EN

FotoFinder®

leviacam

Original user manual

Hardware

Setting the Pace in Skin Imaging Worldwide

www.fotofinder.de

FotoFinder leviacam

Original user manual

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

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Content

1 About these operating instructions

1.1 Introduction

The FotoFinder leviacam facilitates fast documentation in the fields of

- Dermoscopy
- Trichoscopy
- Capillaroscopy and
- Inflammoscopy.

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

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

- The product can only be used, operated and maintained properly and safely with the help of this user manual.
- This user manual refers only to the product indicated on the cover sheet.
- We reserve the right to change this user manual due to further technical developments.
- The operator must ensure that the user manual is read and understood by all persons concerned prior to work.
- The chapter on *Safety* (cf. chapter 3 Safety) provides an overview of all important safety aspects for the protection of personnel and the safe operation of the product.
- The manufacturer is not liable for any damage resulting from non-compliance with this user manual.
- Reprints, translations and reproductions in any form, including excerpts, require the written consent of the publisher.
- Copyright belongs to the manufacturer.
- Safety incidents occurring in connection with the product must be reported to the manufacturer and the competent authority of the respective country in which the operator is established.
- This user manual applies from transportation to final disposal, and must be observed.

1.2 Related documents

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

- EU Declaration of Conformity (cf. 11)
- Software instructions
- Documentation from third-party manufacturers are provided separately

1.3 Presentation of warning labels

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

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

DANGER

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

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.

ATTENTION

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

NOTE

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

1.4 Information on the device label

The following contains explanations of the type plate attached to the device or the type plates attached to system components.

Symbol / Information	Description
	Device manufacturer and manufacturer's address FotoFinder Systems GmbH Industriestraße 12 84364 Bad Birnbach, Germany
www.fotofinder.de	Manufacturer's website
Type	Device type; describes the name of the device, e.g. FotoFinder leviacam
	Unique serial number of the device
	Month and year of manufacture
	Electronic user manual
	Observe the user manual
	CE mark
	Medical device
	Type B applied part
	Do not dispose of electrical and electronic devices with domestic waste
IP	IP protection class
	UK Conformity Assessed Responsible Person for UK: FotoFinder Systems Ltd., 100 Addison Road, W148DD London, United Kingdom

Tab. 1: Explanations of the leviacam and leviabase type plates

2 Components and technical data

2.1 FotoFinder leviacam®

Technical datasheet leviacam

Recommended system configuration:

- Operating system: Microsoft Windows© 10 Pro, 64-bit / Microsoft Windows© 11 Pro, 64-bit (Universe V 3.4.2 or higher)
- 1 × USB 3.0 Typ-A Port

Weight:

leviacam with micro lens:	ca. 325 g (including cable)
leviabase:	ca. 260 g
Total:	**ca. 585 g**

Specifications:

Manufacturer:	FotoFinder Systems GmbH
Address:	Industriestraße 12, 84364 Bad Birnbach, Germany
Protection class:	I
IP protection class:	IP20
Ambient temperature:	0 – 25°C
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 von -425 m to 2000 m a. s. l.
Relative humidity*:	20 – 90 %, non-condensing
Leistungsaufnahme:	max. 900 mA
Power supply:	5 V DC via USB
Application part type:	Type B
Resolution:	Full HD: 1920 × 1080 Pixel / 16:9 5 MP: 2592 × 1944 Pixel / 4:3 8 MP: 3264 × 2448 Pixel / 4:3 13 MP: 4128 × 3096 Pixel / 4:3
Zoom:	20 ×
Optical zoom:	No
Illumination:	LED
Connector:	USB 3.0 Type A
Number of effective pixels:	ca. 13.190.000 Pixel
Minimal object distance (without micro lens):	100 cm
Cable length:	ca. 200 cm
Transport and storage:	The device is shipped in a box.
Dimensions product packaging:	ca. 23,5 × 23,5 × 8 cm
Packet weight:	max. 2 kg
Disposal and environmental protection:	The device cannot be disposed of as domestic waste. Please dispose of the product in a professional and environmentally friendly way.

* applicable for operation, transport and storage

CE The device is manufactured in accordance with ISO 13485.

