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FotoFinder PASIscan®

Original manual

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

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FotoFinder Systems GmbH
Industriestraße 12
84364 Bad Birnbach
Germany

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

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1 Introduction

The FotoFinder **PASIscan**® supports the physician in the computer-assisted PASI (Psoriasis Area and Severity Index) determination by combining standardized whole-body imaging and innovative skin analysis. This allows to objectively determine the PASI score, to quantify the success of a therapy in detail and to document the course of the disease with polarized images.

FotoFinder **PASIscan**® works based on the FotoFinder ATBM®-Technology for Automated Total Body Mapping. It enables standardized documentation of the entire skin surface in just a few minutes. Based on the images thus obtained, the **PASIscan**® Expert system defines the four score values of the PASI: the extent as a percentage of the body surface, the redness (erythema), the thickness of the plaques and the scaling.

Baseline and follow-up images can be compared individually and the **PASIscan**® can visualize the changes in PASI values. This makes it possible to see at a glance whether the therapy goal PASI 50, 75, 90 or 100 has been achieved. Reports show the progress and success of the treatment.

The final confirmation or determination of the PASI score must be made by the physician. The **PASIscan**® provides the visual support for this.

2 Installation

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

3 Safety

3.1 User groups

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

Target group	Qualification
Physician	Professionally qualified as physician

3.2 Intended use

- The software enables the progress documentation of psoriasis on human skin and supports the physician in determining the severity.
- The application may only be used by medical professionals and only in medical environments (dermatology practices, hospitals).
- The application can only be used in combination with the FotoFinder **Universe** software.
- The following applications are ensured:
  - Non-contact, visual imaging and documentation of the entire skin surface (FotoFinder **bodystudio ATBM**®, FotoFinder **Universe** Software)
  - Documentation of patient-related image data (FotoFinder **bodystudio ATBM**®, FotoFinder **Universe** Software)
  - Support in determining the psoriasis severity index (PASI) through digital image analysis of human skin (FotoFinder **PASIscan**®)
  - PASI score documentation of patients (FotoFinder **PASIscan**®)
- The software does not provide a diagnosis. Psoriasis classification is based on statistical analysis. The diagnosis is the responsibility of the physician.

3.3 Patient exclusion criteria

Please note that the determination of a reliable PASI score is not possible for patients fulfilling the following criteria:

- Patients with tattoos
- Patients with excessive facial or body hair
- Patients with severe varicose veins
- Patients with other skin defects/illnesses
- Patients with sunburnt skin
- Patients not of European or Asian skin type (Fitzpatrick Type 5 and 6)

PASIscan® is a visual procedure which these criteria may affect.

NOTE

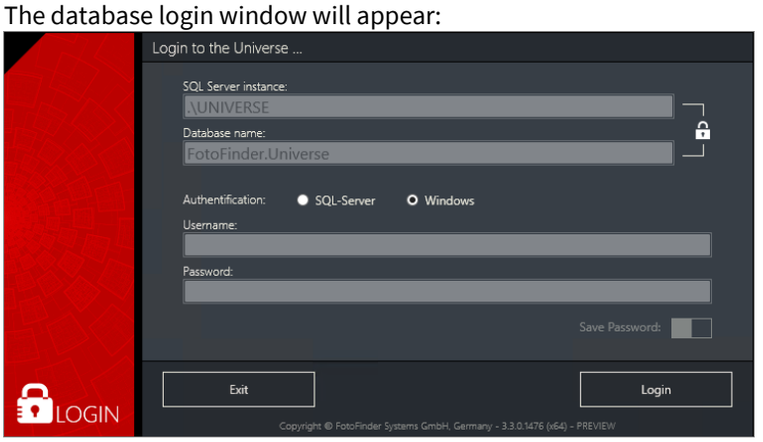
PASIscan® was developed for and tested on patients with European or Asian skin types (Fitzpatrick Type 1 - 4). Other skin types are currently not supported.

4 Starting the System

4.1 Database login

1. To start FotoFinder **Universe**, double click on the desktop icon.

The database login window will appear:



2. Set the connection data if necessary and click on *Login*.

Next 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:

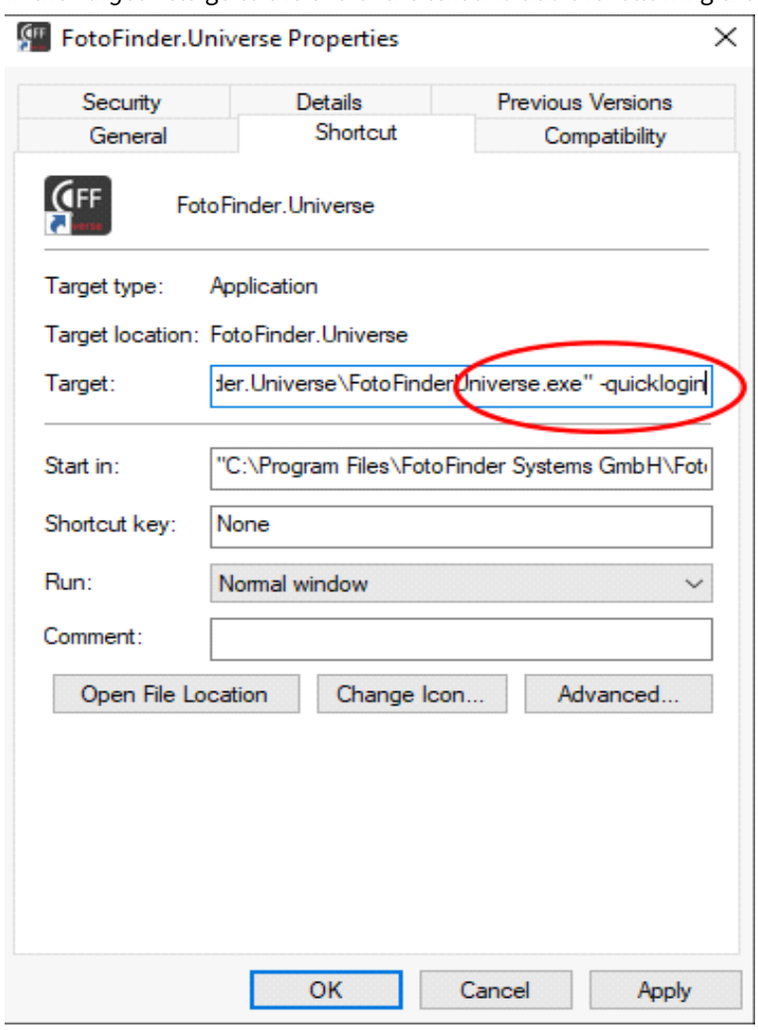
1. Right mouse click on the *FotoFinder.Universe* icon on the desktop.

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**

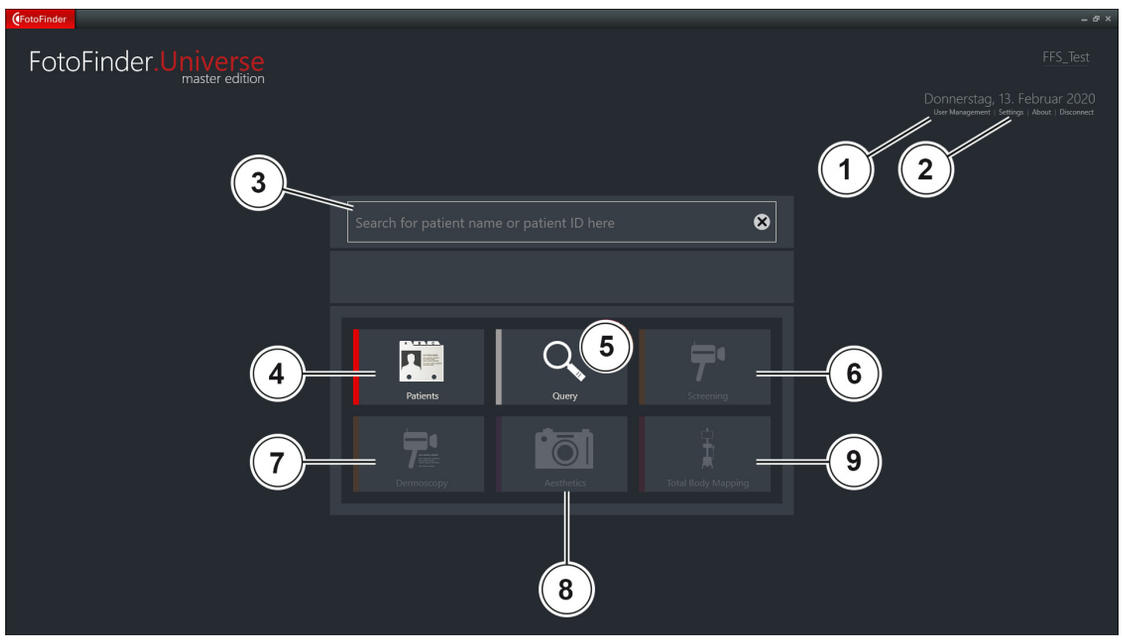


4. Click on *Apply* and then on *OK*.

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

- 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.

Patient Search

1. Enter the patient's first or last name, date of birth or patient number into the input field. The matching patients are already displayed during input.
2. Click to select the patient directly in the Patient Search field (2).

The selected patient's name, date of birth and patient ID are then displayed in the patient search field.

