

skeen

Original user manual

Hardware

FotoFinder skeen

Original user manual

Please read the original user manual carefully before using the product.



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Status: 19.12.2024





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1 Introduction

The FotoFinder skeen is a mobile device which comprises an imaging device, an installed software and a charging station. The device is powered by a rechargeable battery and is supplied with a camera lens system which allows you to capture magnified and unmagnified images with polarised and non-polarised lighting.

The hardware component, including the camera lens, is controlled using an installed software.

The FotoFinder skeen communicates and exchanges data with other FotoFinder software or applications, and can be used in combination with systems manufactured by FotoFinder. The FotoFinder skeen has an interface for transferring image data to another piece of software, e.g., the FotoFinder software.

The main function of the FotoFinder skeen is to capture images with the camera lens system and to save and display the images for the user.

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 5 Safety) provides an overview of all important safety aspects for the protection of personnel and the safe operation of the product.
- The manufacturer is not liable for any damage resulting from non-compliance with this user manual.
- Reprints, translations and reproductions in any form, including excerpts, require the written consent of the publisher.
- Copyright belongs to the manufacturer.
- All serious incidents which occur in conjunction with the product must be reported 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 Delivery scope



Fig. 1: FotoFinder skeen (front and side view) in charging station

- 1 FotoFinder skeen
- 2 skeen charging station
- 3 Shutter release
- 4 Side button
- 5 LED light
- 6 Magnetic attachment lens with removable front cap
- 7 Power cable
- 8 Instructions (not shown)

A CAUTION

LED light may lead to short-term impairment of your eyesight. Never look directly into the LED light.

2.1 Accessories

front cap, closed (Included in the scope of delivery)

Item number: FFP000863 for contact Dermoscopy

front cap, open (optionally available)

Item number: FFS000864 for non-contact Dermoscopy



3 Technical data



skeen

Requirements:

 FotoFinder Hub-Account: Register at https://hub.fotofinder.de



· Internet connection via Wi-Fi

In order to upload images and patient data to the FotoFinder Hub, a wireless internet connection is <u>essential</u>. A LAN connection is not possible.

Technical Datasheet

Specifications:

Manufacturer: FotoFinder Systems GmbH Address: Industriestraße 12 84364 Bad Birnbach, Germany

Dimensions:

17,5 cm × 12,5 cm incl. charging station (H×B×T): $11 \text{ cm} \times 13 \text{ cm} \times 19,5 \text{ cm}$

skeen (w/o Attachment lens) 422 g Weight:

40 g Attachment lens Charging station + power plug 462 g ca. 924 g Total

Protection class: IP 20 IP protection class: 0 - 25°C Ambient temperature: Transport/ storage temperature: 0 - 40°C

Transport/storage: dry room, do not expose to moisture, protect from dust Air pressure*: min. 80 kPa to max. 107 kPA from

-425 m to 2000 m a. s. l. Relative humidity*: 20 - 90 %, non-condensing

AC 100 - 240 VAC / 50 - 60 Hz Supply voltage/frequency:

DC 12V **Current consumption:**

 $hollow\,plug\,\varnothing\,5,5\,mm\,/\,\varnothing\,2,5\,mm$ Connection charging station:

Screen resolution: 1080 × 2340 pixels Kameraauflösung: 48 MP Zoom: 15×, 20×, 40× Aspect ratio: Illumination:

Transport and storage: The device is shipped in a box. **Dimensions product packaging:** ca. 28,6 cm × 23,7 cm × 12 cm

Packet weight: 1655 g

Disposal and

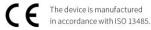
environmental protection:

The device cannot be disposed of a domestic waste. Please

dispose of the product in a professional and environmentally friendly way.