Setting the Pace in Skin Imaging Worldwide

FotoFinder®

- The FotoFinder leviacam can be used, together with the FotoFinder Universesoftware (or with software from TrichoLAB as applicable), to generate overview captures and microscopic captures.
- The leviacam is ideal for everyday intensive use.
- The camera is equipped with integrated LED floodlighting and LED micro lighting (polarised and non-polarised) as standard.
- The integrated floodlighting allows you to make excellent overview captures at a distance of up to 80 cm.
- Micro image captures with the leviacam are generated with 20x zoom.

Fig. 1: FotoFinder leviacam®

1	Release	2	Control buttons
3	leviabase (camera bracket)	4	Operating light

- The red operating light signals whether the camera is supplied with power.

Fig. 2

1 levialens (Detachable micro lens) 2 Illumination

- The illumination turns off automatically after 15 minutes in idle state.

⚠ CAUTION

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

2.1.1 leviacam accessories

Accessories	Item number
FotoFinder Cleaning Kit	FFS090400
FotoFinder leviabase	FFP910079
FotoFinder levialens	FFS720165

Tab. 2: leviacam accessories list

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

The FotoFinder leviacam is an electrically operated and software controlled video dermatoscope intended for capturing microscopic and macroscopic images of the patient's intact skin surface, especially moles, by medical professionals.
The FotoFinder leviacam including its accessories is intended for transient use and has an application time of less than 60 minutes.
The digital dermatoscope provides a connection to the FotoFinder Universe with the possibility of storing and managing the images on a patient-specific basis, without an interface for external software control of the dermatoscope.
The FotoFinder leviacam disposes of an interface for lens attachment (levialens), which support the recording of polarized and non-polarized microscopic images.
Contact with injured skin must be excluded.
The FotoFinder leviacam including its accessories is intended to be used exclusively by medical professionals in a professional healthcare environment, e.g. clinics or hospitals.

3.3 User groups

The following target groups with the required qualifications may work on the device:

Target group	Qualification
Physician	Professionally qualified as physician
Practice personnel	Trained and instructed and professionally qualified through a completed apprenticeship in specialized medicine
Service/Hospital technician	At least 3 years of professional experience in the medical technological sector

We have allocated target groups to life below. The target groups may work on the device dependent on this allocation:

	Target group		
Life phase	Physician	Practice personnel	Service/Hospital technician
Installation			X
Commissioning			X
Operation	X	X	
Malfunction			X
Maintenance			X
Disassembly			X
Disposal			X

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. 3.3).
- The product is intended for use and operation in a patient environment as per EN 60601-1 only.
- Refer to the respective chapter (cf. 3.10)for requirements regarding the physical and technical environment of use.
- There are no additional requirements for the social or clinical environment of use.
- The product is not intended for use by laypersons.

NOTE

Feel free to contact FotoFinder Systems to discuss the best design for your photography room. Please contact us!

NOTE

You can use the following system components in the direct vicinity of the patient with contact to the patient:

- leviacam

3.5 Patient population

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

- General persons with skin lesions
- Patients with multiple nevus syndrome
- Patients with general inflammatory skin disease
- Patients with scalp hair disorders

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

3.6 Indications and contraindications

The device is designed for clinical images as stated in the chapter *Patient target group*. For a detailed list of ICD codes, please contact info@fotofinder.de.

The following parts of the body are suitable for examination with the FotoFinder dermatoscope:

- Intact skin surface of the entire body
- Scalp
- Nails

The device is not designed for capturing images of mucous membranes, eyes or natural or artificial body orifices. The device is not designed for capturing images of injured skin. The device is not used for diagnostic purposes. The diagnosis is the responsibility of the specialist medical staff!

3.7 Improper use

- Any use of the equipment different to the chapter *Intended use* (cf. chapter 3.2 Intended use) and different to the operating instructions is not authorized!
- The manufacturer is not liable for any resulting damages in this regard. The risk is borne by the user/operator alone.
- It is prohibited to modify the equipment in any form.
- It is prohibited to bypass the safety features when operating the device.