3. If required, you can start a new selection by clicking on the cross on the right of the input field.

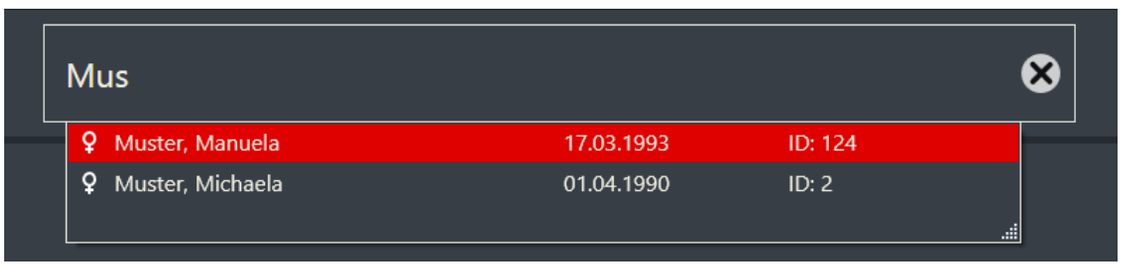


Fig. 1

Settings

While using **Universe** software, you can log out of the database and log in to another one without having to close or reset the program:

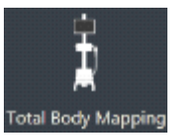
1. Click *Disconnect* in Settings (1) located in the upper right corner.
2. By clicking *About* you can access information on the software version you are using, the runtime of software updates and the contact information of the FotoFinder support.

4.3 Patient preparation

Before starting to capture images, your patient has to be prepared as follows:

- The patient has to be completely undressed. Only black, tight briefs (no boxer shorts) may be worn. Uniform disposable briefs are also possible.
- Make-up may not be worn.
- Severe perspiration should be avoided.
- Hair may not cover parts of the face or body and should be tied up.
- Glasses and jewellery must be removed.

4.4 Starting the application



PASIscan® is an expert system within the *Total Body Mapping* module.
The prerequisite for analysis are a total of 16 patient images (four each of all four body views):

1. Start the *Total Body Mapping* module by clicking on the appropriate button on the dashboard.

The application will start.

4.5 Positioning the patient

With the help of the foot mat and the positioning poster, Automatic Total Body Mapping (ATBM) enables the capture of continuously standardised and therefore comparable images.

During the ATBM capturing process, 20 images are created by default. For **PASIscan**® however, 16 are sufficient: Four each from the various body views front, right, back and left. You can interrupt the capturing process after 16 images.

NOTE

Please note that the thumbs must touch the thighs/hips during the capture of the front and back images.

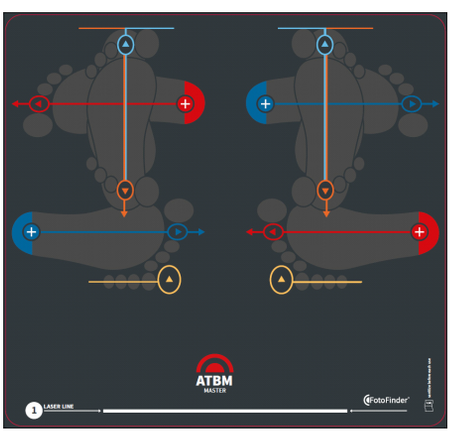


Fig. 2: Ground mat

1. Align the white marking of the ground mat to the laser line of the Laser Liner.
2. Position the patient on the mat according to the markings.

The images are captured in this sequence (starting from upper left to lower left):

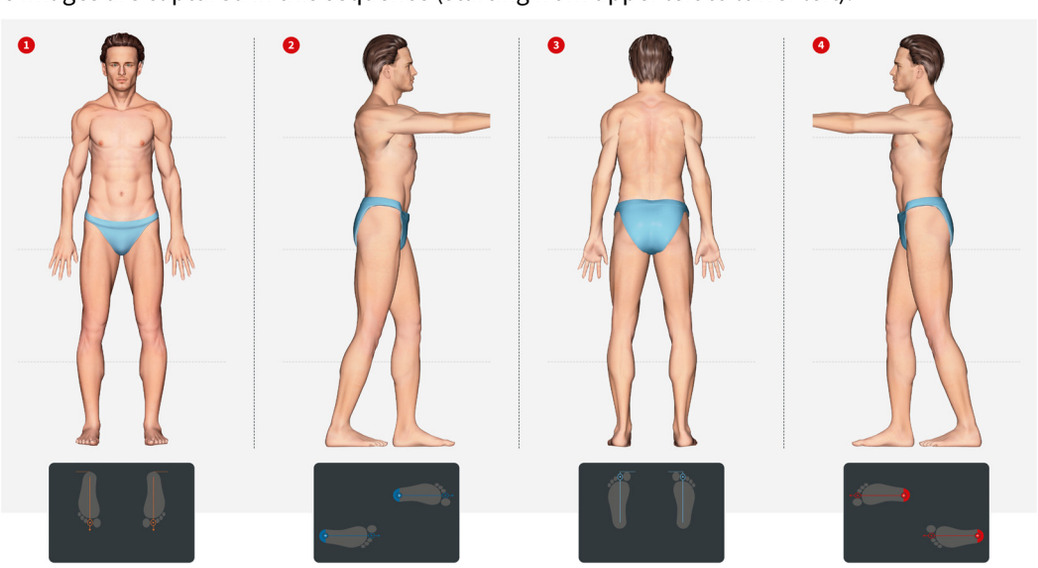


Fig. 3: Capturing position with foot positions

4.6 Creating images

NOTE

The steps of creating patient images are described in the separate manual for Automated Total Body Mapping.

