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FotoFinder Moleanalyzer pro

Original user manual

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

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1 About these operating instructions

NOTE

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

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.
- 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.
- Reprints, translations and reproductions in any form, including excerpts, require the written consent of the publisher.
- Copyright belongs to the manufacturer.

The development and production of all products of FotoFinder Systems GmbH is carried out in accordance with the current ISO 13485 standards.

2 Installation

The Software must be installed by a trained person or a representative of FotoFinder Systems GmbH.

3 Safety

3.1 Adherence to the operating instructions

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 **Moleanalyzer pro** is a software, which is intended to be used in addition to FotoFinder **Universe**. It is intended for the assessment of clinically atypical cutaneous pigmented lesions with one or more clinical or historical characteristics of melanoma, excluding those with a clinical diagnosis of melanoma or likely melanoma. FotoFinder **Moleanalyzer pro** is designed to be used when a dermatologist chooses to obtain additional information for a decision to biopsy. FotoFinder **Moleanalyzer pro** should not be used to confirm a clinical diagnosis of melanoma.
The **Moleanalyzer pro** offers assessments by indicating parameters for the commonly used 3-Point Checklist, 7-Point Checklist or ABCD rule to classify lesions (Asymmetry, Borders, Color and Structures). Optionally, the software uses a convolutional neural network (CNN) algorithm to generate a risk score (AI Score). This AI Score indicates the similarity to malignant lesions by generating a value, which is assigned to different categories. This assessment supports dermatologists in the classification of different types of skin cancer. The accuracy of the algorithm is comparable to the performance of dermatologists.

FotoFinder **Moleanalyzer pro** is only intended for physicians trained in the clinical diagnosis and management of skin cancer (i.e. dermatologists) who have also successfully completed a training program in the appropriate use of FotoFinder **Moleanalyzer pro**.

The software does not provide a diagnosis. Diagnosis and treatment are the responsibility of the dermatologist. The accuracy of parameters or segmentations cannot be claimed. The AI Score is based on statistics.

3.3 User groups

The following target groups with the required qualifications may work with the software:

Target group	Qualification
Medical professionals	Professionally qualified as physician or dermatologist

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 not intended for use by laypersons.

Requirements for the physical as well as technical usage environment are described in detail in the separate system manuals (e.g. *Dermoscopy* and *Automatic Total Body Mapping*), which must also be observed.

There are no other applicable requirements for the social or clinical environment of use.

3.5 Patient population

Patients with one of the following characterizations are intended to be examined with the software:

- General persons with skin lesions, moles
- Patients with multiple nevus syndrome

The intended patient population includes patients regardless of demographic factors (e.g. gender, age, profession), physical factors (e.g. weight, height, strength) or social, religious and cultural background.

3.6 Indications and contraindications

The software is intended for the conditions mentioned in chapter *Patient population* (cf. chapter 3.5 Patient population). For a detailed list of ICD codes, please reach out to info@fotofinder.de.

The **Moleanalyzer pro** only supports microscopic images of a lesion. The software is not intended to support pre-assessment of images from acral skin, mucosa, eyes and natural or artificial body orifices. The software does not diagnose a disease.
The AI Score is only able to assess lesions with a diameter from 2 mm – 20 mm. The evaluated lesion should not be located in a hairy area and should not be located near contaminations or markings (e.g. tattoos) within an area of 30mm.
Moleanalyzer pro is only intended to be used on lesions captured on intact skin. The assessed lesion should not be located in areas of psoriasis, eczema, acute sunburn or similar skin conditions.

Scale bars in micro images might have a negative effect on the CNN's accuracy.

3.7 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 requirements.
- The use of the software in a medical context on devices that do not meet these OS specifications is prohibited.

3.8 Foreseeable misuse

The following points describe foreseeable misuse of the software:

- The physician incorrectly assumes that the software provides a diagnosis.
- The physician bases their diagnosis exclusively on results of software.
- The application for documentation is performed on non-intact skin, mucous membranes or in body orifices.
- The physician believes that the accuracy of the AI Score can be claimed and assumes that the score is indicative of the malignancy of the mole.
- The physician requests an AI Score for an image that does not meet the requirements, e.g., due to body hair, visible tattoo, or size.

NOTE

For information on the foreseeable misuse of connected hardware components, please refer to the respective device's user manual.

3.9 Residual risks

WARNING

Despite compliance with all regulations and the implementation of risk-minimizing measures, not all risks can be completely excluded. Residual risks that exist in connection with the use of the product are listed below.

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.
- If the user bases the diagnosis solely on the results of the software (incl. AI Score), it may lead to unnecessary or delayed treatment of a skin condition.

  Misinterpretation of the algorithm cannot be ruled out.

3.10 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:

⚠ WARNING

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

⚠ CAUTION

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

NOTE

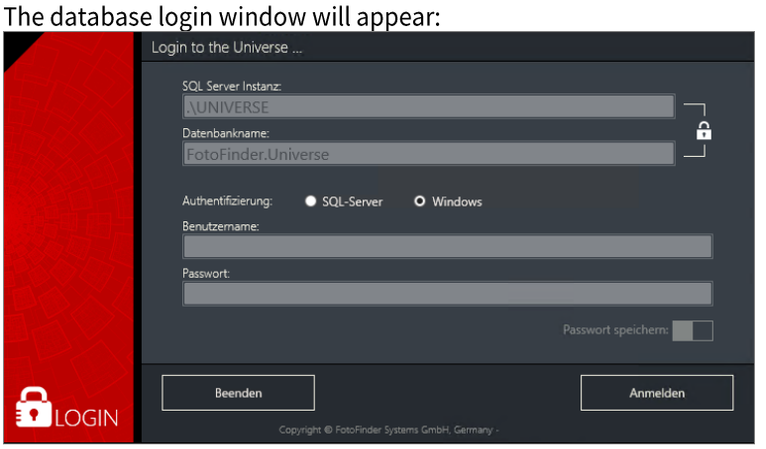
Additional safety and operating information is described in detail in the separate system manuals (e.g., *Dermoscopy* and *Automatic Total Body Mapping*), which must also be observed.

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.

NOTE

The *QuickLogin* function cannot be enabled if the optional User Management is activated in **Universe**.

The QuickLogin can be activated as follows:

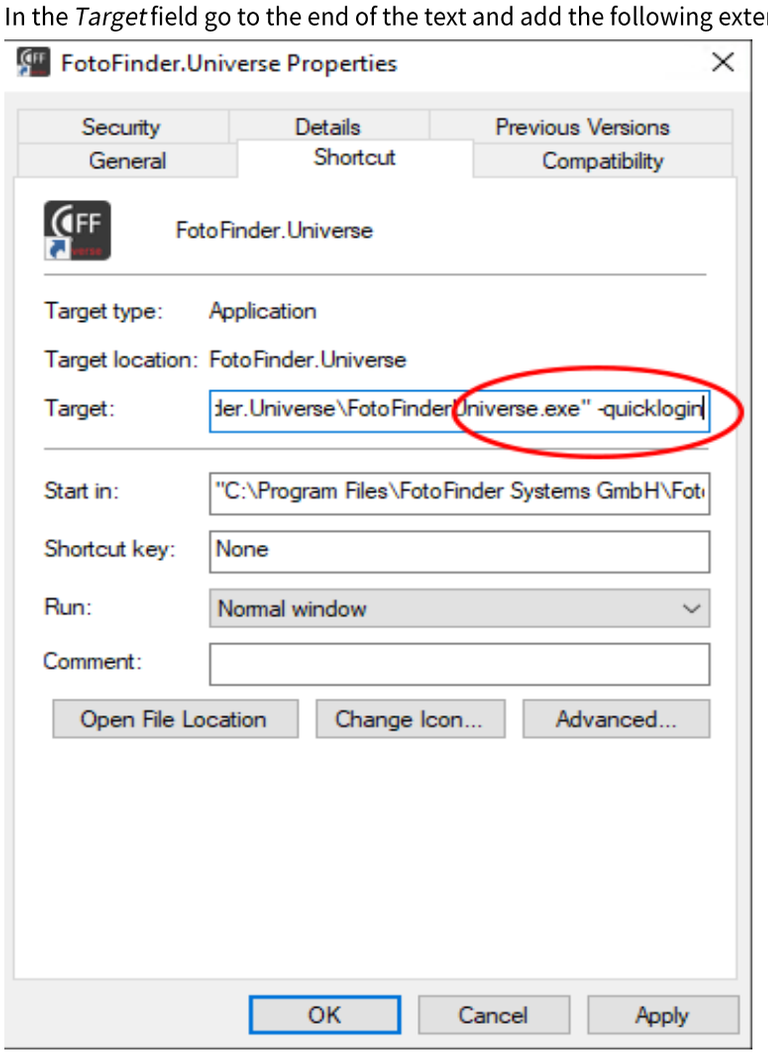
1. Right mouse click on the *FotoFinder.Universe* icon on the desktop.

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**

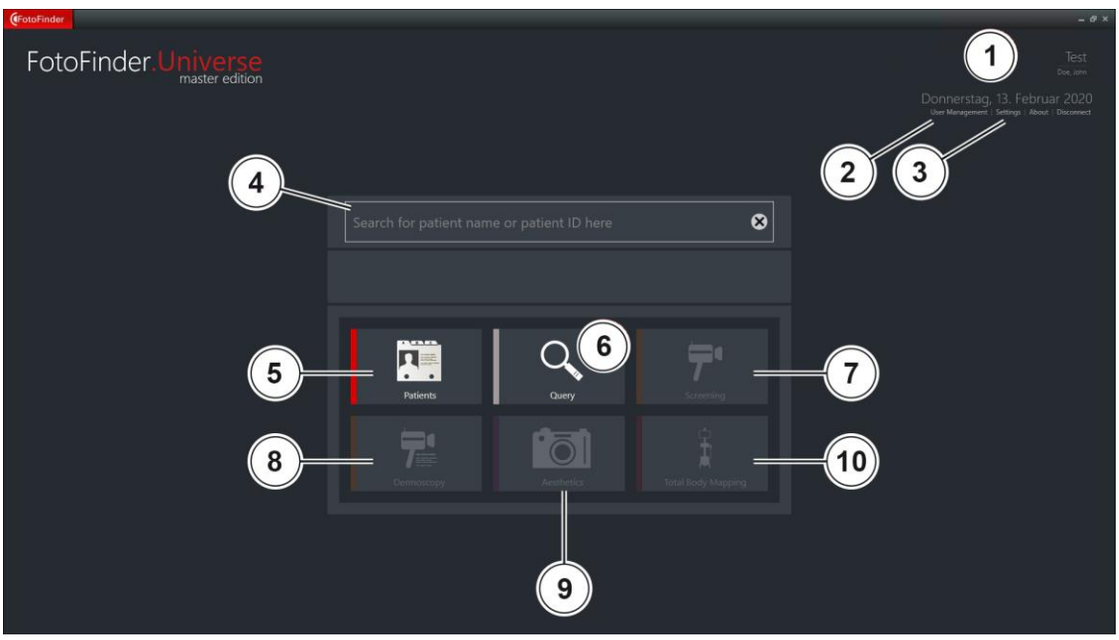


4. Click on *Apply* and then on *OK*.

Afterwards when **Universe** is started, the login window will be skipped and you will be directed to the dashboard.

4.2 Dashboard

After successful database login the following dashboard will appear:



The dashboard consists of the following modules and functions, which are available depending on your program licensing:

1	About section	6	Query
2	User management (optional)	7	Screening
3	Settings	8	Dermoscopy
4	Patient search bar	9	Aesthetics
5	Patient management	10	Total Body Mapping

- The Patient management, Query and Screening can be used immediately after the program start.
- In order to start Dermoscopy, Aesthetics or Total Body Mapping, you have to select a patient first. These buttons are therefore initially inactive.

4.2.1 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.

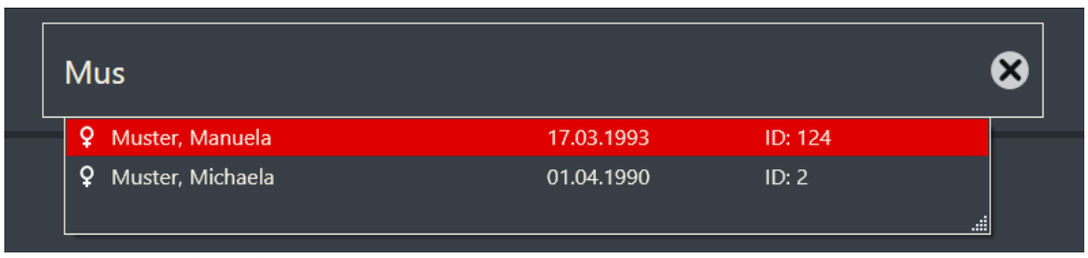


Fig. 1: Example of a patient query

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*. 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.

4.2.1 The About section

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

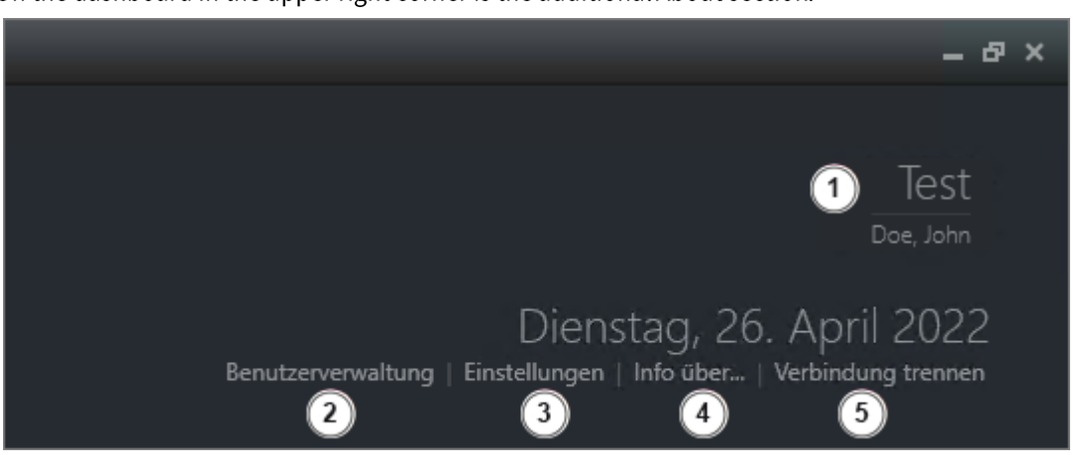


Fig. 2: The About section

Next to the ***User management*** **(2)** and the ***Settings (3)*** options 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.

