field stays empty, there will be no encryption.

Delete original files

When exporting to DICOM with activated ZIP archiving, the data will be duplicated on the target medium:

- the DICOM files
- the ZIP file



The information from the FotoFinder database will not be affected or deleted by this option.

13.4.2 Export options

These options allow you to determine which images and data will be exported from FotoFinder Modules and how.

Dermoscopy

If this option is activated, all images associated with this patient and which have an overview image created in the Dermoscopy module are exported to DICOM.

If this option is not visible, the patient does not have associated images.

Total Body Mapping

If this option is activated, all images associated with this patient and which have an overview image created in the *Total Body Mapping* module are exported to DICOM.

If this option is not visible, the patient does not have associated overview images from this module.



Activate at least one module from which the images are to be exported!

Render image marker

By choosing this option, markers and editions (marker, black bar etc.) can also be exported to DICOM. The system will offer you additional configuration options.

Image compression

If Image compression is active, the requested space for the exported DICOM files is considerably reduced. The time required for export is extended.

Without compression, the image quality is consistent. This could create larger files, depending on the image type and recording device. You will then require several hundred megabytes per DICOM export. The manufacturer recommends activating image compression if you have insufficient memory space, e.g. when sending the files via the Internet or burning them to a CD-R.

13.4.3 Options for image markers

Apart from patient information and captured images, you can also export image markers, e.g. in order to save references to the corresponding micro images. You can define the rendering type with the following selection options.

■ Render to a new frame

In this option you export two different versions of the image. This allows you to fade the markers in and out at a later stage.

Render on the original frame

Image markers will be directly rendered in the pixel data of the original. This saves half of the storage space during export. However, markers cannot be turned off in the DICOM Viewer.

Render on the original frame

This mode is basically the same as the option *Render on the original frame*. The difference is that markers will not be rendered with complete opacity but semi-transparently.

13.4.4 Start Export

1. Click on the *Export to DICOM* button at the end of the dialog after you have made all the necessary settings.

(NOTE

The export may take a few minutes. The duration depends on the size and scope of the patient data record and on the selected options. It is influenced by the number and type of the images.



14 Malfunction and troubleshooting

14.1 Error handling

This section contains information on troubleshooting. If the system does not start functioning correctly, then please call the support team on: 0049 8563 97720-45 or send an E-mail to: support@fotofinder.de.

Remote support over the Internet (remote control of your computer) is a great help in this situation. If you wish to use it, please download the Teamviewer software from the following site: www.fotofinder.de/support. Then inform us of your ID and the password shown in the Teamviewer software during the course of the support call. Please also name your system / license holder.

14.2 Problems with the software

14.2.1 Software error: The software is no longer functioning correctly

■ Close the software, restart the computer and run the software again

If the software error persists or the software is still not functioning correctly, please contact the support team.

15 Appendix



(FotoFinder

Diese Erklärung ist gültig, bis sie durch eine neue Version ersetzt wird / This declaration is valid until superseded by a new version.

Bad Bimbach, 19.09.2023

(FotoFinder

EU - DECLARATION OF CONFORMITY

EU-KONFORMITÄTSERKLÄRUNG

FotoFinder Systems GmbH Industriestraße 12 84364 Bad Birnbach Deutschland/Germany Hersteller / Manufacturer. Adresse / address:

Single Registration Number (SRN):

TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 München / Munich Germany DE-MF-000007084 Benannte Stelle / Notified Body

Wir erklären hiermit in eigener Verantwortung, dass nachstehendes Produkt

FotoFinder Universe Artikelnr. / Product code: FFS001502

Version: 3.5

otoFinder Universe is a standalone software intended for: Zweckbestimmung / Intended Use:

- acquiring, processing annotating, comparing and visualizing microscopic and macroscopic inages of the
 human side in yaredical professionals and demonologists
 storing, and managing images, patient and user data
 the standardized documentation of the intact skin surface and skin changes over time for pre-essessment
 and diagnosis support of skin conditions
 allowing the combination, communication and exchange of data with hardware devices and software
 manufactured by FotoFinder

der Risikoklasse / of risk class:

426015845FFU001XY Basis UDI-DI / Basic UDI-DI:

lla (Annex VIII MDR)

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

Annex IX, (EU) 2017/745 Konformitätsbewertungsverfahren/