Create your patient images according to the ATBM patient positions.

For the **PASIscan**® images, please note the following:

- The images must polarized. This largely suppresses reflections from the skin (cf. chapter 4.6.1 Polarized Bodymapping).
- Use only the solid dark blue background from FotoFinder, or a surface painted in a comparable color as the background for the imaging.
- The images must not be too dark or blurry to be able to analyze them with the **PASIscan**®. The software issues an error message if the images are too dark or blurry.

Only keeping these conditions enables a realistic analysis of the images.

4.6.1 Polarized Bodymapping

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

FotoFinder bodystudio ATBM master	**FotoFinder bodystudio ATBM (1. Generation)**
1. In the Settings at *Devices* / *Automatic Tower* set the camera profile to *Polflash XE RAW* or Polflash XE.	1. In the Settings at *Devices*/ *Automatic Tower* set the camera profile to *AutomaticTowerPolarization* (from *AutomaticTowerDualFlash)*. **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.	2. 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.

5 PASIscan® Software

Start **PASIscan**® by clicking on the *PASI SCORE* icon in the menu bar of the *Total Body Mapping* module.

The **PASIscan**® expert system will open.

5.1 Disease type selection (acute or chronic)

For each patient, at the first time it must be selected whether it is acute or chronic psoriasis. You will be prompted to select when starting the application:

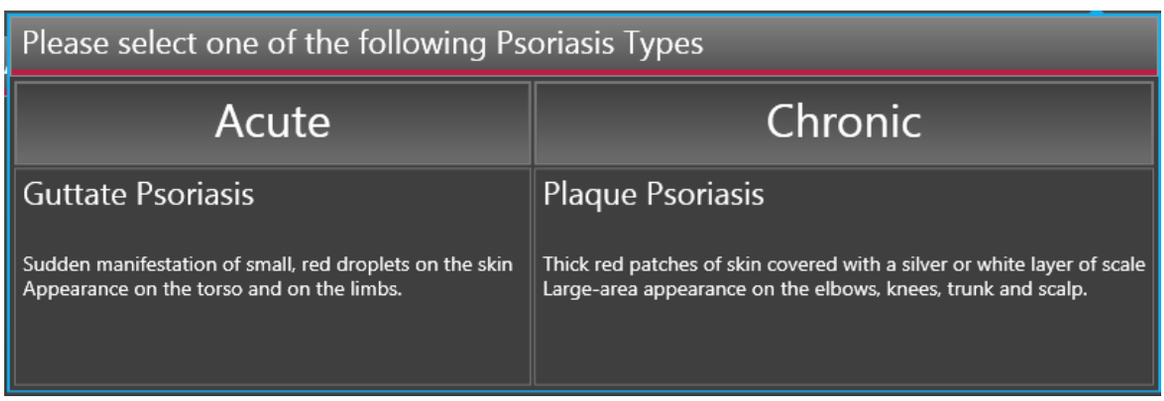


Fig. 4: Disease type selection window

1. Select *acute* or *chronic*.

The selected disease type will be displayed later in the patient data field in the user interface. After the selection, the software automatically starts generating the values for all images.

2. Please wait until this process is completed.

The results are then displayed in the PASI score overview (cf. chapter 5.3 PASI Score Overview (PASIboard®)).

5.1.1 Changing the disease type

1. Click on the disease type in the patient data field.

The above shown dialog box opens.

2. Select the type of disease.

5.2 The Desktop

Fig. 5: User interface **PASIscan®**

1	Menu bar	5	Preview window
2	Patient data field	6	Evaluation
3	Segmentation selection	7	Alternating sections
4	Gallery		

5.2.1 Menu Bar

Clicking on *Quit* will return you to the user interface of the *Total Body Mapping* module. **PASIscan**® is closed.

With *Edit Evaluation Area* you can individually edit the sections recognised by the Software (cf. chapter 5.4 Editing the evaluation section).

Fit Screen allows you to adjust the height and width of the currently displayed image in the preview window.

You can individually adjust the enlargement of the image display with the help of the slider bar or by turning the mouse wheel. You can change the displayed section by moving the image while clicking and holding the left mouse button.

1:1 will present each pixel of the image with exactly one pixel of the screen.

With *Report* you can choose between different reports (cf. chapter 5.6 Reports).

5.2.2 Patient data field

The patient data field displays the patient's name, date of birth, ID number and selected psoriasis type (Acute/Chronic). You can change the selected psoriasis type here.