5 Moleanalyzer pro

5.1 Starting the application

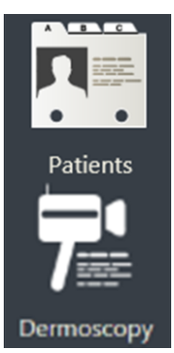
Moleanalyzer pro is an Expert Module available in *Dermoscopy*.
As a prerequisite a micro image is necessary.

Recognized capturing devices are:

Camera	Supported magnification
■ **medicam 1000**	20x, 30x or 40x
■ **medicam 800HD**	20x
■ **medicam 500**	20x
■ **leviacam**	20x
■ **iPhone**	20x, manual calibration may be required
■ **Other devices**	manual calibration is required

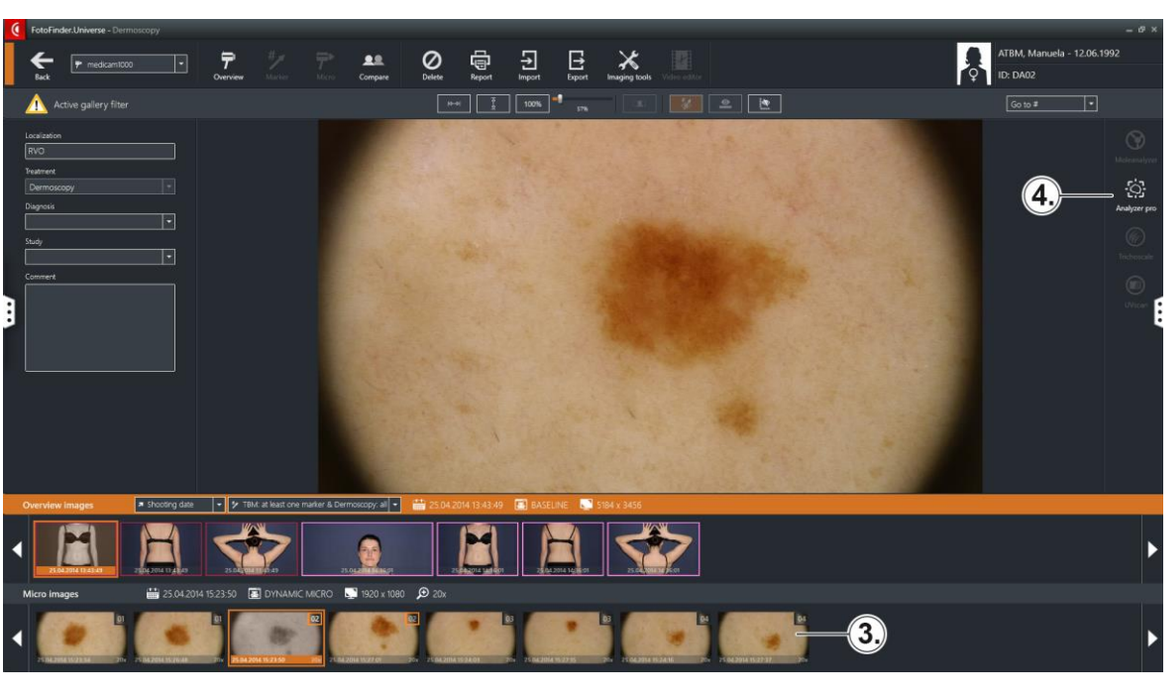
NOTE

For the AI Score analysis a 20x magnification is necessary.



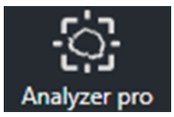
1. Select the patient form your Patient List.

2. Start the *Dermoscopy* module from the Dashboard.



3. Choose the required micro image from the **SmartGallery**.

The selected image will be highlighted with an orange frame and now displayed in the preview window.



The icon of the expert system **Moleanalyzer pro** on the right side of the screen will become active now.

4. Click on this icon.

The **Moleanalyzer pro** will open.

NOTE

The user interface of the *Dermoscopy* module is described in detail in the separate system manuals (e.g., *Dermoscopy* and *Automatic Total Body Mapping*).

5.2 The Desktop

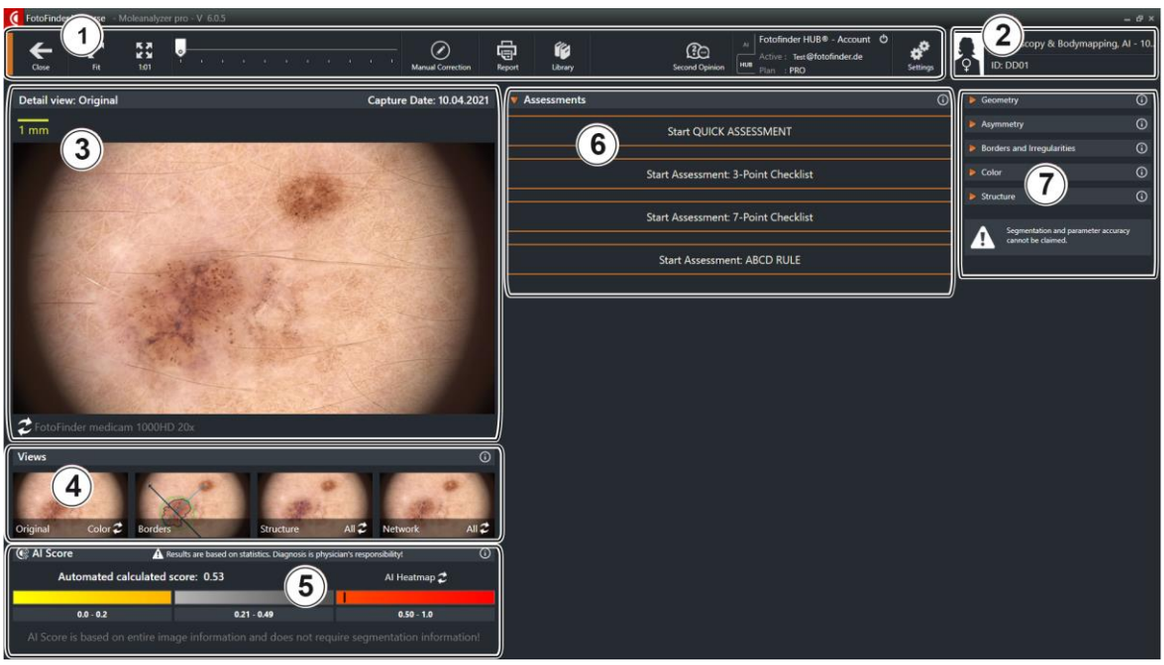


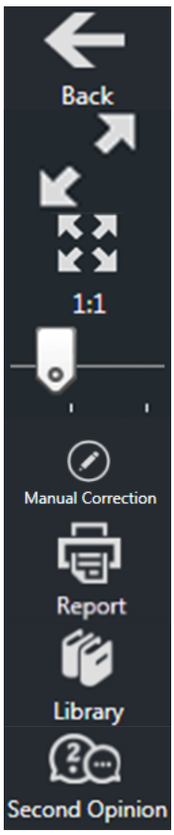
Fig. 3: Example view of Moleanalyzer pro user interface

1	Menu bar	5	AI Score (artificial intelligence)
2	Patient data field	6	Assessment queries
3	Detailed image	7	Parameters
4	Views		

You can see this symbol on various areas on your user interface. With clicking on it, a window will appear with helpful information.

You can see this symbol on various areas on your user surface. With clicking on it, you can open the scroll down menus.

5.2.1 Menu bar



Close will close the software.

With *Fit* the currently displayed image is adjusted in height and width into the Detail view.

With *1:1* you can display every pixel of the image with one pixel at a time.

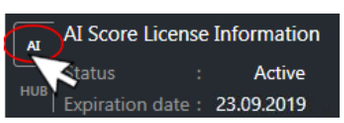
With the help of the slide bar or by turning the mouse wheel the magnification of the displayed image can be set individually. By clicking and holding the left mouse button you can shift the shown image section.

The *Manual Correction* allows you to adjust the results of the analysis.

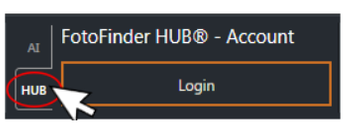
Click on *Report* if you wish to print the results or to save them as a PDF file (cf. chapter 5.11 Reports).

In the *Library* you will find a selection of already categorized lesions. You can use these for comparison purposes (cf. chapter 5.6 Library).

The *Second Opinion* is an additional service (cf. chapter 5.9 Second Opinion).



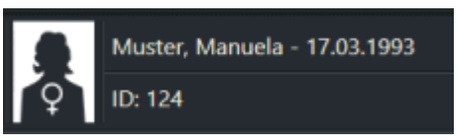
Here you will see the information about the optionally available AI Offline Score license (cf. chapter 5.7 The AI Score).



Here you can log in and out of the FotoFinder HUB or see which user is currently logged in (cf. chapter 5.8 The FotoFinder Hub® Account).

Within this function you can add your user information which will be added in the reports and adjust the application settings (cf. chapter 5.3 Settings).
With clicking on *About* you will see detailed information about the software.

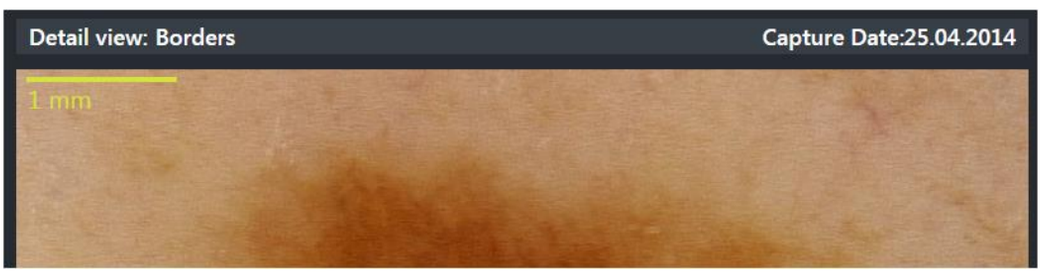
5.2.2 Patient Data Field



The patient data field displays name, birthdate, ID and gender.

5.2.3 The Detail view

- Above the detail view you will see which detail view is currently selected and the capture date:



- With right mouse click on the Detail view you can change between the analyzed and original image.

- With the mouse wheel or with the help of the slide bar you can set the magnification. Hold down the left mouse button in the Detail view to shift the image section.
- Double click on the Detail view will open the image in full screen mode. Double click again to exit the full screen mode.

5.2.4 Views

Four different views can be selected for the detail image with a simple mouse-click on the respective view.

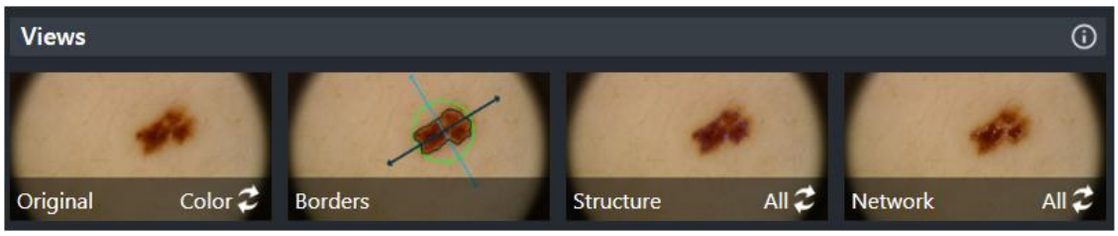
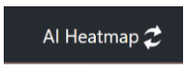
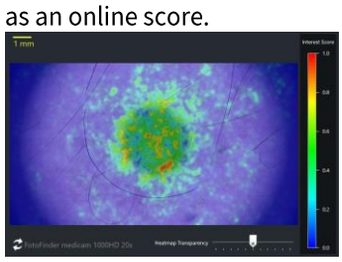


Fig. 4: Views for selection



The Heatmap is available as an additional view. The prerequisite is an AI Score that has been requested as an online score.

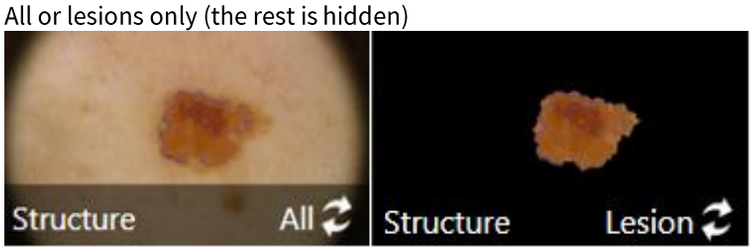


Please note the explanations for this view in the separate chapter (cf. chapter 5.7.3.1 AI Score Heatmap view)!