3.8 Foreseeable misuse

The following points describe foreseeable misuse of the device:

- Incorrect setup
- Non-compliance to operating data
- Non-compliance to maintenance intervals
- Operation without or damaged components serving the safety of persons or the device

The following points describe foreseeable misuse of the medicam / leviacam:

- Incorrect connection and handling
- Use on and in natural and artificial orifices on the body
- Use on damaged skin
- Non-compliance to operating data
- Non-compliance to cleaning instructions
- Non-compliance to maintenance intervals
- Operation with damaged components serving the safety of persons or the device

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.

- Improper operation by untrained personnel and non-compliance with the specified safety and warning instructions may result in harm to the patient or operator.
- In case of improper handling or damage to the device, there is a risk of injury from electric shock. Serious injury or death may result.
- The device can emit electromagnetic radiation, which can influence or interfere with other devices.
- The device can be affected by emission of electromagnetic radiation from other electrical devices, or by electrostatic discharge, so that the live image is interrupted, or the device is damaged.
- Despite the used materials tested for body compatibility, in rare cases irritation of the skin may occur upon contact.
- If the unit is not adequately cleaned or disinfected after each patient, it could lead to infections due to poor hygiene.
- Any accessories that are not intended for the product or the modification of the system, can lead to the device no longer being functional or being able to be used in accordance with it´s intended use.
- During longer operation, the surface of the device may get warm.
- Maintenance or servicing that is not performed on time or improperly can endanger operational safety.
- The magnets used in the FotoFinder dermatoscope can influence sensitive devices, e.g. pacemakers.
- Use of damaged front caps (e.g. breaks or cracks in the material) can cause skin injuries.

3.10 Ambient conditions

- Only use the device indoors. The system must not be exposed to any moisture.
- Make sure that there is a sufficient air supply so that there is no build-up of heat in the devices. If computers are connected, e.g., a Silent Medical Server, the ventilation slats must not be sealed or covered.
- Do not set up the devices near to heat sources, e.g. heaters, or in places in which they are exposed to direct sunlight, unusually high levels of dust, mechanical vibrations or impacts.
- Do not set up the system near to other devices which generate a strong magnetic field, e.g. power converters or high-voltage lines.
- Only use the device in bright, well-illuminated rooms.

3.11 Operator duties

- The operating instructions are an essential component of the device.
- The operating instructions must be stored with the device and must be accessible at all times at the location of use.
- The operator must ensure that the operating instructions are read and understood by everyone working on and with the device. Only trained staff who are familiar with the fundamental occupational safety standards and have been instructed on use of the device may be assigned to operate it.
- The manufacturer is not liable for damages caused by the failure to observe product-related documentation.
- A final production check is carried out on the entire system or, if applicable, the components as per EN 62353 during in-house production. When commissioning is performed by a FotoFinder contact, the operator is encouraged to check and confirm the values of the in-house inspection. Alternatively, the operator is free to have a repeat inspection carried out independently.
- Before the device is commissioned and after repair work or constructional changes, the device must be inspected by a specialist/technician in order to ensure that it complies with standard EN 62353.
- The device must be operated in a manner that is safe for its intended use and anticipated stresses.
- Non-medical electrical devices (e.g. existing PC equipment) as defined by EN 60601-1 must not be used or operated within the patient environment of 1.5 m. If the operator fails to adhere to this rule, the operator is responsible for checking before commissioning that the limit values of the leakage current as per EN 60601-1 are not exceeded.
- Requirements in chapter *Service information* (cf. chapter 8 Maintenance) must be met.

3.12 Electric safety

⚠ WARNING

- An electric shock may occur if the system and all externally connected devices are not properly grounded.
- Do not remove the casing of the device: there is hazardous current inside. The casing must be correctly mounted. All repairs and replacements must be made by a qualified FotoFinder representative.
- Check the casing and cables before use. Do not use the device and disconnect it completely from the power supply, if the casing is cracked, chipped or broken, or if the casing or the cables are damaged.
- Always disconnect the system from the power supply before cleaning it.
- Avoid locations where it is likely to be difficult to disconnect the unit from the power supply.
- The system must only be connected to a power supply outlet that is properly grounded to avoid electric shock.

3.12.1 ESD

Electrostatic discharge (ESD), commonly referred to as a static shock, is a naturally occurring phenomenon. ESD occurs most often during low humidity, which can be caused by heating or air conditioning. Under such circumstances electrical charges naturally build up on individuals, creating static electricity. An ESD occurs when an individual with an electrical energy build-up comes in contact with conductive objects such as metal doorknobs, file cabinets, computer equipment, and even other individuals. The static shock or ESD is a discharge of the electrical energy build-up from a charged individual to a lesser or non-charged individual or object.