^{*} applicable for operating, transport and storage



Setting the Pace in Skin Imaging Worldwide





4 General explanation of symbols



CE mark



Adhere to the user manual



UK Conformity Assessed

Responsible Person for UK: FotoFinder Systems Ltd., 100 Addison Road, W148DD London, United Kingdom



Do not dispose of electrical and electronic devices with domestic waste

The following explains the information on the device's type plate.

| Information | Description |
|---|--|
| | Device manufacturer and manufacturer's address |
| FotoFinder Systems GmbH | |
| Industriestraße 12 84364 Bad Birnbach, Germany | |
| Type | Device type; describes the name of the device, e.g. FotoFinder skeen station |
| Input | Compatible input voltage |
| Output | Nominal voltage/nominal current at the isolating transformer output |
| SN | Unique serial number of the device |
| | Date of manufacture |
| IP | IP protection class |

5 Safety

5.1 Intended use

The FotoFinder skeen is a handheld image capturing device, which is controlled by an embedded software. The battery-powered and chargeable device is intended to capture, display and store magnified as well as non-magnified images with polarized and non-polarized illumination. It is intended to allow transferring image data to other software, e. g. FotoFinder software.

5.2 User groups

The FotoFinder skeen is a mobile device without a medical purpose and can therefore be used by laypersons and medical professionals such as dermatologists and general practitioners, in conjunction with other FotoFinder software.

5.3 Use environment

The FotoFinder skeen is a portable device for mobile use. It can be also be used in the professional healthcare sector, e.g., in clinics or practices, if it is used in combination with other FotoFinder software or systems.

ATTENTION

Do not immerse the device in liquid and never place products which could leak liquids near your device. Penetrating liquids will cause serious damage.

ATTENTION

The device has a built-in lithium-ion battery. Adhere to the following instructions in order to prevent damage to the device:

Do not expose the device to impacts.

Immediately stop use of the device if parts of the device are broken, or if there is smoke or the smell of fire.

Do not use the device in areas which are at risk from fire or explosion (e.g. an oxygen-rich environment).

Do not expose the device to direct sunlight for extended periods.



5.4 Residual risks

A WARNING

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

- Improper operation or failure to adhere to the specified safety information and warnings can cause damage to the user or third parties.
- There is a risk of injury from electric shock if the device is handled incorrectly or damaged. This could result in serious injuries.
- The device can emit electromagnetic radiation which can affect or even destroy other devices.
- The device can be disrupted by the emission of electromagnetic radiation from other electrical devices or by electrostatic discharge, causing the live image to be interrupted or, in the worst case, damage to the device.
- The use of accessories which are not designed for the product or modification of the device can render the device no longer functional or render it unsuitable for use in accordance with its intended use.
- If operated for an extended period, the surfaces of the device can become hot.
- The magnets used in the attachment optics can influence sensitive devices, e.g. pacemakers.
- Use of damaged front caps (e.g. breaks or cracks in the material) can cause skin injuries.

6 Cleaning and disinfection

€NOTE

Clean and disinfect the front cap after each use.

ATTENTION

Sanitize with wipes only.

Sanitize any components with sanitizing wipes only.

ATTENTION

Please do not spray directly onto the camera lenses, only on to a cleaning wipe. Any direct contact with liquids can damage the lense or the camera.

ATTENTION

Only work with devices which are in flawless condition. Note that the front cap must not be re-used if, for example, there are visible material clouding or discolourations, contaminations in glued areas or cracks in the plastic. Otherwise, the imaging quality of your images would be severely compromised.



7 Operation

7.1 Charging the battery

ATTENTION

To charge the device, use the supplied charging station only. Other charging stations could damage the device.

- 1. Connecting the charging station to the mains power
- 2. Place the skeen in the charging station. Ensure correct contact with the charging pins.

An LED on the charging station lights up to indicate various charging statuses:

| Status | LED colour | Meaning |
|--------|---------------------|---|
| 1 | Green pulsing light | Charging is in progress |
| 2 | Blue constant light | Charging process complete |
| 3 | Blue pulsing light | Evaluation of the charging current, automatic switch to status 1 or status 2 after two to three seconds |

If the LED does not light up, the skeen is not inserted in the charging station correctly or the charging station is not being supplied with power.

ATTENTION

For safety reasons, you must not attempt to remove the battery. Failure to properly remove the battery may result in battery and device damage, personal injury, and compromised device safety. In case of a faulty battery, contact the manufacturer.