5.2.3 Segmentation selection

Use this drop-down menu to select what you would like to be highlighted in the preview window. The following is available for selection:

- Surface area
- Redness
- Scaling
- Thickness

5.2.4 Gallery

Here you can see all of the patient's images which are available for this body region and which were included in the calculation. By clicking on the respective image, it will be displayed large in the preview window. This makes checking the score easier.

5.2.5 Preview window

This enlarges the image currently selected in the gallery. Use the display tools in the menu bar to change the view.

5.2.6 Evaluation

This displays information on the currently selected body region and the available evaluation. These you can change and either accept or reject the score.

Information windows

The information windows available for the segments Redness, Scaling and Thickness are very helpful during evaluation. They display example images for each of the evaluation stages 0 - 4, which you can use to orientate yourself.

1. To open the required information window, click on the i button on the right in the evaluation window.

2. This opens the information window.

You can leave the window open while you adjust the evaluation.

NOTE

You can alternate between the three possible information windows (Redness, Scaling and Thickness) by clicking on the appropriate i button without having to close the open information window first.

3. To close, use the left mouse button to click on the X at the top right in the information window.

5.2.7 Alternating sections

Here you can

– alternate between the displayed body sections and

– call up the total overview of the PASI Score calculation (cf. chapter 5.3 PASI Score Overview (PASIboard®)).

5.3 PASI Score Overview (PASIboard®)

Values are calculated for the following regions:

- Head and Neck
- Trunk
- Upper Extremities
- Lower Extremities

The overall result (Total Pre-Score) is displayed below.

Fig. 6: **PASIboard®** *with displayed Total Pre-Score before adjustment or approval*

The automatically calculated individual values must be verified, confirmed and, if required, adjusted by a physician.

NOTE

Please note that the scalp, genitals, hands and feet are not taken into consideration during the PASI Score's automatic calculation. It is the physician's responsibility to examine the skin in these body regions and to appropriately adjust the PASI values in accordance with the diagnosis.

The values are framed in colour:

- red frame: automatically calculated value
- blue frame: manually adjusted or already evaluated value

NOTE

The automatic calculation of surface area, redness, scaling and thickness are only a prognosis and has to be verified, confirmed and, if required, adjusted by a physician.

1. Adjust the individual values by clicking directly on the respective value.

The effect on the overall result will be calculated immediately during the adjustment of the individual values.

2. Accept all values, one after the other, by clicking on *Approve Score.*

The value for this region will then turn blue.

Already approved values can be changed again by clicking on *Reject Score*.

Once all the values from all four body regions are approved, the total PASI Score is highlighted in blue and displayed as the evaluated PASI Score.

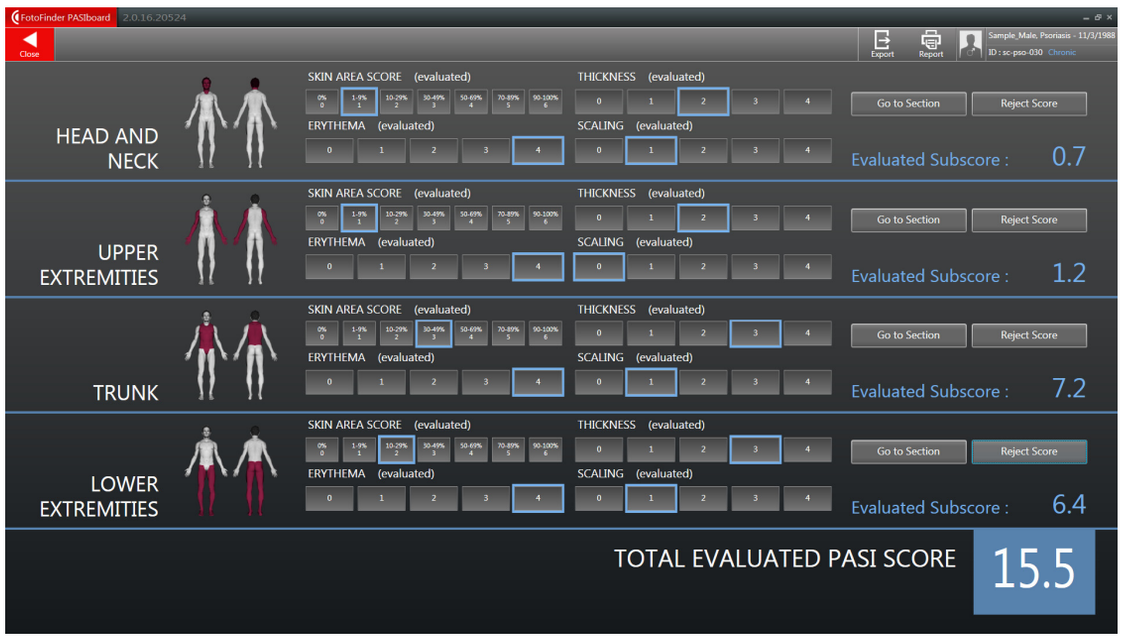


Fig. 7: **PASIboard**® *displaying the total evaluated PASI Score*

The *Go to Section* button takes you to the user interface, where you can see the available individual images for the respective region. You can also adjust the evaluation results there.