⚠ CAUTION

The electrostatic discharge of a user or patient to the FotoFinder device can damage the system or camera.

3.12.2 EMI

Although this system has been manufactured in compliance with the existing EMI (Electromagnetic Interference) requirements, an electromagnetic field can cause momentary disturbance of the camera live image. If this occurs often, FotoFinder Systems suggests a review of the environment in which the system is being used, to identify possible sources of interference. These could be from other electrical devices used within the same or a nearby room. Even communication devices such as cellphones and pagers can cause such emissions. The existence of radios, TVs, or microwave transmission equipment nearby can also cause interference.

⚠ CAUTION

In case an EMI is causing disturbance, it may be necessary to relocate this system.

3.12.3 EMC

The testing for EMC (Electromagnetic Compatibility) of this system has been performed according to the international standard for EMC with medical devices (IEC 60601-1-2:2014+A1:2020). This IEC standard complies with the European norm (EN 60601-1-2:2015+A1:2021).

European publication	Surroundings of professional medical facilities	Deviation from basic EMC standards or EN 60601-1-2
EN 55011:2016 + A1:2017 +A11:2020 +A2:2021	Group 1 Class A	Yes ☐ No ☒
EN IEC 61000-3-2:2019	Class A	Yes ☐ No ☒
EN 61000-3-3:2013 +A1:2019	---	Yes ☐ No ☒
EN 61000-4-2:2009	± 8 kV contact ± 2 kV, ±4kV, ±8 kV, ±15 kV air	Yes ☐ No ☒
EN IEC 61000-4-3:2020	3 V/m 80 MHz - 2.7 GHz 80 % AT at 1 kHz	Yes ☐ No ☒
EN 61000-4-3:2020	According to 8.10 Table 9 of EN 60601-1-2:2015+A1:2021	Yes ☐ No ☒
EN 61000-4-4:2012	AC port: ± 2 kV (100 kHz) SIP/SOP: ± 1 kV (100 kHz)	Yes ☐ No ☒
EN 61000-4-5:2014 +A1:2017	AC line to line ± 0.5 kV, ± 1 kV AC line to earth: ± 0.5 kV, ± 1 kV, ± 2 kV	Yes ☐ No ☒
EN 61000-4-6:2014	3 V 0.15 MHz – 80 MHz (6 V in ISM frequency bands) 80 % AM at 1 kHz	Yes ☐ No ☒
EN 61000-4-8:2010	30 A/m 50 Hz or 60 Hz	Yes ☐ No ☒
EN IEC 61000-4-11:2020 +AC:2020	0 % U_T; 1/2 period at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315°	Yes ☐ No ☒
Additional information: Conformity for each EMISSIONS and IMMUNITY standard or test specified by this supplementary standard, e.g., EMISSIONS class and group and IMMUNITY test level.		

This device has no essential performance characteristics according to EN 60601-1:2013+A1:2020. Therefore, no deterioration or failure of these functions can be caused by electromagnetic interference.

3.12.4 Instructions and manufacturer's information on electromagnetic radiation

This device is intended for use in the electromagnetic environment described below. The user of this device should ensure that it is used in such an environment.

Radiation test	Compliance	Electromagnetic environment - Directive
RF emission CISPR 11	Group 1	The FotoFinder device is not likely to cause interference with other electronic devices in the vicinity.
RF emission CISPR 11	Class A	The FotoFinder device is approved for use in professional medical facilities such as hospitals and doctors' surgeries. For residential use (which requires CISPR11 Class B), the device may not provide adequate protection against radio interference.
Harmonic distortions IEC 61000-3-2	Class A	
Fluctuating interference IEC 61000-3-3	Complied	

ATTENTION

The use of this device directly next to other equipment or with other equipment stacked should be avoided, as this could cause it to malfunction. If it is still necessary to use it in the manner described above, this device and the other equipment should be first observed to ensure that they are operating properly.

3.12.5 EMC tested cables, transformers and accessories

The cables used with this device may affect the radiation of the device. Use only the cable types and lengths listed in the following table.