7.2 Mounting the lens



Fig. 2: FotoFinder skeen with attachment lens removed

- 1 Two positioning pins
- 2 Magnets
- 3 Contact pins

The lens is connected to the FotoFinder skeen using a magnetic mount.

(NOTE

Both when using and cleaning, take care not to touch the glass surfaces of the camera and the lens with your fingers. Otherwise, contamination from fingerprints etc. will affect the image quality.

Attaching the lens

- 1. Do not touch the glass surfaces when holding the attachment lens.
- 2. Fasten the attachment lens to the skeen so
 - that the contact pins of the attachment lens and the skeen touch and
 - the two round recesses on the attachment lens are filled by the positioning pins of the skeen.

No further fastening is required as the mount is magnetic.

Detaching the lens

The lens can be detached with a gentle pull.

Fastening the front cap

- 1. Do not touch the glass surface while holding the front cap.
- 2. Turn the front cap on the attachment lens clockwise until it is firmly locked in place.

Removing the front cap

The front cap can be removed by turning it anti-clockwise (e.g. for cleaning and disinfection).



7.3 Creating images

- 1. Switch on the FotoFinder skeen with the side button.
- 2. Place the device with the lens on the skin and hold it steady.
- 3. Press the shutter release.

Refer to the installed software for the exact sequence.

8 Malfunction and troubleshooting

8.1 Safety



Please always observe all safety instructions in this manual!

A DANGER

Danger of electric shock due to high voltage!

Severe injury or death could result when touching an energized conductor.

Work on electrical systems may only be conducted by authorized electricians.

Disconnect the power supply and secure against reconnection before starting any work.

Do not try to open any electric components of the equipment.

8.2 Error handling

This section contains information on troubleshooting.

If the system is not working correctly, please call the support team on:

+49 8563 97720-45 or send an e-mail to: support@fotofinder.de.

8.3 Attachment not detected

- Detach the attachment lens from the skeen and attach it again
- Check that it is attached correctly
- Adhere to the instructions in this user manual (cf. chapter 7.2 Mounting the lens).

8.4 LED on charging station does not light up/battery does not charge

- Check whether the charging station is connected to the mains power
- Check whether the device is inserted in the charging station correctly (in contact with the charging pins)

(cf. chapter 7.1 Charging the battery)



9 Appendix



KONFORMITÄTSERKLÄRUNG DECLARATION OF CONFORMITY

Hersteller / Manufacturer: Adresse / address: FotoFinder Systems GmbH Industriestraße 12 84364 Bad Birnbach Deutschland/Germany

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

FotoFinder skeen Artikelnummer / Art. No.: FFP000860

Zweckbestimmung / Intended Use:

The FotoFinder skeen is a handheld image capturing device, which is controlled by an embedded application. The battery-powered and chargeable device is intended to capture, display and store magnified as well as non-magnified images with polarized and non-polarized illumination. It is intended to allow transferring image data to other software, e.g. FotoFinder software.

The FotoFinder skeen is a mobile device with no medical purpose and can therefore be used by lay people, but also by medical professionals such as dermatologists and general practitioners in interaction with other FotoFinder software. The FotoFinder skeen is a mobile device, which can be used location-independent. It can also be used in professional healthcare environment, such as clinics or practices, when used in combination with other FotoFinder software or systems.

 $\label{lem:continuous} \mbox{den Anforderungen der normativen Vorgaben der IEC 60335-1 und der IEC 62133-2 entspricht} \\ \mbox{Meets the requirements of the normative requirements of IEC 60335-1 and IEC 62133-2} \\ \mbox{den Normative Normative$

und in Erfüllung der Vorgaben der Verordnungen (EU) 2014/53, (EU) 2023/1542 und (EU) 2023/988 in Verkehr gebracht wird.

and is placed on the market in accordance with regulations (EU) 2014/53, (EU) 2023/1542 and (EU) 2023/988.

Diese Erklärung ist gültig, bis sie durch eine neue Version ersetzt wird / This declaration is valid until superseded by a new version.

Bad Birnbach, 24.05,2024

Julian Mayer, Authorized Officer

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