By clicking on the toggle symbol in the respective field, the views can be distinguished further:

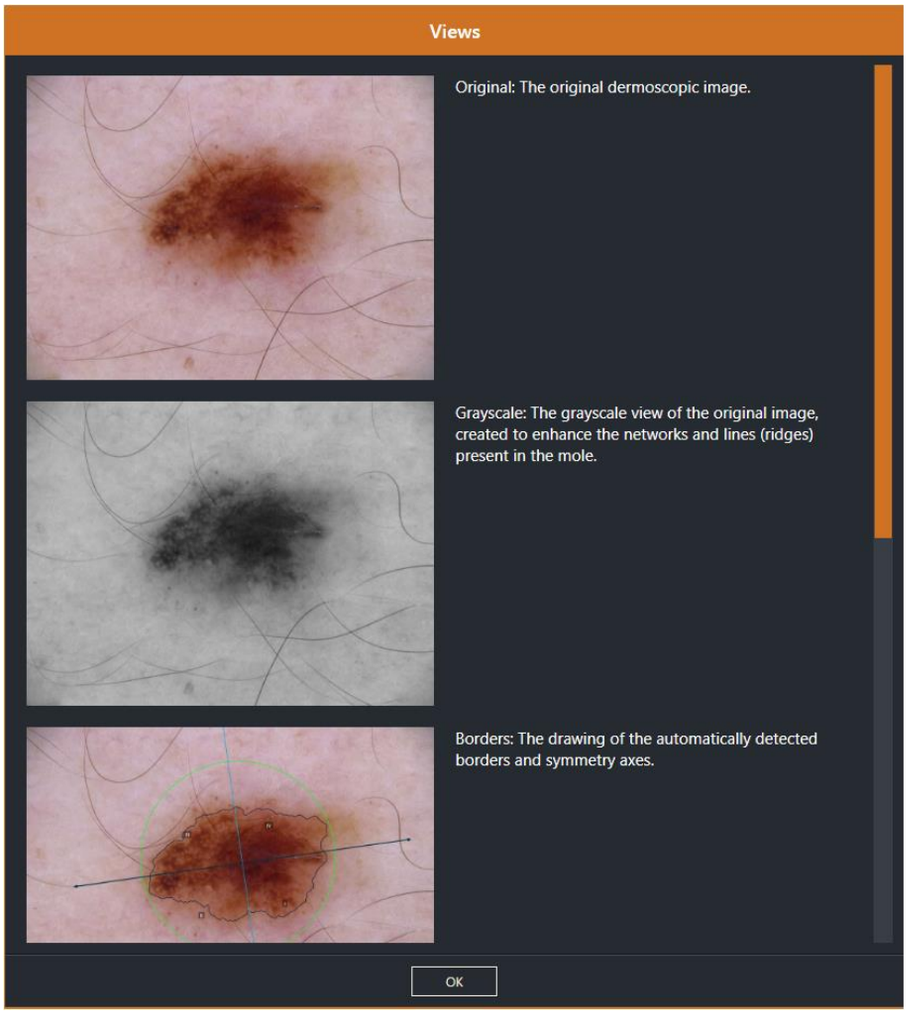
- *Original*:
  Change view between colour and greyscale

- Structure:
  All or lesions only (the rest is hidden)



- Network
  All or lesions only (the rest is hidden)

You can call up detailed descriptions via the *Info button*:


Views
Original: The original dermoscopic image.
Grayscale: The grayscale view of the original image, created to enhance the networks and lines (ridges) present in the mole.
Borders: The drawing of the automatically detected borders and symmetry axes.
OK

5.3 Settings

You can access the settings menu of the **Moleanalyzer pro** via *Settings*. Here you can store individual adjustments in the software, which are explained below:

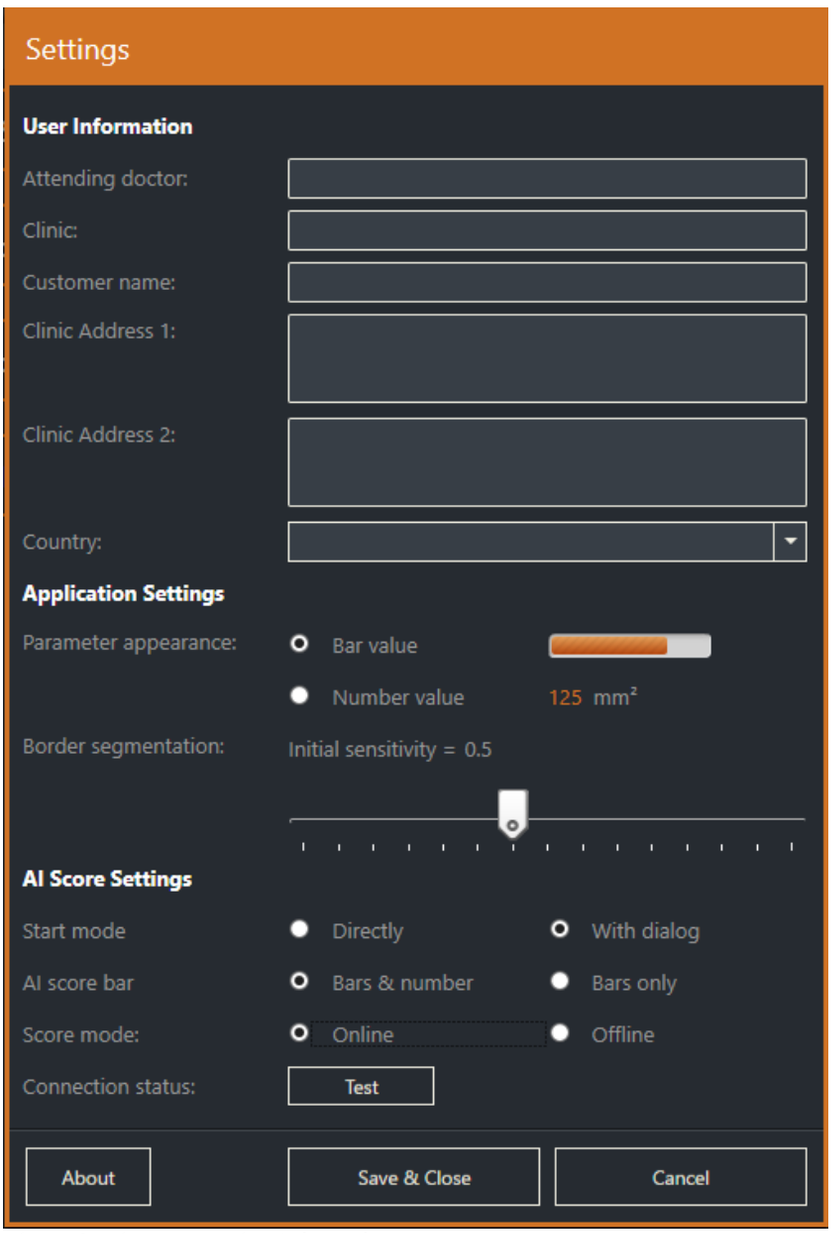


Fig. 5: Settings menu in Moleanalyzer pro

User information

These data appear on reports, for example.

1. Record your data in the appropriate input fields.
2. Confirm your input by clicking on *Save & Close*.

Application settings

1. Click to select whether you want the parameter values in the user interface to be displayed exclusively as numerical values or partly as bar values.
2. Adjust the skin-lesion border segmentation to your needs by clicking on the scale.
3. Confirm your input with *Save & Close*.

AI Score settings
Below you will find an overview of what the different *AI Score settings* do.

NOTE

The distinction between AI Score and AI Offline Score is described in the separate chapter (cf. chapter 5.7.1 Difference between AI Score and AI Offline Score).

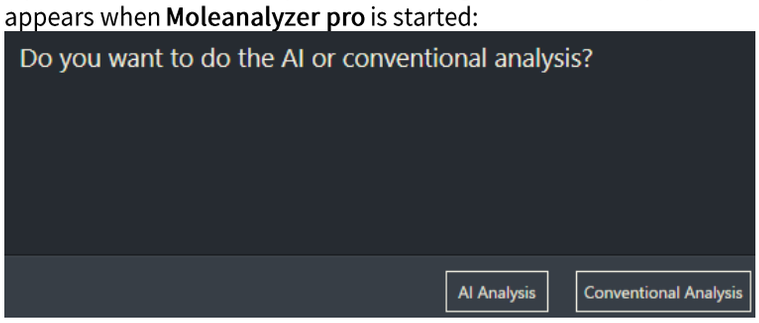
■ **Type of start: Direct**

If you have selected the option *Direct* for the *Start type*, the further course depends on your *Score Mode*:

For *Online* Score mode:		For *Offline* Score mode:	
Is the user already logged in to the FotoFinder HUB?		Is the AI Score licence active?	
Yes	No	Yes	No
User interface with AI Score opens.	User interface opens. AI Score can only be requested after logging in to FotoFinder HUB (cf. chapter 5.8 The FotoFinder Hub® Account).	User interface with AI Score opens.	User interface opens. AI Score can only be requested after activation of an AI-Offline-Score licence (please contact FotoFinder Systems.).

■ **Type of start: With dialogue**

If you have selected the option *With dialogue* under *Start type*, the following dialogue window appears when **Moleanalyzer pro** is started:

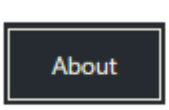


AI Analysis	*Conventional analysis*
As with *Start type: Direct.* See table above!	User interface opens. AI Score can be requested depending on the FotoFinder HUB plan or licence.

■ **AI Display**

You can choose between two different display modes:
- *Bar & Number*: The AI Score is displayed as a numerical value and as a line on the score bar.
- *Bar only*: A white frame indicates in which of the three areas the AI Score lies.

Also refer to the separate chapter (cf. chapter 5.7.3 AI Score result information)



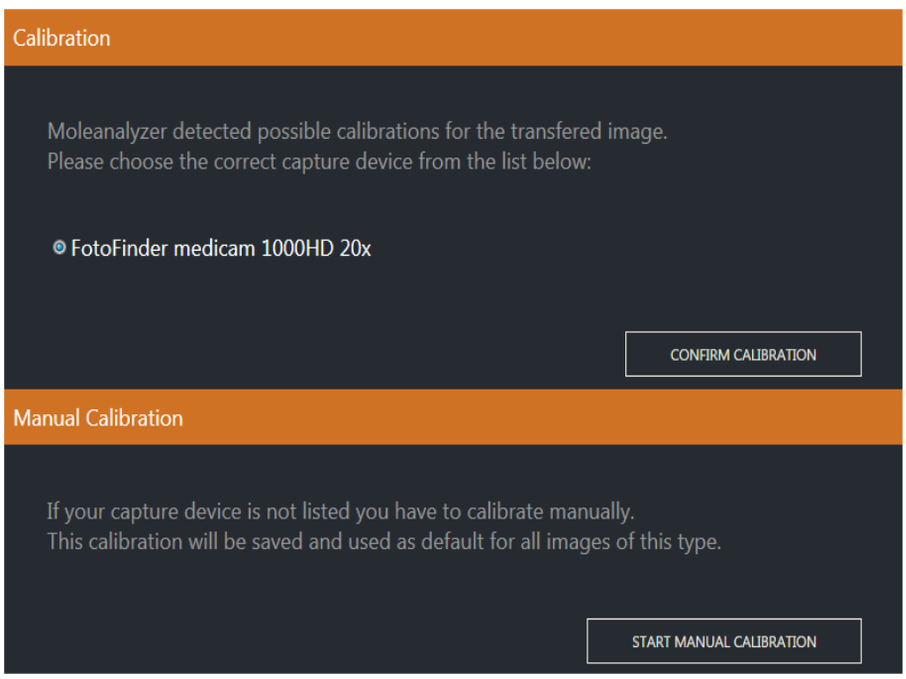
About:
By clicking on *About*, you can call up further software information, such as the programme version.

5.4 Calibration

In case the software cannot recognize the device the image was made with, the calibration menu will appear.

- Multiple options are available, for example in case an iPhone was used as capturing device.

As an example, the following list appears:

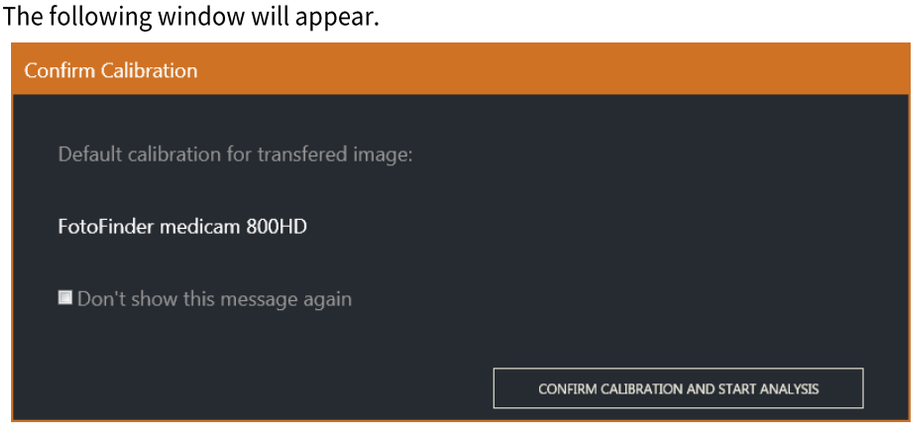


5.4.1 Calibration of recognized devices

If the device you're using is listed, then continue as follows:

1. Choose the appropriate device.
2. Click on *Confirm calibration.*

The following window will appear.



By marking the checkbox at *Don't show this message again* all future images with the same resolution will automatically be calibrated for the same device and this window will not appear again.

3. Click on *Confirm calibration and start analysis.*

The analysis will start now.

5.4.2 Manual Calibration

In case your capturing device was not listed, the following options are available:

- use a saved calibration, or
- start a manual calibration.

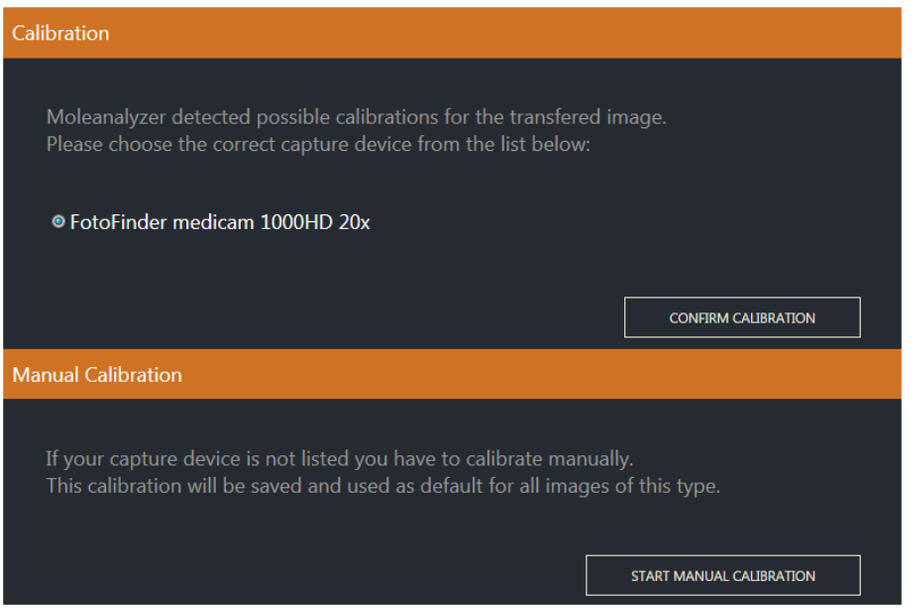


Fig. 6: Example for a calibration display

5.4.2.1 Use a saved calibration

If you already have saved a device for a specific resolution then follow these steps:

1. Click on *select saved calibration.*

A list will appear with the saved devices.