⚠ CAUTION

When connecting other customer-supplied accessories to the system, it is the user's responsibility to ensure the electromagnetic compatibility of the system. Only use devices that are compliant with the CISPR 11 or CISPR 22, Class B standards.

⚠ WARNING

The use of cables, adapters or peripherals other than those specified may result in increased emission or decreased compatibility of the FotoFinder device.

leviacam

Cable	Type	Length
USB 3.0	Shielded	2 m

3.12.6 Recommended minimum distance between portable and mobile RF communication devices and the FotoFinder device

This product is intended for use in an electromagnetic environment where the radiated RF disturbances are controlled. The user of this device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and this device as recommended below, according to the maximum output power of the equipment.

Maximum nominal power of transmitters	Minimum distance according to the frequency of the transmitter [m]		
	150 kHz to 80 MHz $d = [\frac{3,5}{V_1}]\sqrt{p}$	80 MHz to 800 MHz $d = [\frac{3,5}{E_1}]\sqrt{p}$	800 MHz to 2,5 GHz $d = [\frac{7}{E_1}]\sqrt{p}$
	V_1 = 0,01 Veff	E_1 = 3 V/m	E_1 = 3 V/m
0,01	35,00	0,11	0,23
0,1	110,68	0,36	0,73
1	350,00	1,16	2,33
10	1106,80	3,68	7,37
100	3500,00	11,66	23,33

For transmitters with different maximum power rating from what is listed above, the recommended distance (“d”) in meters (m) can be calculated using the same equation as for transmitters, where “p” is the maximum power rating in watts (W) according to the manufacturer's specifications.
NOTE 1: The 80 MHz and 800 MHz are the distances for higher frequency range devices.
NOTE 2: These guidelines cannot be applied to all circumstances. Electromagnetic transmission is affected by absorption and reflection from structures, objects and people.

ATTENTION

Portable RF communications devices (radios, including their accessories such as antenna cables and external antennas) should not be used within 30 cm (or 12 inches) of the parts and cables of the ME equipment specified by the manufacturer. Not observing this warning may reduce the performance characteristics of the device.

4 Installation

⚠ DANGER

A device of Protection Class I Danger of injury due to electric shock.
Connect the device to a properly grounded power outlet only.

⚠ 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.

4.1 Delivery scope

- leviacam including USB 3.0 cable
- levialens
- leviabase
- Packaging box

NOTE

Report any damages or defects to your distributor or the manufacturer immediately and in written form.

NOTE

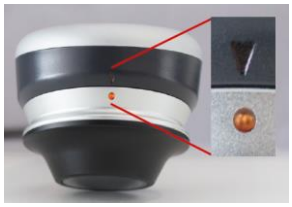
Please also refer to the separately available installation instructions.

4.2 Connecting the camera to the computer

■ Connect the leviacam to a USB 3.0 port on your PC.

4.3 Mounting the lens

■ The levialens, the lens used for light microscope images, is connected to the leviacam with a magnetic mount:



1. Insert the lens onto the contacts at the front of the camera so that the red dot on the levialens is at the top. The appropriate point on the camera is marked with a red arrow. Additional attachment is not required, as the bracket is magnetic.
2. The lens can be removed by pulling on it gently.

■ Do not touch the glass surfaces of both the camera and the lens with your fingers when using or cleaning them. This could leave behind finger prints etc, which could influence image quality (cf. chapter 7 Cleaning and disinfection).

5 Settings

You can adjust the settings of your device in the software.
You will find the *Settings* button at the top right of the the dashboard in the FotoFinder Universe software.

5.1 Image Capture Devices

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

NOTE

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

5.1.1 General

Here you can adjust the settings for the image display:

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

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

5.1.2 leviacam

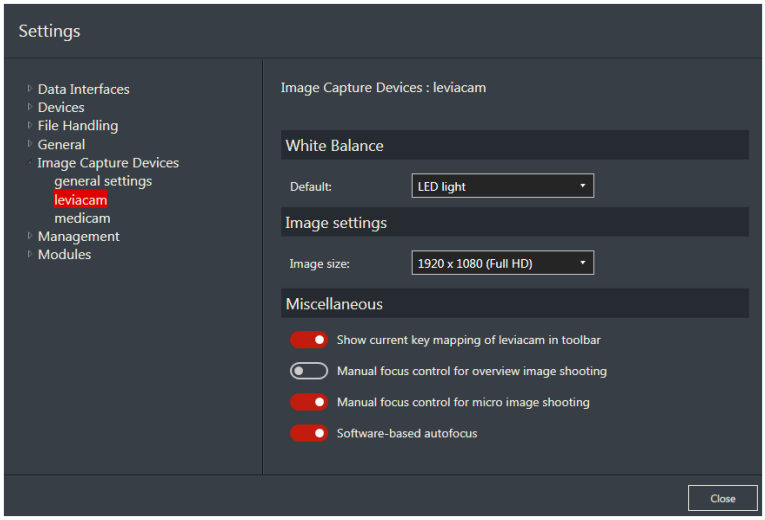


Fig. 3: Example view of the Image Capture Devices settings - leviacam

Image Settings
Here you can choose between these resolutions:

- 1920 x 1080 (Full HD)
- 2592 x 1944 (5 Megapixel)
- 3264 x 2448 (8 Megapixel)
- 4128 x 3096 (13 Megapixel)

The Full HD image size corresponds with the resolution of the medicam.

Miscellaneous

- Show/hide current key layout of the leviacam in the menu bar:

Fig. 4: Software example view for leviacam key layout

- Enable/Disable manual focus control for overview or micro image capturing.
- Enable/Disable the software-based autofocus for micro images here. By default, it is activated.

Any changes made will become active after a program restart.

6 Operation

ATTENTION

Never place any product that could leak on your equipment or over the power supply cables.
Liquids could cause serious damage.

ATTENTION

May damage the camera cable.
Do not bend the camera cable.
Do not step on the camera cable or subject it to any other strain.

6.1 Visual inspection before use

1. Before each use, check the system for visible damage.
2. Pay particular attention to the supply lines and attachment lenses.
3. Check the cables for possible damage, e.g. caused by sharp edges or improper use.
4. Make sure that all cable connections are correctly and firmly inserted.
5. The system must not under any circumstances be commissioned if
   - the power supply cable is visibly damaged
   - cables or covers are visibly damaged
   - the camera has been dropped.
6. Check the system regularly according to the valid rules of technology, but at least every 12 months.

6.2 Operating the leviacam®

6.2.1 General

- The camera is controlled by the FotoFinder Universe software and can only be used in combination with this software (or software from TrichoLAB), if applicable.
- Depending on the type of image (overview or microimage), the camera must be used with or without a reflected-light microscope attachment lens.

Most of the camera's features can be controlled using the buttons on the rear or optionally using the Software.

You can have the software display an overview of the respective button assignment. Activate this additional user tool in your settings (cf. chapter 5 Settings).

Fig. 5

6.2.2 Handling the leviabase (camera bracket)

The leviacam is delivered together with the camera bracket leviabase for safe storage.

Fig. 6 leviacam in leviabase

To prevent damage to the camera or the lens, please observe the following points:

- The front part of the camera tip should be anchored below the edge of the leviabase.
- To remove the camera, lift the camera handle and carefully remove the camera upwards and out.

6.2.3 Capturing with the leviacam

1. Connect the camera to a USB 3.0 port on your PC.
2. To capture an image, press the release button on top of the camera.

NOTE

FotoFinder recommends that you always work with alcohol spray. Immersion oil or gel can cause soiling of the inside of the camera attachment.
With polarised captures, e.g. with the FotoFinder dermatoscope, you do not require any immersion liquid.

WARNING! Magnetic field

Magnets can influence the function of pacemakers and defibrillator implants.
Never place the leviacam without levialens directly next to pacemakers or implanted cardioverter defibrillators (ICDs), and ensure a sufficient distance.

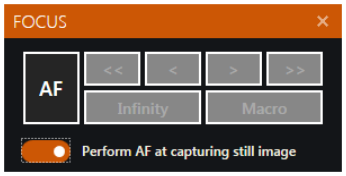
NOTE

You will find further information on generating images in the separate user manual for the software.

6.2.4 leviacam autofocus

You can activate the autofocus of the leviacam. This causes the camera to automatically focus, which prevents blurred images.