With *Export* you can optionally export and save the patient data as csv, tsv or xls files.

With *Report* you can choose between different reports (cf. chapter 5.6 Reports).

5.4 Editing the evaluation section

With *Edit Evaluation Area* you can individually edit the sections recognised by the Software.

1. Click on the button in the menu bar.

This will open the following view:

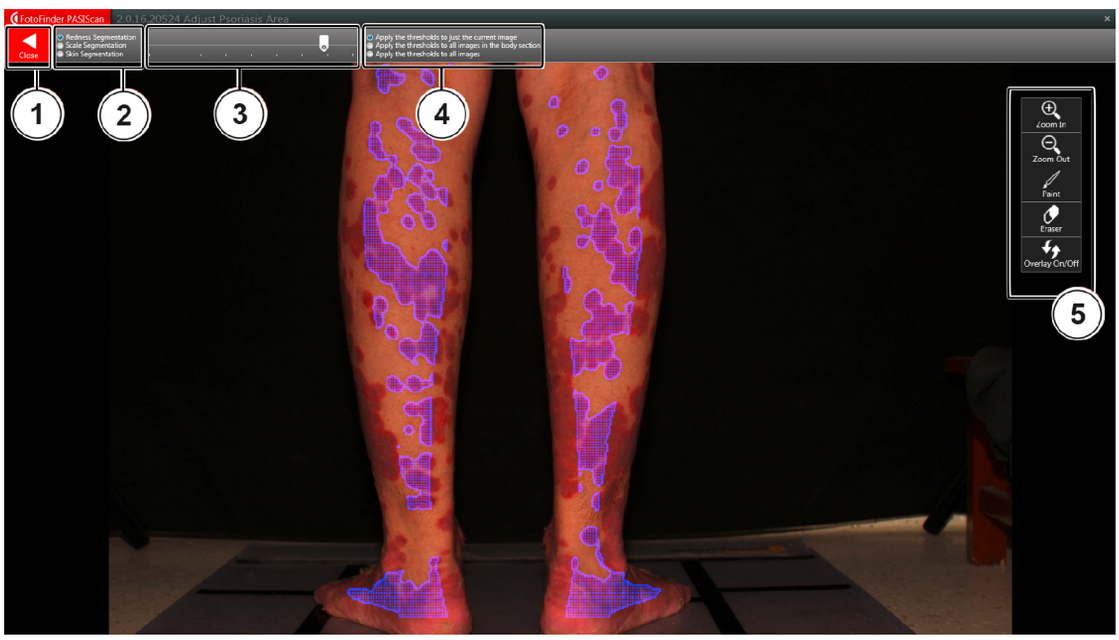


Fig. 8: Example view of Adjust Psoriasis Area

1 If you click on *Close*, a dialogue will appear. Select whether you want the PASI score to be recalculated. You are then returned to the user interface of **PASIscan**®.

2 Here you select the segment you want to adjust: Reddening, Scaling or Skin (segmented skin surface).

3 Use the slide bar to set the threshold from which this segment should be highlighted.

4 Here you select whether the set threshold must be applied for
- just the current image
- all images in this body section, or
- to all images of the patient

5 The following tools are also available:

Zoom In to enlarge the displayed image. You can use the mouse wheel to scroll up or down in the enlarged image.

Zoom Out to reduce the displayed image.

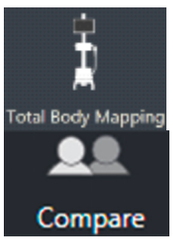
Use *Paint* to draw in additional segments, which are then considered in the selected segment.

Use *Eraser* to delete segments, which were previously considered in the selected segment.

With *Overlay On/Off* you can fade the segment highlighting in or out.

5.5 Comparing images

The **PASIscan**® image comparison allows you to compare between individual images from different capturing sessions based on the PASI score to evaluate the treatment success.
You can do this for either one body segment or for a partial segment (ROI = Region of Interest).