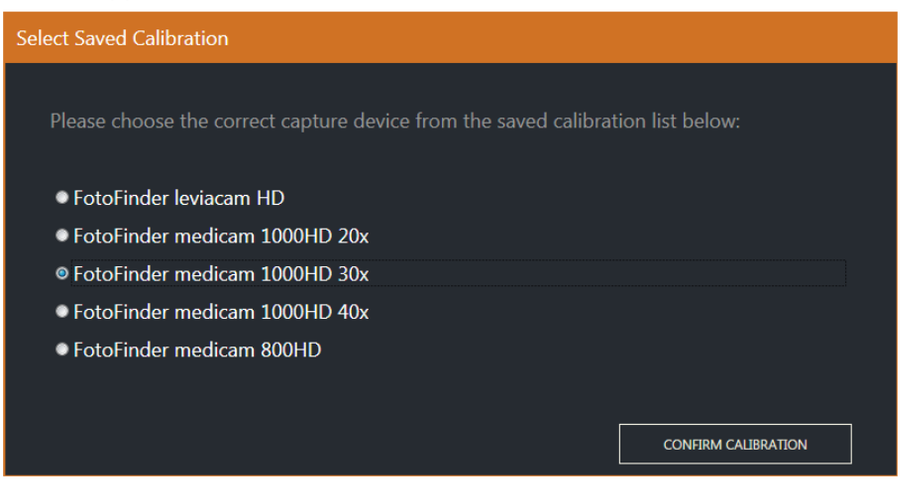


Fig. 7

2. Select the correct device and click on *Confirm Calibration.*

5.4.2.2 Start manual calibration

In case you have not yet saved a calibration for your capturing device, please follow as described below:

1. Capture a micro image of a graph paper or a ruler and choose this image when starting the **Moleanalyzer pro**.
2. Click on *Start Manual Calibration*.

The selected image will appear 1:1 on your screen.

3. With holding the left mouse button draw a line of known length.
4. In the appearing window insert the known length of the line and the measuring unit.
5. Name your calibration.

If you wish to always use the same device for capturing and analysis, you will be able to choose this calibration under the given name, or even permanently set it.

6. Click on *Save*.

At the next image import your calibration will also appear in the device list offered by the program.
You can then delete the micro image of the graph paper or ruler.

5.4.2.3 Manual calibration with scale

If you are using the **medicam®** micro lenses with a scaled glass tube, you will see a scale in your image which can be used for image analysis and calibration.
Here the distances between the long lines are 1 mm and between the short lines are 0,5 mm.

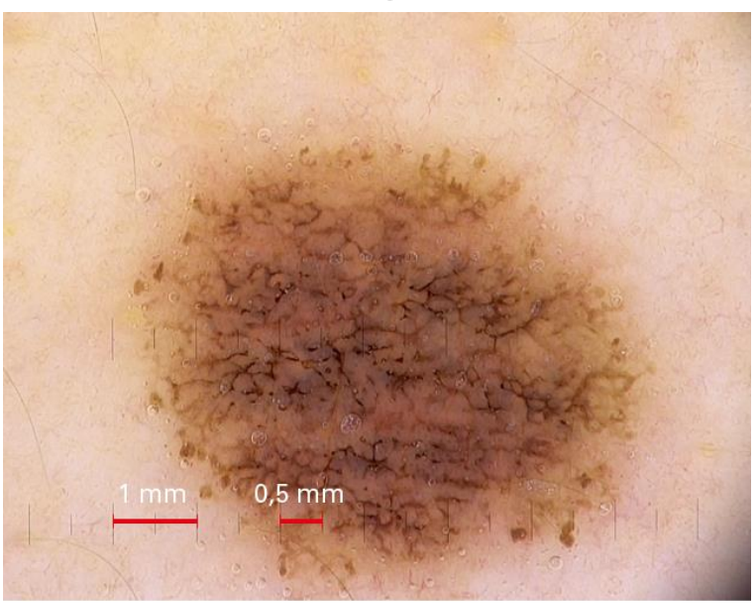
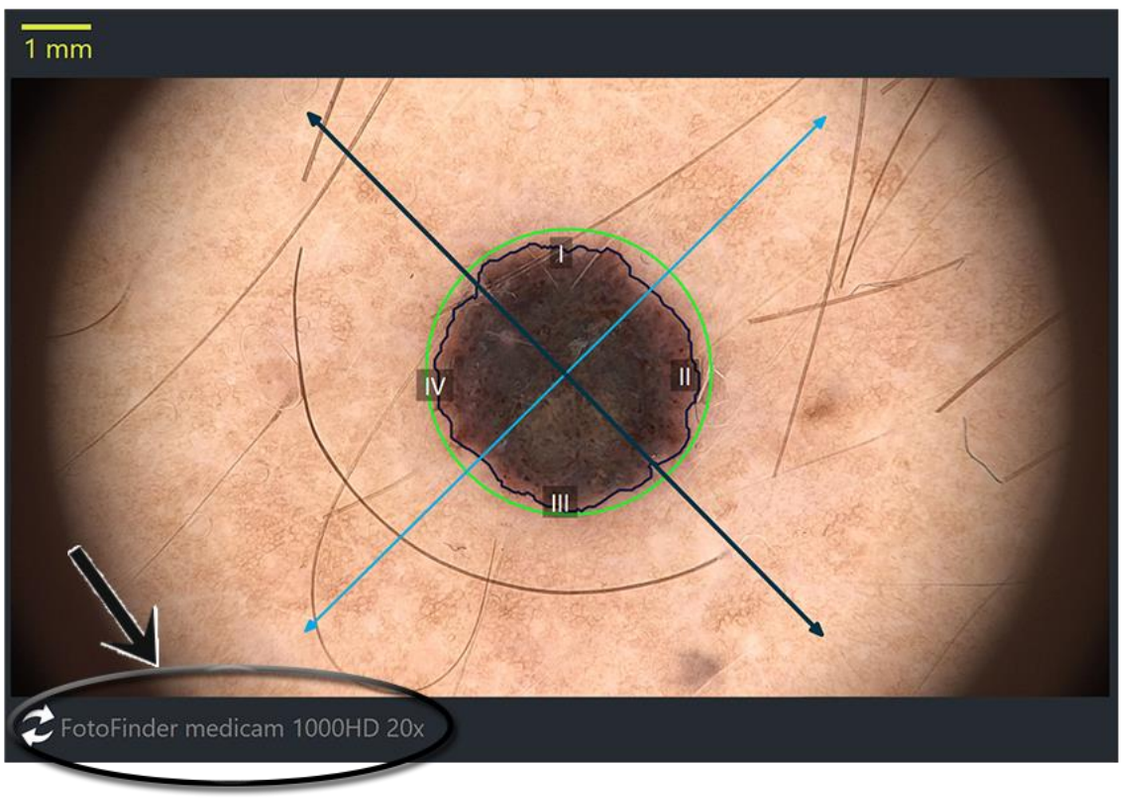


Fig. 8: micro image with scale

- Turn the glass tube on the medicam to assure a horizontal position of the scale in the image.
- Go to manual calibration and continue as previously described (cf. chapter 5.4.2 Manual Calibration).

5.4.3 Changing the calibration

You will see the selected calibration in the Detail View in the lower left corner.



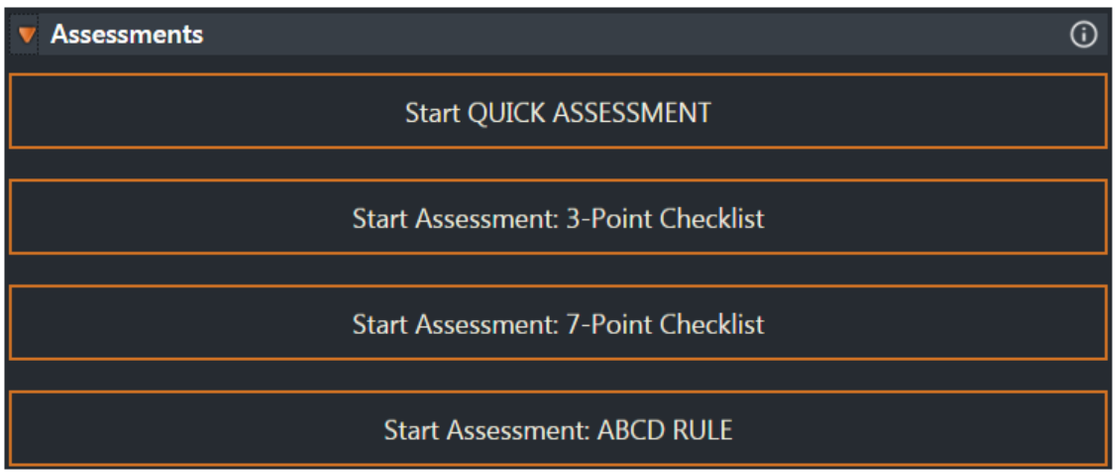
Before starting the analysis there is also an option to change the calibration:

1. Click on the displayed calibration.

You will be directed back to the device list.

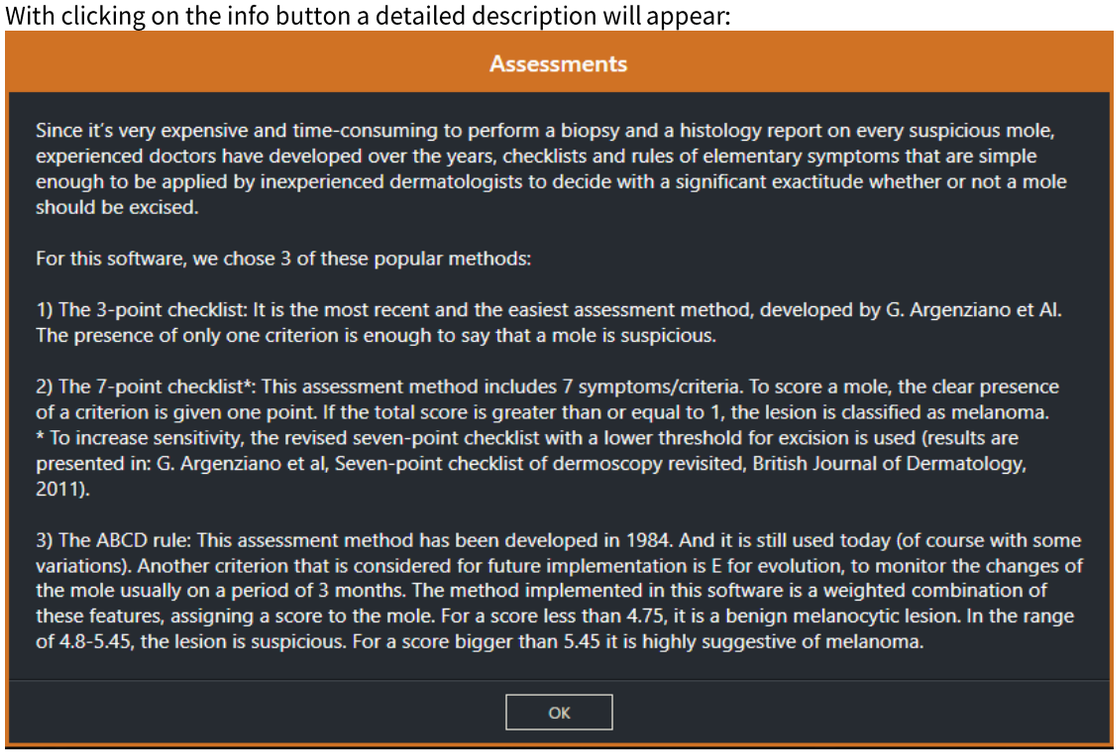
5.5 Assessments

Choose one from the following assessments:



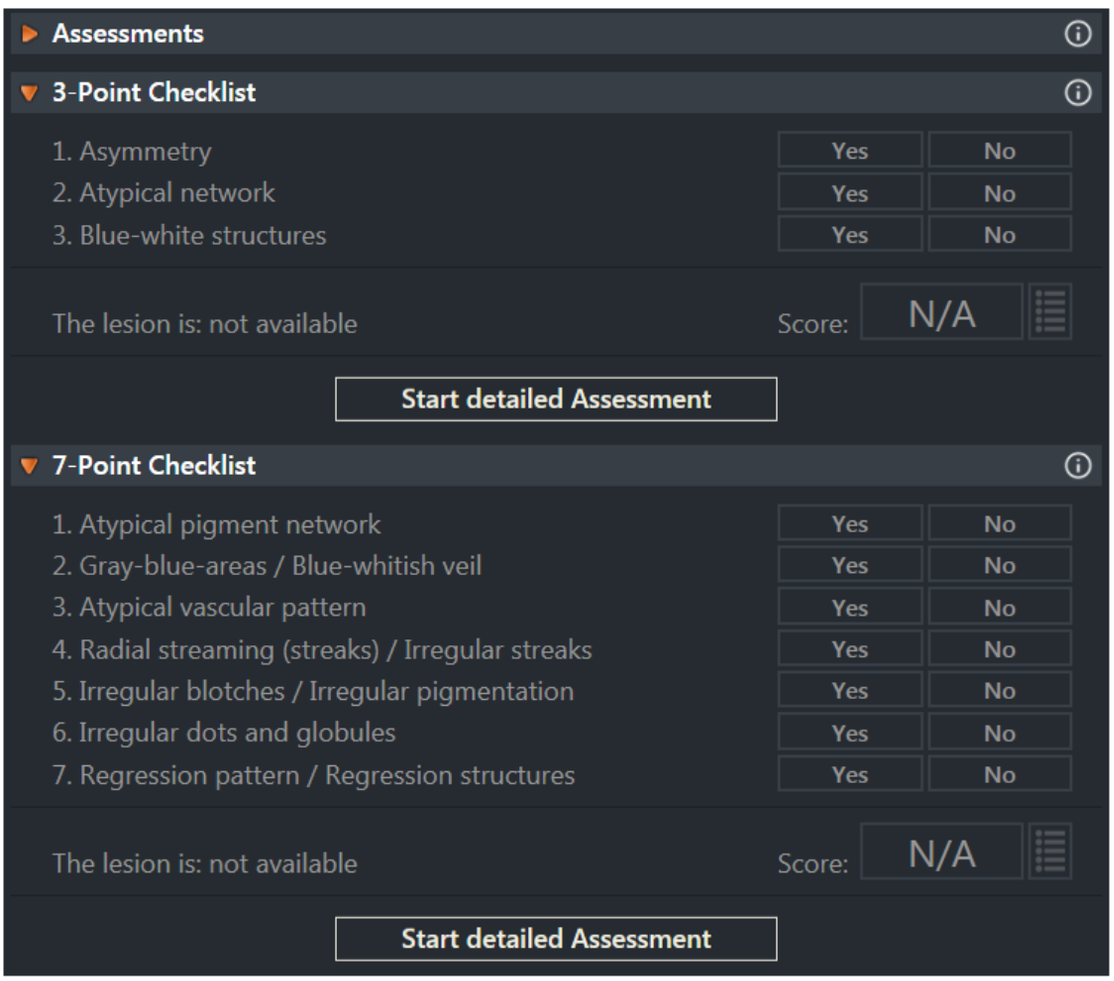
- The ABCD rule assessment is optional.