1. Use the right mouse button to click on the preview image during the capturing process (overview or micro image).
2. Select the *Focus* option in the appearing context menu.

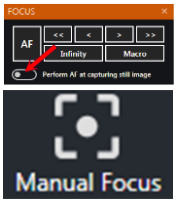


3. Move the adjuster at *Activate AF before image capture* to the right.

Your leviacam will now automatically focus when capturing images. Hold the camera steady until the capture is completed.

6.2.5 Manual focus with the leviacam

For a more precise focus when capturing with the leviacam a manual focus mode is also available. This allows you to set a focus point.
This feature is available in both overview and micro image modes, as far as enabled in the settings (cf. chapter 5 Settings).



1. Start the overview or micro image mode in the Dermoscopy module.
2. Deactivate the leviacam autofocus in the context menu *Focus*. Use the right mouse button to click on the live image during the capturing process to open the context menu.
3. Click on the *Manual Focus* button.

In the menu bar you will now see the changed layout of the leviacam key assignment (if activated in the settings):

4. Use the leviacam's arrow keys to select the best possible focus manually.
5. Continue with your capturing as usual.

Please keep in mind:

- Micro image mode:
  The manually set focus point will be saved and is still available after a program restart.
- Overview image mode:
  The focus point has to be redefined after a program restart.

HINWEIS

If you re-enable the leviacam autofocus, the manual focus settings will become inactive. Pressing the Manual Focus button again will reactivate your manual focus settings.

6.3 Ending operations

1. Close Universe and any open software modules.

This will also automatically log you out of the software.

2. Shut down the computer.
3. Press the main switch on the device.
4. Disconnect the power plug from the power supply.

7 Cleaning and disinfection

⚠ WARNING

Risk of infection as a result of insufficient hygiene.
Clean the applied part after each patient.

ATTENTION

Sanitize with wipes only.
Sanitize any components with sanitizing wipes only.

ATTENTION

Damage to the device and the screen caused by unsuitable cleaners.
Do not use abrasive agents or sponges!
Do not use solvents such as alcohol or gasoline!
Do not use glass cleansers with anti-static solution!
Only use the provided brush to clean the lens!

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.

7.1 Cleaning

NOTE

We recommend the FotoFinder Cleaning Kit (cf. chapter 2.1.1 leviacam accessories), comprising FotoFinder Cleaning Solution and the FotoFinder Cleaning Wipes for cleaning purposes.
The FotoFinder Cleaning Kit is suitable for all FotoFinder camera modules and lenses.

1. Carefully remove the levialens from the leviacam for cleaning. To do so, you only need to pull the levialens from the magnetic mount.
2. Use a suitable glass cleaner and a lint-free cloth.
3. Spray the glass cleaner onto the cloth and clean the lens from the front and rear.
4. Make sure that the cloth is not too wet.
5. Wipe dry.
6. Attach the levialens again after cleaning. In the process, the red dot on the levialens must be at the top. The corresponding position on the leviacam is marked with a green arrow (cf. chapter 4.3 Mounting the lens).
7. 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.

7.2 Disinfection

- The leviacam and the levialens (detachable reflected light microscope) must be disinfected before each use on the patient.
- For disinfection of the leviacam, use alcohol-free quick disinfection wipes
  e.g. Schülke mikrozid® sensitive wipes. The disinfection wipes should be suitable for disinfection of ultrasound heads.
- The following means can be used to disinfect the levialens:

  Disinfection spray:
  – Kodan Tinktur forte colourless (manufacturer: Schülke & Mayr GmbH)
  Wipes for quick disinfection:
  – Cleanisept Wipes (manufacturer: Dr. Schumacher GmbH)
  – mikrozid AF wipes (manufacturer: Schülke & Mayr GmbH)

8 Maintenance

NOTE

Please always observe all safety instructions in this manual!

DANGER

Maintenance must be performed by qualified personnel and may only be carried out when the device or its components are not being used on a patient and, if not required for maintenance, are disconnected from the mains supply.

- Warning! This device must not be modified without the approval of the manufacturer!
- To ensure your system functions perfectly, subject your device to periodic inspections and repeat checks. At FotoFinder Systems we recommend that you carry out repeat checks as per EN 62353 every 12 months.
- Specialist staff are required for carrying out all servicing work.