1. Start the *Total Body Mapping* module by clicking on the appropriate button on the dashboard.

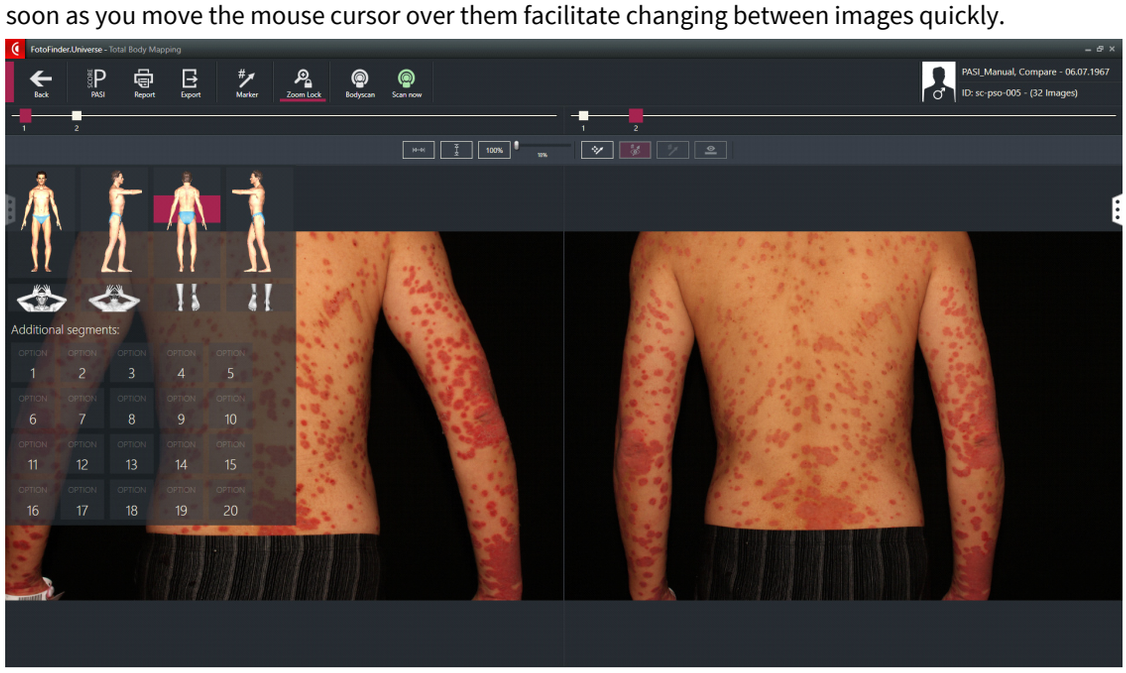
2. Start image comparison.

NOTE

The Image Comparison user interface is described in the separate manual **Automatic Total Body Mapping**.

3. Select the images required for the image comparison here. Changing your selection of the images is not possible once you are in **PASIscan**® image comparison.

The navigation arrows and the localisation puppet appearing on the left and right edge of the screen as soon as you move the mouse cursor over them facilitate changing between images quickly.



You can select capturing sessions via the timeline above the images. The currently selected session is marked as a coloured square.

4. Start **PASIscan**® by clicking on the *PASI SCORE* button at the top in the menu bar.

This will open the **PASIscan**® image comparison.

Here, values are only displayed after the analysis.

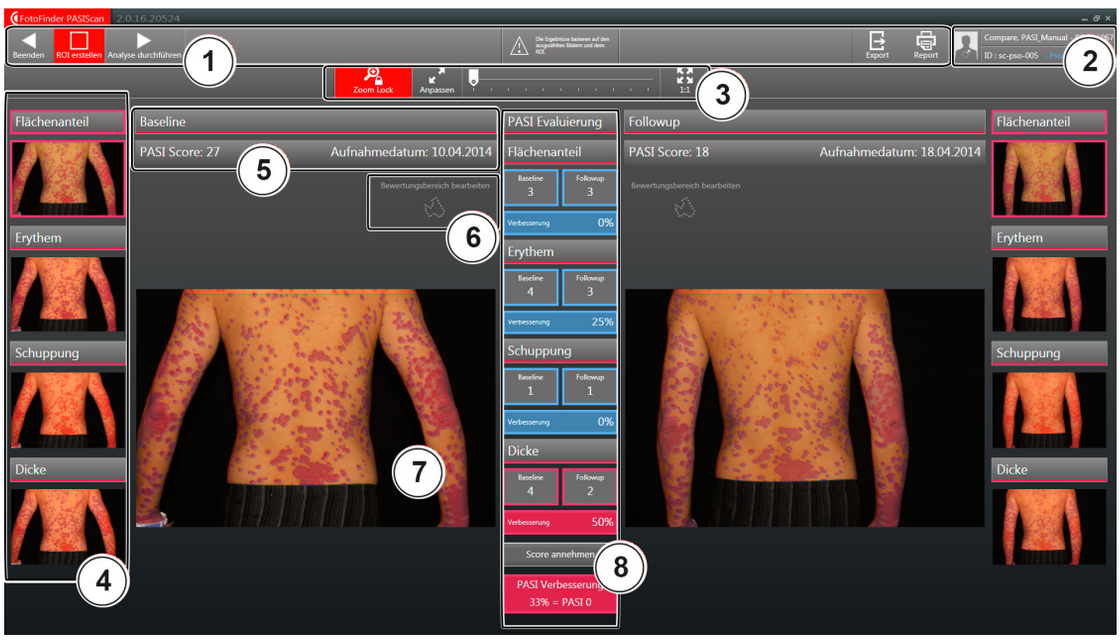


Fig. 9: User interface **PASIscan**® *image comparison (with values)*

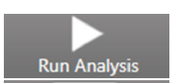
1	Menu bar	5	Image information
2	Patient data field	6	Editing the evaluation section
3	Image display tools	7	Preview window
4	Segmentation selection	8	PASI Evaluation / Evaluation results

Segments 4 to 7 are available for both images.