With clicking on the info button a detailed description will appear:



5.5.1 The Quick Assessment

Clicking on *Quick Assessment* the following sheet will appear:



Here you can assess different factors according to different checklists. You can choose between 3-point and 7-point checklists or ABCD (optional) rule.

1. Select one of the assessment options.
2. At the subsequent criteria, choose the correct points regarding your analysis.

The software will give you a score.

If you would like to do a more detailed assessment, you can switch to that by clicking on *Start detailed Assessment* (cf. chapter 5.5.2 The 3-point and 7-point Checklists, and the optional ABCD rule).

After evaluating all factors, this button becomes active. Click on this to go directly to the result summary (cf. chapter 5.5.3 The Result summary).

5.5.2 The 3-point and 7-point Checklists, and the optional ABCD rule

Here you will be guided through the different criteria step-by-step. On the lower part of this sheet the software also shows the scores at the parameters for simplification (cf. chapter 5.2 The Desktop).

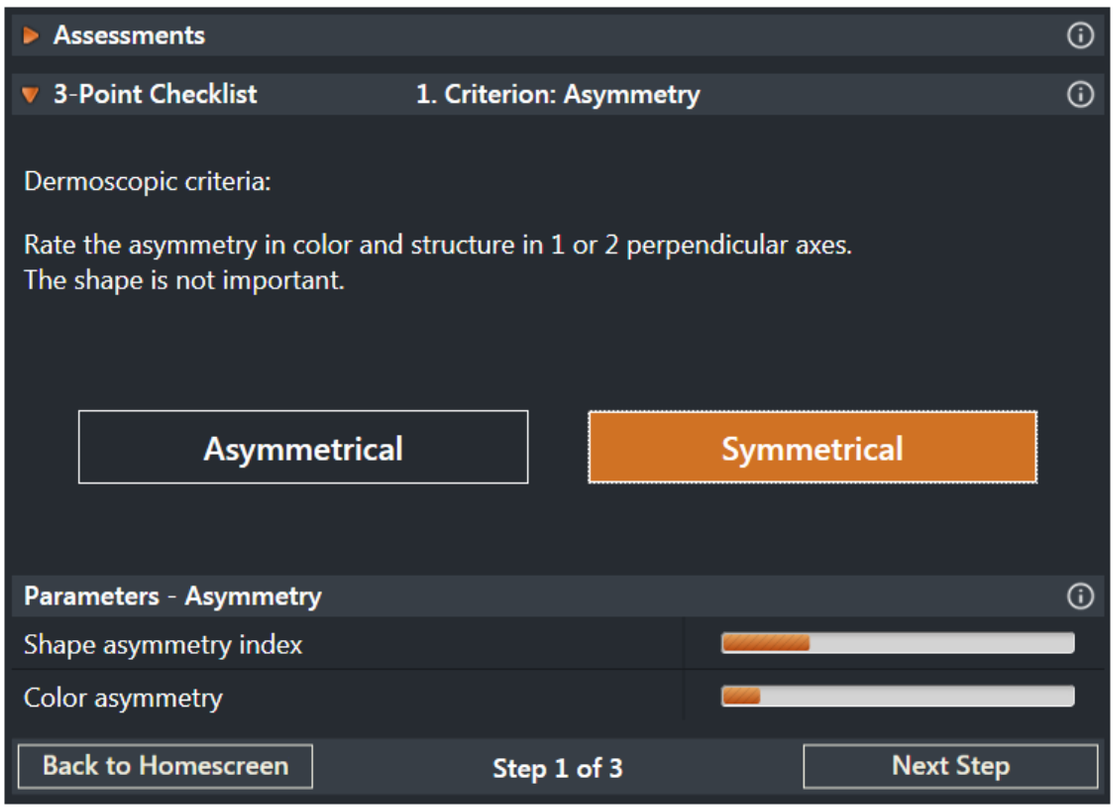


Fig. 9: Example for the 3-point Checklist

1. Select the corresponding field.
2. Click on *Next Step* to set all criteria one by one.

After evaluating all points, you will be taken to the Result summary (cf. chapter 5.5.3 The Result summary).

5.5.3 The Result summary

You can see the details listed here and can call up each criterion if necessary.

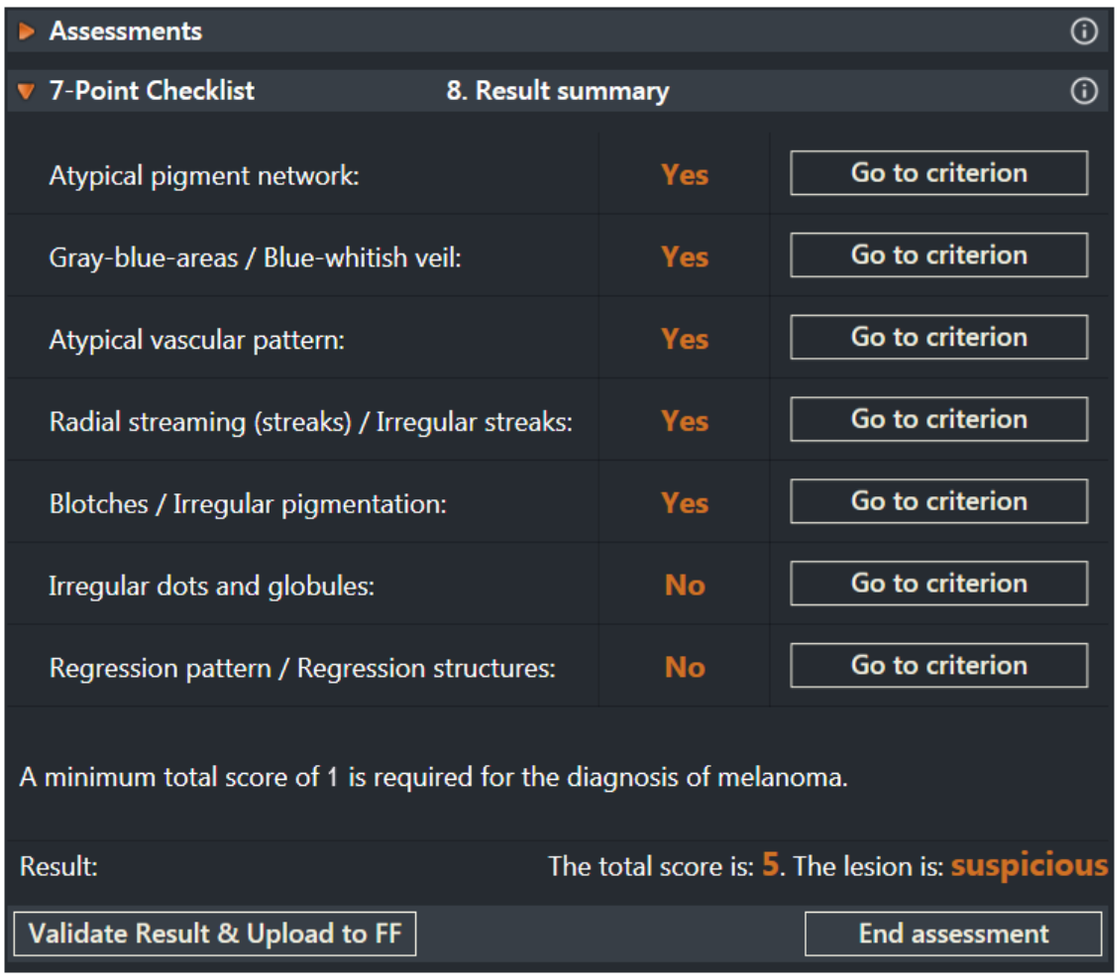


Fig. 10: Example for the result summary

⚠ CAUTION

The displayed total score is based solely on user input and does not represent an independent evaluation of the lesion by the software.

To go to a specific criterion just simply click on *Go to criterion*.

To complete your assessment you have two options:

- *Validate Result & Upload to FF*:
  The assessment will be saved and a window will appear to upload to FotoFinder.
- *End assessment*:
  The assessment will be saved and the evaluation window closes.

5.5.4 The Parameters

The display of the parameters may differ. The parameters are divided into five sections:

- Geometry
- Asymmetry
- Borders and Irregularities
- Color
- Structure

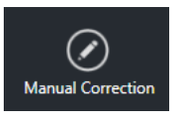
The values are automatically generated by the software on the basis of the segmentation.

The info section will display detailed information about each parameter.

NOTE

Segmentation and parameter accuracy cannot be expected or claimed.

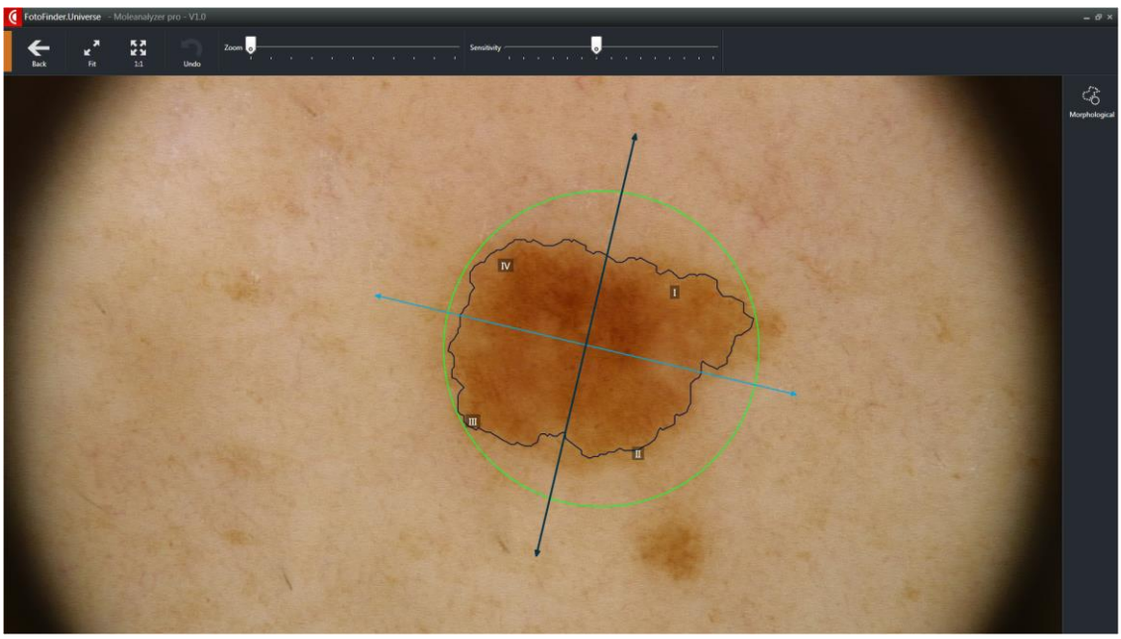
5.5.5 Editing the evaluation section



You can manually adjust the calibration of the analyzed surface.

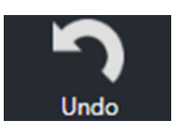
1. Click on *Manual Correction* in order to adjust the result of segmentation.

The following editing window will open.



- With right mouse click you can show/hide the symmetry axes and borders.
- With holding down the left mouse button you can move the image.

In Manual Correction these functions are available:



With *Undo* you can cancel your previous action.

With this scale you can adjust the sensitivity of the edge detection.

With the *Morphological* tool you can manually adjust the automatically segmented border.