NOTE

Safety checks and mechanical checks as per sections 11 and 14 of MPBetreibV (German Medical Devices Operator Act)

Safety checks and mechanical checks as per sections 11 and 14 of MPBetreibV (German Medical Devices Operator Act) are not legally required for FotoFinder products and systems as they do not fall into the product categories indicated in annex 1 and 2 of MPBetreibV (German Medical Devices Operator Act).

Nevertheless, we recommend that operators have a safety check as per section 11 of MPBetreibV (German Medical Devices Operator Act) carried out on the respective medical products at least every 24 months. The operators are responsible for organisation of the necessary servicing and maintenance work. FotoFinder Systems is not qualified to carry out these checks. For this purpose, contact a qualified service technician.

9 Malfunction and troubleshooting

NOTE

Please always observe all safety instructions in this manual!

9.1 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.

9.2 Problems with the hardware

9.2.1 Interrupted USB connection to leviacam®

If the USB connection to the leviacam was interrupted, please note the following:

- Restore the USB connection to the computer by inserting the plug of the leviacam to the designated USB connection on the computer.
- Please ensure that all captured images were saved correctly.
- Recapture any unsaved images.

9.2.2 Malfunction in Live view or when saving

In the event of an external power disturbance (fluctuations, so-called bursts), there may be interferences in the display of the live image and/or saving the image (stripes or distortions in the image).

1. Wait until the power disturbance is over.
2. Restart the PC and
3. Capture the image again.

10 Disposal

ATTENTION

Risk of environmental damages caused by improper disposal.
For disposal, observe local regulations and legal requirements.

By properly disposing of and recycling old equipment and used components, natural resources can be conserved and the environmental impact minimized. Therefore, please note the following points:

- The operator is responsible for proper disposal.
- Disposal must be carried out in accordance with applicable local regulations and laws.
- This product or its components must not be disposed of as normal household waste. Contact your local authority, municipal waste disposal companies or specialized dealers for information on acceptance points for recycling electrical and electronic devices.
- If necessary, the device must be disassembled into separate sections and materials at the end of its service life before it can be taken to a specialized company for recycling.

FotoFinder

EU - KONFORMITÄTSERKLÄRUNG

EU - DECLARATION OF CONFORMITY

Hersteller / *Manufacturer:*	FotoFinder Systems GmbH
Adresse / *address:*	Industriestraße 12 84364 Bad Birnbach Deutschland/Germany
Single Registration Number (SRN):	DE-MF-000007084
Benannte Stelle / *Notified Body*	Nicht anwendbar / *Not applicable*

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

FotoFinder leviacam
Artikelnr. / *Product code*: FFS720160

Mit folgendem Zubehör
With the following accessories

leviabase
levialens
Medizinischer Trenntransformator / *Medical Isolating Transformer*

Zweckbestimmung / *Intended Use:* Videodermatoskop / *Videodermatoscope*

Elektrisch betriebenes, handgeführtes Instrument zur mikroskopischen Untersuchung der äußeren Hautschichten durch Erstellung digitaler Bilder. Das Gerät verfügt über ein optisches sowie elektronisches Vergrößerungssystem, das im Rahmen einer so genannten Dermatoskopie digitale Bilder der Strukturen der Epidermis und des Epidermis-Corium-Übergangs zur Anzeige auf einem Monitor liefert. Dieses Gerät wird gewöhnlich zur Untersuchung von Hautstrukturen und zur Bewertung anormaler Farb- und Formänderungen pigmentierter Hautschäden verwendet.

An electrically-powered, hand-held instrument intended to be used for the microscopic examination of the external skin layers through the production of digital images.The device has a built-in light source(s) and an optical and electronic magnification system that provides the user with digital images of the structures of the epidermis and epidermal-dermal junction for visualization during dermatoscopy. This device is commonly used for the examination of skin structures and to assess abnormal colour and pattern changes of pigmented skin lesions.

der Risikoklasse / *of risk class:* I (Annex VIII MDR)

Basis UDI-DI / *Basic UDI-DI:* 426015845LC001W5

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

Konformitätsbewertungsverfahren / *Conformity assessment* Annex IX, (EU) 2017/745

FotoFinder

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

Bad Birnbach, 01.06.2021

Julian Mayer, Authorized Officer

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