You can find explanations on functions only found in image comparison below. All other explanations are described on the user interface (cf. chapter 5.2 The Desktop).

Menu Bar (1)

Here in image comparison you can find the following additional functions:



With *Run analysis* you can start calculating the values.

With *Set ROI* you can limit the analysis area to a certain segment of the image (ROI = **R**egion **o**f **I**nterest).

1. Click on *Set ROI*.
2. Draw up a rectangle in the image with the mouse.
3. Click on *Run analysis* again.

Only the selected segment will be considered during analysis.

The drawn up ROI segment can be moved individually in every image. This may be required when the two images to be compared do not match perfectly. Click and hold the mouse button to move the respective rectangle until they cover the same segment in both images.

With *Export* you can optionally export and save the patient data as csv, tsv or xls files (cf. chapter 5.6 Reports).

Image display tools (3)

Here in image comparison you can find the following additional functions:

The *Zoom Lock* function is activated by default when you call up image comparison. Use this function to zoom in and move both images simultaneously. This permits an objective comparison of the images. Without Zoom Lock you can display both images independently.

1. Click on the Zoom Lock button again.

Zoom Lock is deactivated and a second zoom bar appears.

Segmentation selection (4)

Click on the respective image, the results of which you want to highlight the preview window (7).

Editing the evaluation section (6)

Use the *Magic Brush* or the *Brush* to draw in additional segments, which are then considered in the selected segment. However, this function recognises the respective segment based on its colour and therefore mark relatively accurately.

PASI Evaluation / Evaluation results (8)

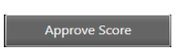
You can see the calculated values of the two compared images in the centre of the screen. Individual values for surface area, reddening, scaling and thickness also have to be confirmed by the physician and adjusted as necessary:

1. Click on the respective value.

This opens a scale.

2. Click to select the required value or click on *Approve Score* if you do not want to change anything.

As soon as values have been changed or approved, they are no longer highlighted in red but in blue instead.
The values can be edited in both the initial capture (Baseline) and the subsequent capture (Follow-up).



3. Click on *Approve Score* after you have finished evaluating.

All values are now highlighted in blue and the PASI comparison result will now be evaluated.

The improvement of individual values is calculated automatically. The overall result of improvement is displayed right at the bottom: PASI 50, 75, 90 or 100.

5.6 Reports

The *Report* button in the menu bar of the user interface allows you to create various types of reports.

There are various report types available, depending on where in the Software you click on the Report button.

In the PASI Score overview:
PASIscan_Summary

- patient data
- all summarised values acc. to PASIboard
- no images

PASIscan_Full

- patient data
- all summarised and individual values acc. to PASIboard
- all images for the patient

On the **PASIscan**® user interface:
PASI sub-region

- patient data
- only contains information on the currently selected body region (optionally Head, Upper Extremities, Trunk or Lower Extremities)
- individual and summarised values
- all of the patient's images of the selected body region

In **PASIscan**® image comparison:
PASI Comparison Report

- patient data
- contains the two compared images
- contains the values of both images as well as the improvement values in per cent.

6 Malfunction and troubleshooting

6.1 Error handling

This section contains information on troubleshooting.
Please try to work through the following points step by step. If none of the steps solves the problem and the system does not start functioning correctly again, 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 Attachment

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 *PASIvision* ®
(Software- Version FotoFinder Universe, FotoFinder PASIscan)

in der Systemkonfiguration mit
in the system configuration with
dans la configuration avec
nella configurazione con
consistente en

Medical PC "FotoFinder Silent Medical Server"
Gerätewagen/ cart/chariot mobile/ carello medicale/ portaaparatos "ATBM Tower"
Digitalkamera/ digital camera/ •Système d'appareil photo réflex /fotocamera digitale/ camera digital "Canon EOS with "Polflash"
Positionierhilfe/ aligment device / "strumento allieneamento / equipo alineamiento "LaserLiner"
Bildschirm / Monitor / Ecrán / Schermo / Pantalla
Drucker / Printer / Imprimante / Stampante / Impresora
Trenntransformator / Isolating Transformer / Transformateur d'Isolement / Trasformatore d'Isolamento / Transformador de Aislamiento

der Klasse / of class/ de la classe / della classe : 1

allen Anforderungen der Medizinprodukterichtlinie 93/42 EWG entspricht, die anwendbar sind.
meets all the provisions of the directive 93/42 EEC which apply to it.
remplit toutes les exigences de la directive sur les dispositifs médicaux 93/42 CEE qui le concernent.
soddisfa tutte le disposizioni della direttiva 93/42 CEE che lo riguardano.
al que se refiere esta declaración, con las disposiciones aplicables de la Directiva 93/42 CEE.

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

Bad Birnbach, 15 March 2017

Julian Mayer, Authorized Officer

8 For your notes