1. Click on the *Morphological* icon.
2. Adjust the size of the drawing ring with the mouse wheel.
3. Holding down the left mouse button you can move the blue borders either from inside to outside, or vice versa (see white arrow):

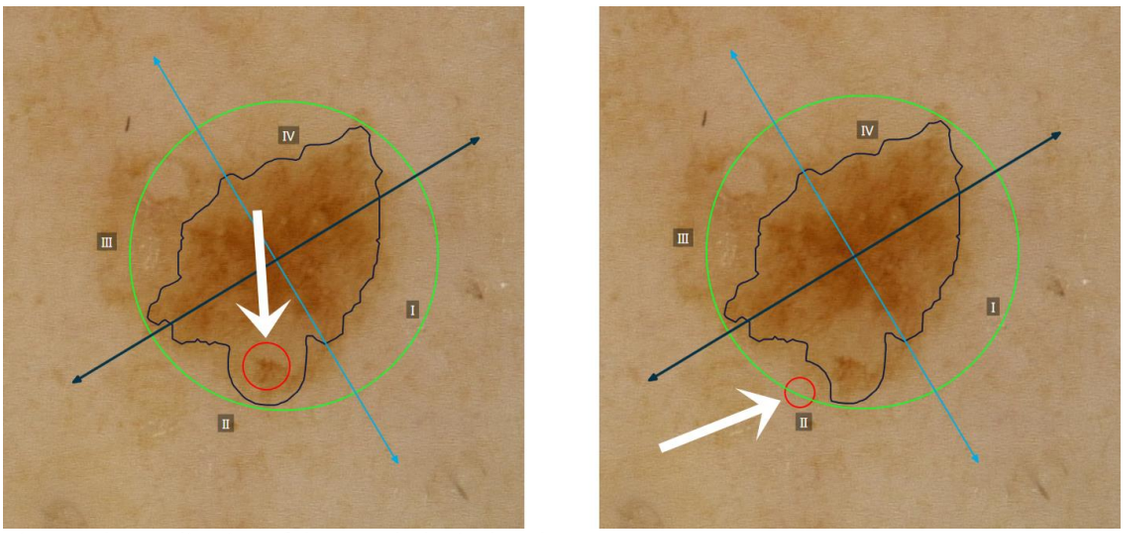


Fig. 11: The application of the Morphological tool.

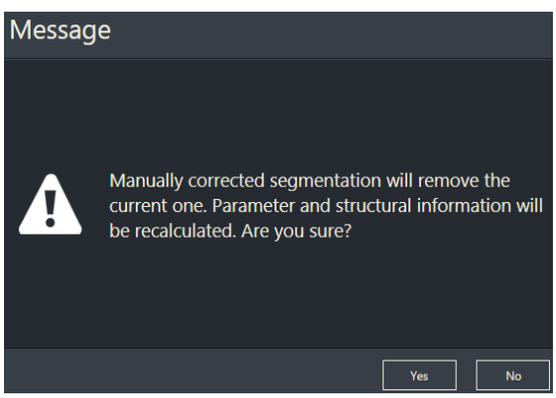


Fig. 12

When you leave the *Manual Correction* with clicking on *Back*, the program will ask you if you want to recalculate the values. Choose *Yes* or *No*.

The unsaved manual adjustments are going to be lost when leaving this function.

5.6 Library

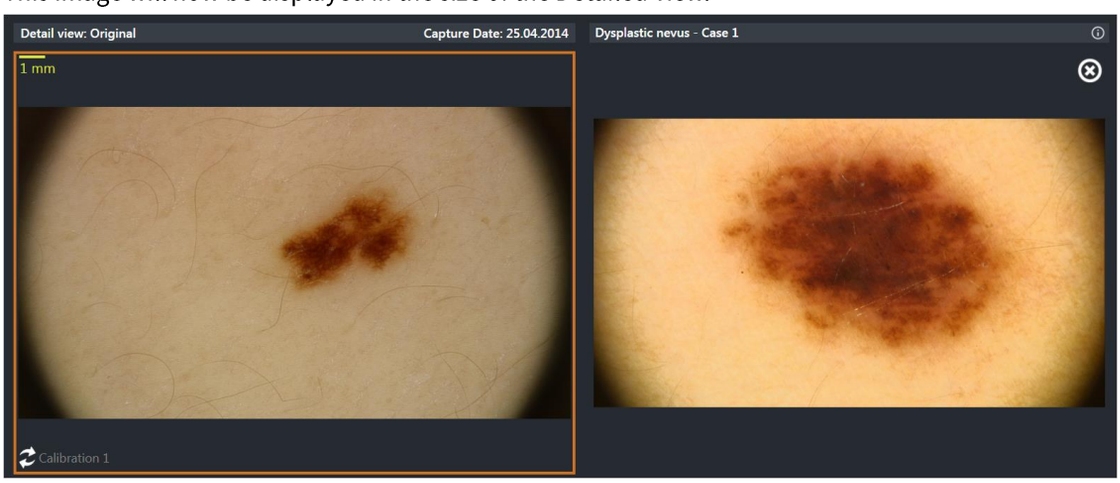
In the *Library* you will find a selection of already categorized lesions. You can use these for comparison purposes.

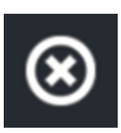
1. Click on Library.

Instead of the Assessments the Library will open.

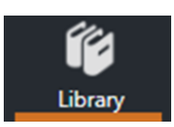
2. Click on the name of one of the main categories to see the comparison images.
3. If necessary, click on one of the images to enlarge it.

This image will now be displayed in the size of the Detailed view:





Clicking on the *X* at the top right corner you can close the enlarged view of the library image and return to the normal view of the library.



As long as the Library is open, the button in the menu bar is underlined with orange.

Click on *Library* again to close it.

5.7 The AI Score

The FotoFinder **Moleanalyzer pro** uses a Convolutional Neural Network (CNN) algorithm for the so-called AI Score. The sensitivity as well as the specificity of the algorithm were proven in a clinical study.

NOTE

The AI Score can be requested for images with 20x magnification.
The lesion must completely be in the image frame.
For manually calibrated images the AI Score result shall be considered with reservations.

- The AI Score is based on comparisons with images of malignant skin tumors (Melanoma, Basal Cell Carcinoma, Lentigo Maligna, Squamous Cell Carcinoma, Actinic Keratosis). The Score indicates how similar a lesion to a typical malignant skin tumor is.
- The AI Score does not assess the malignancy of the examined lesion! It only provides an estimate of whether a lesion is possibly malignant.

WARNING

The AI Score is based on statistics. The accuracy of the AI Score can therefore not be guaranteed. It is intended as additional support for the doctor.
The AI Score is not a substitute for the physician's overall clinical diagnosis!

NOTE

Note the various setting options that Moleanalyzer pro offers you for the AI Score (cf. chapter 5.3 Settings).

5.7.1 Difference between AI Score and AI Offline Score

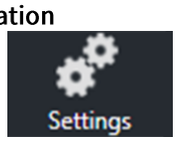
There are two ways to use the **AI Score**:

- as an AI Score with online access to the AI algorithm or
- as AI Offline Score with locally installed classification program (AI algorithm)

To find the optimal solution for you, please contact our sales department (info@fotofinder.de / phone 08563/977200), or our local distributors.

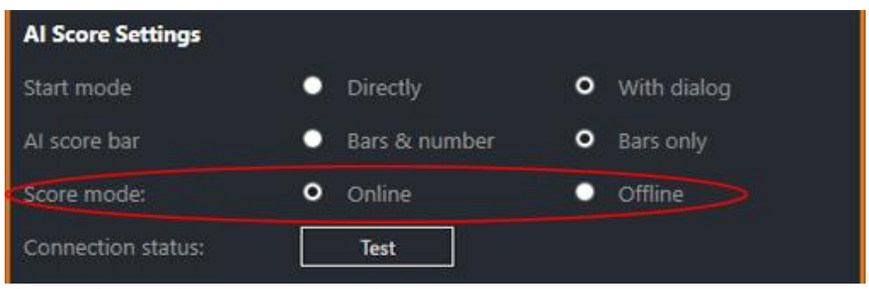
	AI Score	AI offline Score
Prerequisite	■ FotoFinder **HUB**® account with chargeable *Pro* Plan (cf. chapter 5.8 The FotoFinder Hub® Account) required	■ chargeable license required

Activation



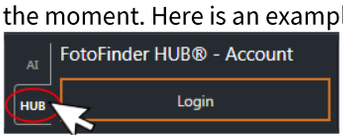
In *Settings* you can select which AI method would you like to use:

1. Click on *Online* or *Offline*.

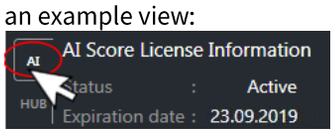


If you select *Online*, you can test the server connection with clicking on the Test button.

In the menu bar you can log in to the HUB or see which account is in use at the moment. Here is an example view:



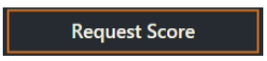
In the menu bar you will see information about your license. Here is an example view:



Note

In order to be able to use the **AI Score** function, make sure that you have an Internet connection, because the pictures will be transferred to a FotoFinder server anonymously in order to be classified. In addition, port 443 und 5006 must be open in the firewall in order to request a score.

5.7.2 Request Score



If you click on *Request Score*, a value (0 to 1) is given and displayed to you in bar form or the corresponding area in the score bar is framed in white. The display depends on your settings (cf. chapter 5.3 Settings).

The Score is also shown on the reports (cf. chapter 5.11 Reports).

As soon as the AI Score has been requested, automatic segmentation is hidden in the preview image, as these are independent of each other.

5.7.3 AI Score result information

The AI Score is designed to assess whether a lesion is potentially malignant. This is merely a confidence score of the algorithm, i.e. an assessment of the similarity to malignant lesions. Thus, the score does not make any statement regarding the medical risk or malignancy of a lesion.
Lesions with a high score should be observed with great attention.

- **0 - 0.49 inconspicuous**, follow-up in a reasonable time
  - 0 - 0.2 inconspicuous
  - 0.21 – 0.49 further clarification necessary
- **0.50 - 1.0 conspicuous**, should be observed with great attention

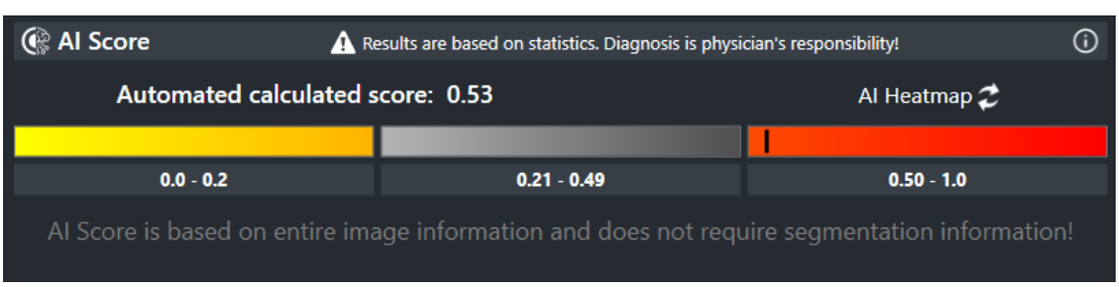


Fig. 13: Example view AI Score with selected AI display "Bar & Number"

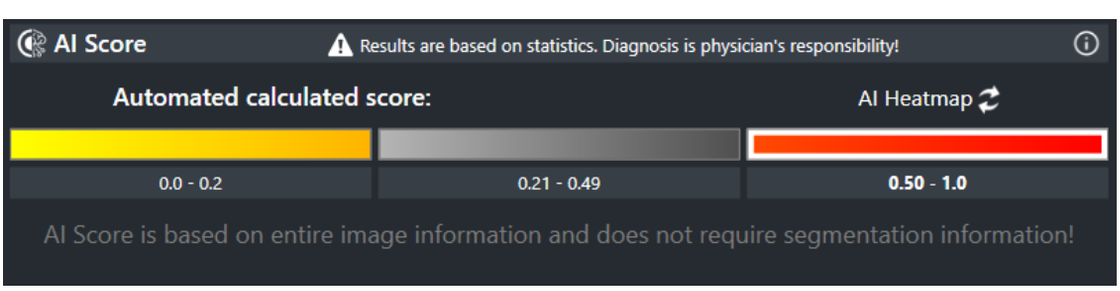


Fig. 14: Example view AI Score with selected AI display "Bar only"

5.7.3.1 AI Score Heatmap view

NOTE

This view is only available if you use the AI Score with online access to the AI algorithm, not the AI offline Score (cf. chapter 5.7.1 Difference between AI Score and AI Offline Score).

If the AI Score was requested, the *Heatmap* button appears next to or above the Score. By clicking on the button, you can display a type of thermal image view in the detailed view.

In this case, colours will indicate which areas of the lesion were particularly decisive for the calculation of the AI Score. For example, red areas were particularly interesting, while blue areas were more insignificant. For orientation, you can also see this colour rating displayed as a colour gradient with a scale on the right of the detailed view.

The Heatmap view makes the result of the AI Score more transparent and helps to see if possible interfering factors in the image affect the result.

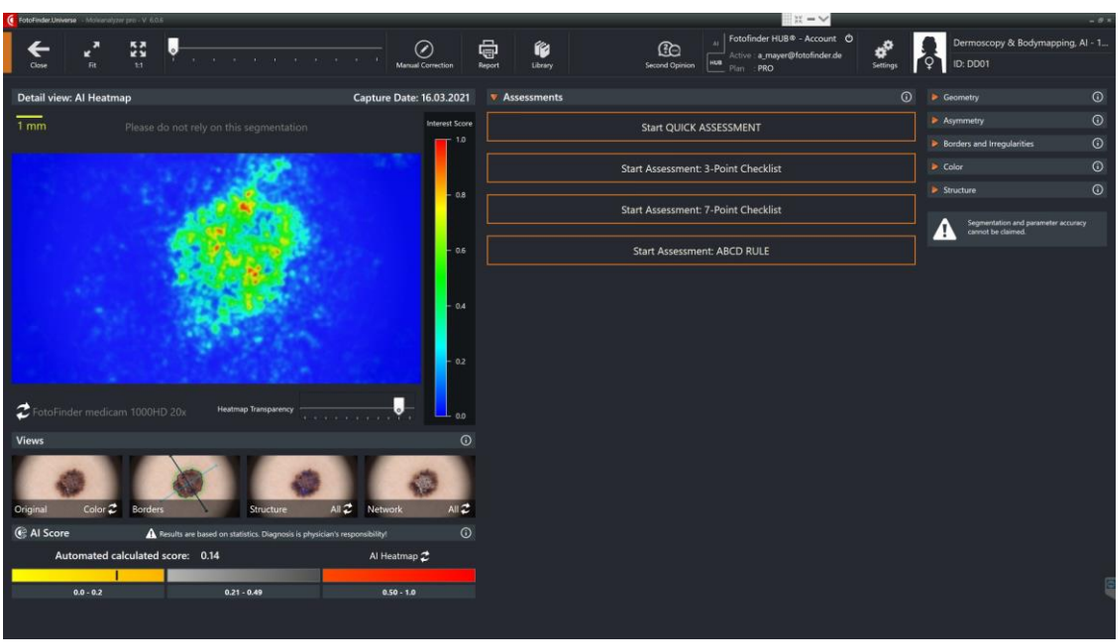


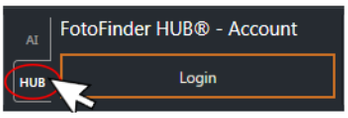
Fig. 15: Moleanalyzer pro view of AI Score and Heatmap

Use the slider below the detail view to adjust the transparency of the heat map view. Higher transparency will let you view the microimage behind it more in more detail.

You can leave the Heatmap view by clicking on one of the other views (cf. chapter 5.2.4 Views).

5.8 The FotoFinder Hub® Account

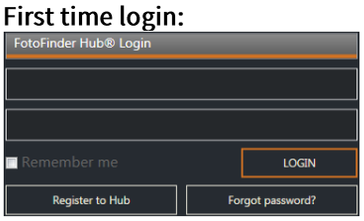
You can log in to your FotoFinder **Hub**® account with following these steps:



1. Click on *LOGIN* in the menu bar of the **Moleanalyzer pro**.

The login window will appear.

First time login:



2. At your first login click on *Register to Hub*.

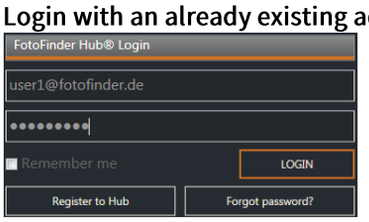
3. On the following sheet fill out all the required information and then click on *Register*.

Shortly after, you will receive an email with a conformation link.

4. Click on this link to conform your registration.

Your registration is then complete.

Login with an already existing account:



2. Type in your account's email address, password and click on *LOGIN*.

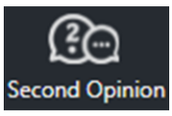
You are now signed in.

Marking the checkbox next to *Remember me* will save your login credentials and you will be automatically logged when starting the software.

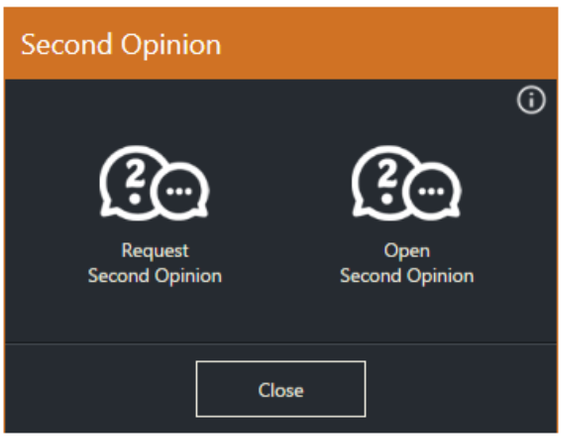
Logging out from the FotoFinder **Hub**® account:

To log out from the FotoFinder **Hub**® click on this symbol. You can find the button in menu bar of the **Moleanalyzer pro** next to the FotoFinder **Hub**® when an account is actively logged in.

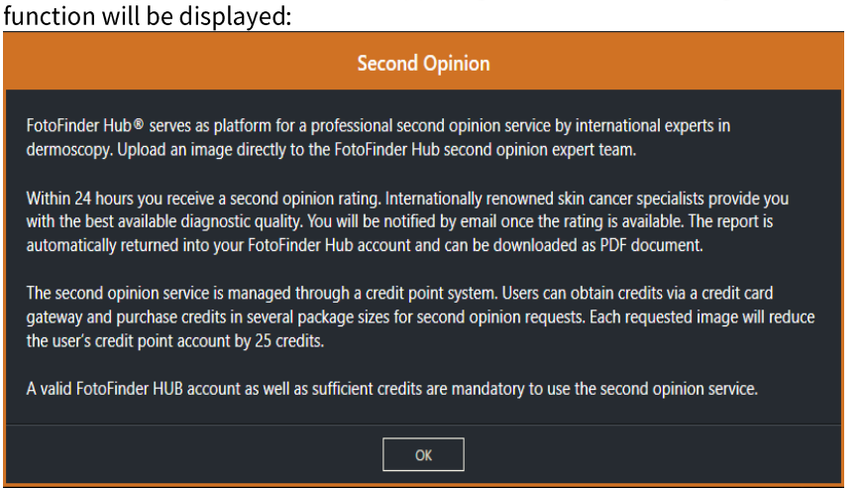
5.9 Second Opinion



Start the additional service Second Opinion by clicking on the adjacent button in the menu bar.
A window will appear with the following option:



With clicking on the i-button in the upper right corner of the dialog box a detailed description of the function will be displayed:



NOTE

The Second Opinion Service does not support private groups. Images cannot be uploaded to a private group.

You can choose between

- *Request Second Opinion* and
- *Open Second Opinion*

5.9.1 Requesting a Second Opinion

After clicking on *Request Second Opinion* and logging into your **Hub**® account the following window will appear (cf. chapter 5.8 The FotoFinder Hub® Account).

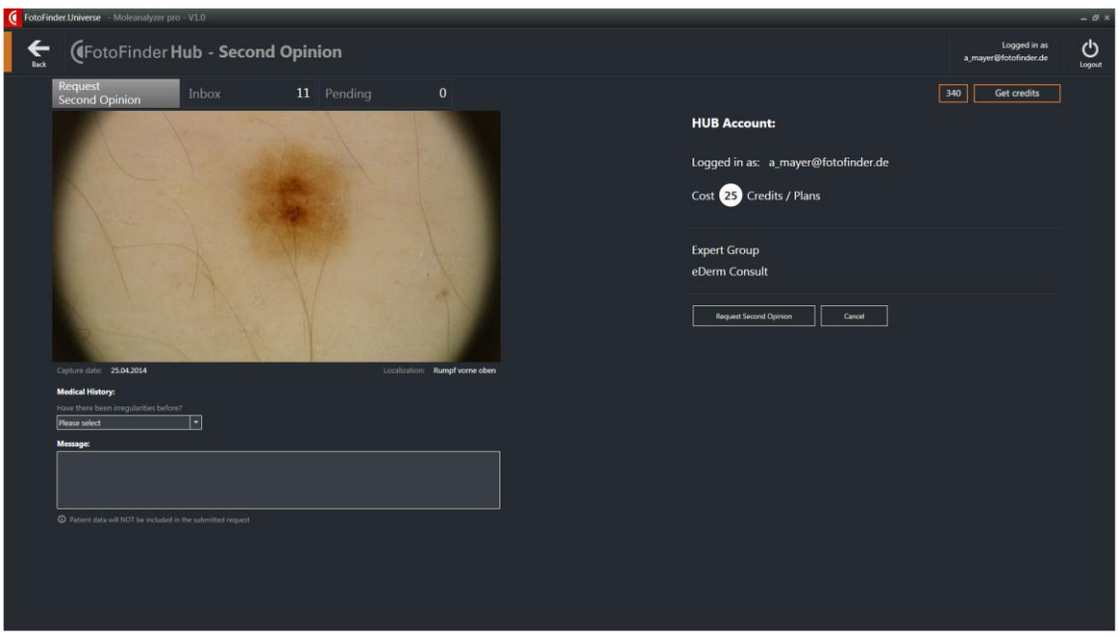


Fig. 16: FotoFinder Hub® – Second Opinion, Request Second Opinion window

Here you will see the chosen image again.

1. Below the image view, select if the patient had any irregularities before.
2. If necessary, enter your comment in the message field.
3. Click on *Request Second Opinion* to upload the data.

You will receive an answer within 24 hours.

On the right side of the screen, you will find information about your **Hub**® account:

- active user
- Second Opinion costs (25 Credits/Plans)
- Expert Group

In the upper right corner, you can see your current credit balance (here 90) in an orange frame and you also have the possibility to buy credits to restock your **Hub**® account.

You can access the Second Opinion service from the compare view (cf. chapter 5.10 Comparing images). Both images will be sent for the evaluation.

5.9.2 Open Second Opinion

Select *Open Second Opinion* after logging in to your **Hub**® account and you will be taken straight to the overview of your already requested second opinions (cf. chapter 5.8 The FotoFinder Hub® Account).

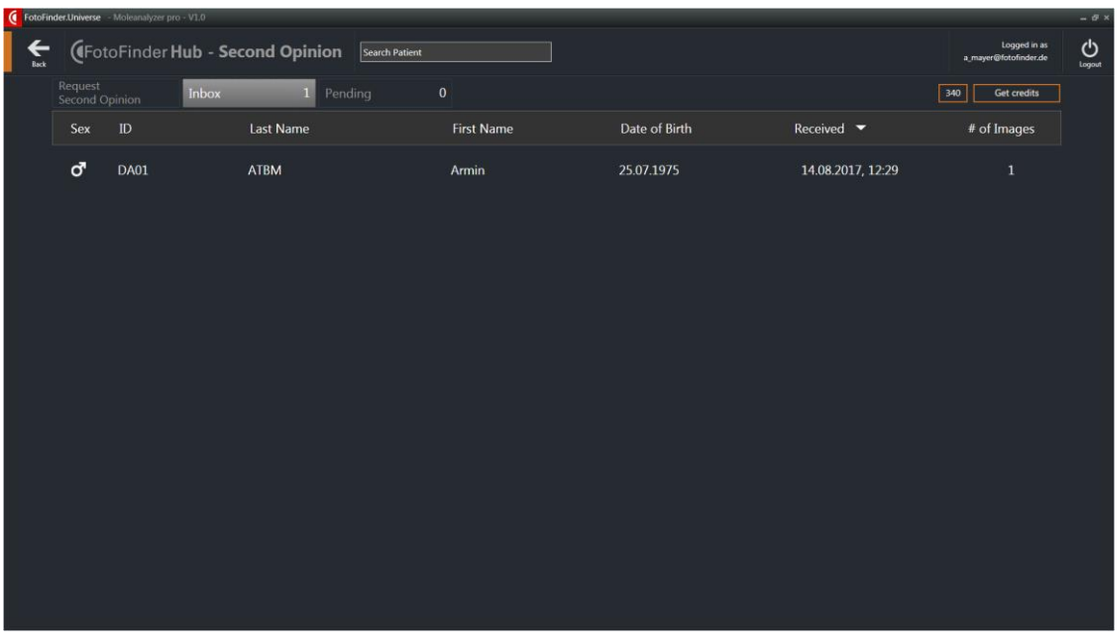


Fig. 17: FotoFinder Hub® – Second Opinion, overview of already requested cases

With a double-click on any patient you can open, print or save a pdf report.

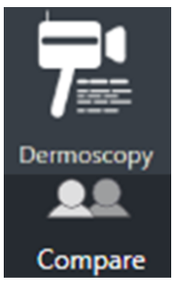
You can navigate to different sections by clicking on one of these index tabs:

- *Request Second Opinion* and
- *Pending*

In the *Pending* sections you will find all your cases which have not yet received a Second Opinion.

5.10 Comparing images

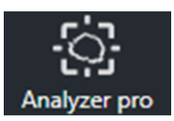
In the **Moleanalyzer pro** image compare mode you can compare images from different capturing sessions.



For starting the **Moleanalyzer pro** image compare follow these steps:

1. Start the Dermoscopy module from the Desktop of your software.
2. Select the micro image that you want to analyze.
3. Open the image comparison by clicking on this button.

You are now in dermoscopy image comparison. By default, the most recent micro image is displayed as a comparison image. If necessary, with holding down the left mouse button you can pull another image from the SmartGallery into the preview window.



4. Start the **Moleanalyzer pro** image compare with clicking on the *Analyzer pro* button above the images in the menu bar.

The **Moleanalyzer pro** image comparison window will open.

NOTE

The user interface of the *Dermoscopy* module is described in detail in the separate system manuals (e.g., *Dermoscopy* and *Automatic Total Body Mapping*).

At startup you will be asked for the calibration (cf. chapter 5.4 Calibration).

5.10.1 User interface

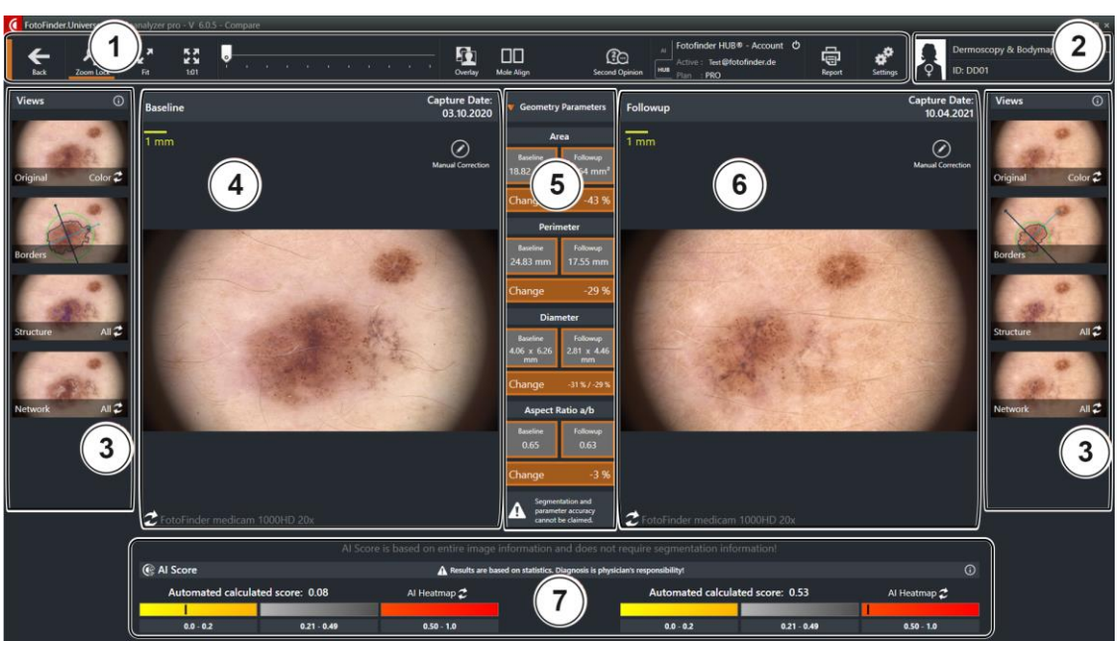


Fig. 18: **Moleanalyzer pro** *Image Compare user interface*

1	Menu bar	4	Detailed baseline view
2	Patient data field	5	Geometric parameters
3	Change views (fields available twice)	6	Detailed follow-up view
		7	AI Score

5.10.2 The Geometry Parameter

On the right side of the screen you will find the geometry parameters that are calculated by the software:

- Area
- Perimeter
- Diameter
- Aspect ratio

The values are given for both images. In addition, the value of the change in percent is calculated.

NOTE

A segmentation and parameter accuracy cannot be expected or claimed.

In case you would like to enlarge the detail views even further you can hide the Geometry parameter section:

1. Click on the Hide icon (see marked arrow in the figure below).

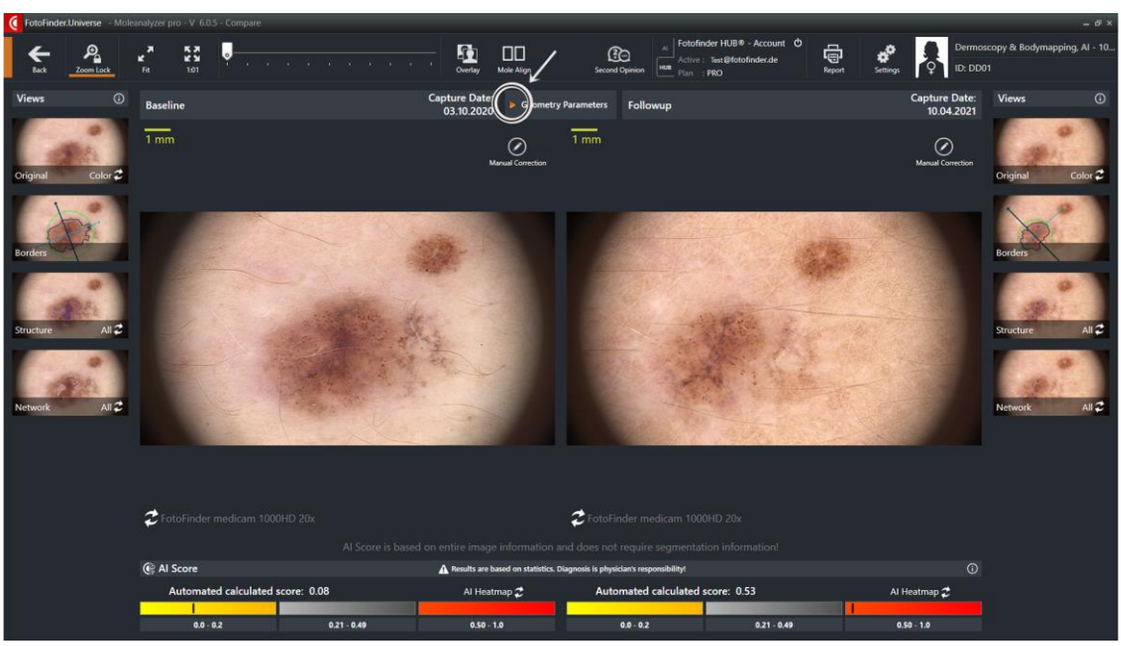
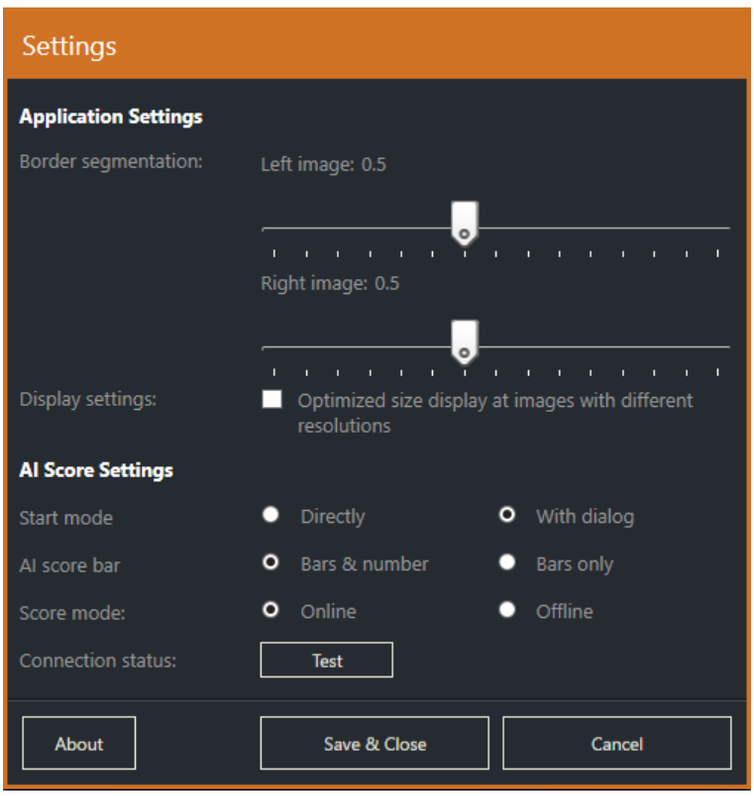


Fig. 19: User interface with enlarged detail views

2. Click the arrow again to show the geometry parameters again.

5.10.3 Image Compare settings

You can access the settings menu via *Settings*. Here you can store individual adjustments for Image Compare in **Moleanalyzer pro**.

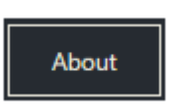


Application settings

- Adjust the standard skin-lesion border segmentation by clicking on the scale.
- When comparing images with different resolutions, you can set a check mark at *Display settings*. This automatically adjusts the size display of the images.

Confirm your input with *Save & Close*.

AI Score settings
(cf. chapter 5.3 Settings)



About
By clicking on *About*, you can call up further software information, such as the programme version.

Below you can see the explanations of functions that can only be found in the image comparison. Everything else is described in the user interface (cf. chapter 5.2 The Desktop).

5.10.4 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.

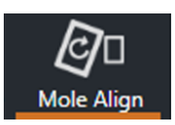
5.10.5 Aligning lesions

The *Mole Align* function adjusts the angle of both images. This will help you in the image comparison, if the images were not captured in the same angle.

1. Click on the *Mole Align* button.

After the first mouse click, the image on the right side will be rotated so that the display angle corresponds to the image on the left.
The button design in the menu bar also indicates this.

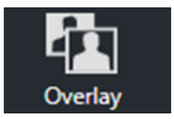
2. Click again on *Mole Align*.



After the second mouse click, the right image is rotated back to its original position, and instead the left image is rotated now so that the display angle matches to the right image.
The button design in the menu bar also again indicates this.

3. Click on the *Mole Align* button again to switch back to the initial view.

5.10.6 The Overlay function



The *Overlay* function visualizes lesion changes. The two images previously selected in the image comparison mode are laid on top of each other.

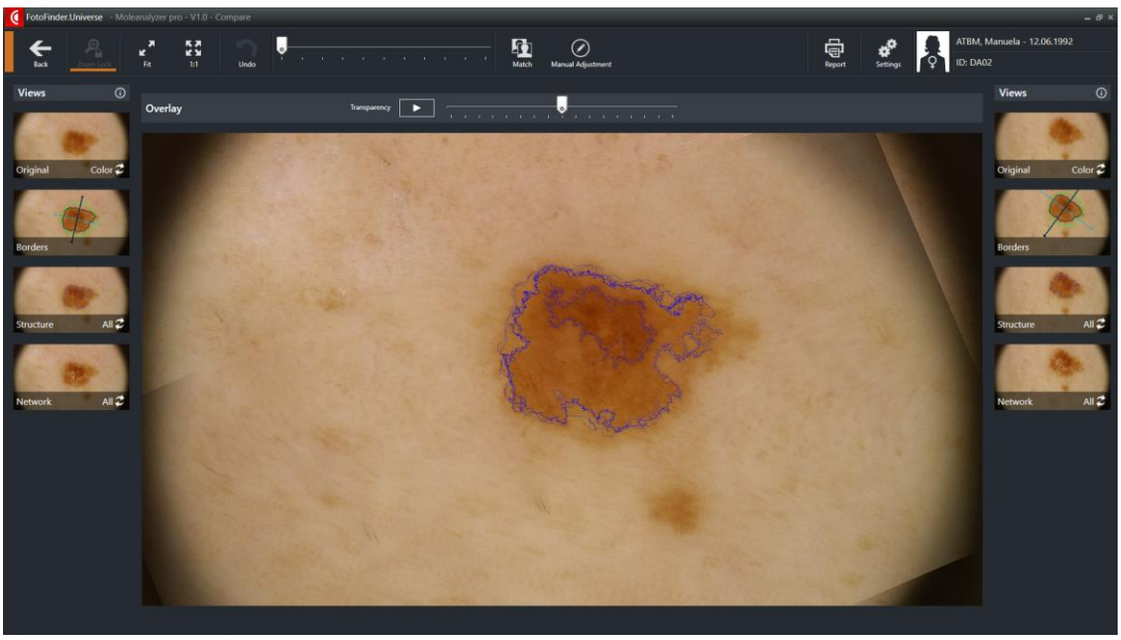
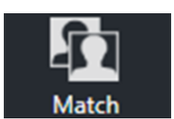
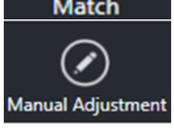


Fig. 20: Overlay mode



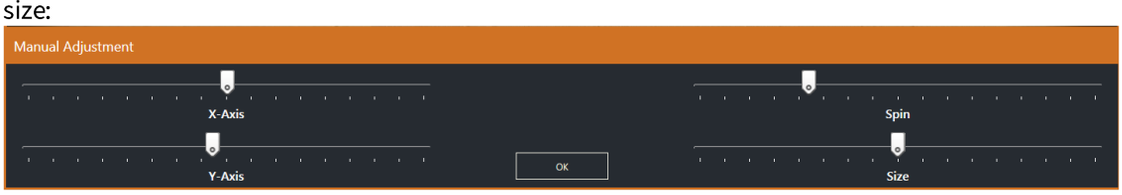


Click on *Match* to automatically adjust the lesion overlay positions against each other.

The *Manual Adjustment* feature allows you to manually adjust the overlay of the two images.

1. Click on Manual Adjustments.

At the bottom of the screen four slide bars will appear where you can adjust the position, orientation, and size:



2. Adjust the values as needed.

You will see the changes immediately in the detail view.

NOTE

The size of the image should not be changed when images are captured with the same camera model.

3. Confirm the changes with OK.

Transparency

Above the preview image are the *Transparency* tools:

This function can be used to adjust the visibility of the front exposure from invisible (to the left on the bar) to opaque (to the right on the bar).

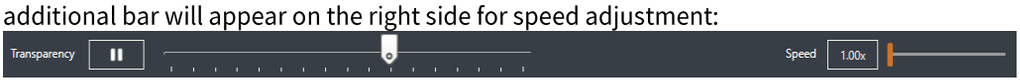
1. Move the pointer with the left mouse button.

The visibility in the preview image will be immediately adjusted.

It is also possible to let the transparency change run automatically:

1. Click on the *Play* icon.

The pointer on the scroll bar will now move continuously from left to right and back. Furthermore, an additional bar will appear on the right side for speed adjustment:

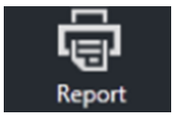


2. Adjust here the speed of the bar if necessary.

3. Click on *Pause*, if you want to stop the automatic scrolling.

Click on *Back* to return to the **Moleanalyzer pro** image comparison interface.

5.11 Reports



You can use the *Report* button in the menu bar of the user interface to create various types of reports.

5.11.1 Embedding the practice logo

You can embed your own practice logo in the reports:

1. You will need the logo as a png file.
2. Save this file to C:\ProgramData\FotoFinder Systems\External as *logo.png*.

The logo will now be added to your reports.

5.11.2 Report types

Depending on where in the software you click on the report button, different types are available.

In the **Moleanalyzer pro** user interface:
Summary report:

- Patient information
- Three different views of the image:
  - Original image
  - Image with the Borders analysis
  - Image with the Structure analysis
- Image information
- Assessment according to the 3-point and 7-point checklist and, if applicable, the ABCD rule, including the Score
- Moleanalyzer AI Score (if it was requested)
- Comment section

3-Point Checklist Report
In the report only the results of the 3-point checklist will be shown.
7-Point Checklist Report
In the report only the results of the 7-point checklist will be shown.
ABCD rule Report
In the report only the results of the ABCD rule will be shown.
AI Score Report
In the report no assessment will be shown, instead the results of the

- AI Score and
- Geometry

In the **Moleanalyzer pro** image comparison:
Original images

- Patient information
- Original baseline and follow-up images
- Image information
- Geometry parameters
- Moleanalyzer AI Score (if it was requested)

Segmented images

- Patient information
- Baseline and follow-up images with border segmentation
- Image information
- Geometry parameters
- Moleanalyzer AI Score (if it was requested)

6 Malfunction and troubleshooting

6.1 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.

6.2 Problems with the software

6.2.1 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.

7 Appendix

FotoFinder

KONFORMITÄTSERKLÄRUNG

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

FotoFinder Systems GmbH
Industriestraße 12
84364 Bad Birnbach
Deutschland

Wir erklären hiermit in eigener Verantwortung, dass nachstehendes Produkt

We declare under our sole responsibility that the product

Nous déclarons sous notre propre responsabilité que le produit

Dichiariamo sotto nostra responsabilità che il prodotto

Declaramos bajo nuestra exclusiva responsabilidad la conformidad del producto

FotoFinder Moleanalyzer pro
Version 6.0.5

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

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

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

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

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

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

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

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

Bad Birnbach, 25.05.2021

Julian Mayer, Authorized Officer

8 For your notes