EN

FotoFinder®

medicam 1000

Original user manual

Hardware

Setting the Pace in Skin Imaging Worldwide

www.fotofinder.de

FotoFinder medicam 1000

Original user manual

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

CE

for FotoFinder medicams with the serial number MC1000-4
Status: 19.06.2024

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Content

1 About these operating instructions

1.1 Introduction

The FotoFinder medicam facilitates fast documentation in the fields of

- Dermoscopy
- Trichoscopy
- Capillaroscopy and
- Inflammoscopy.

This user manual is also valid for the FotoFinder dermoscope desktop (cf. 2.5) version.

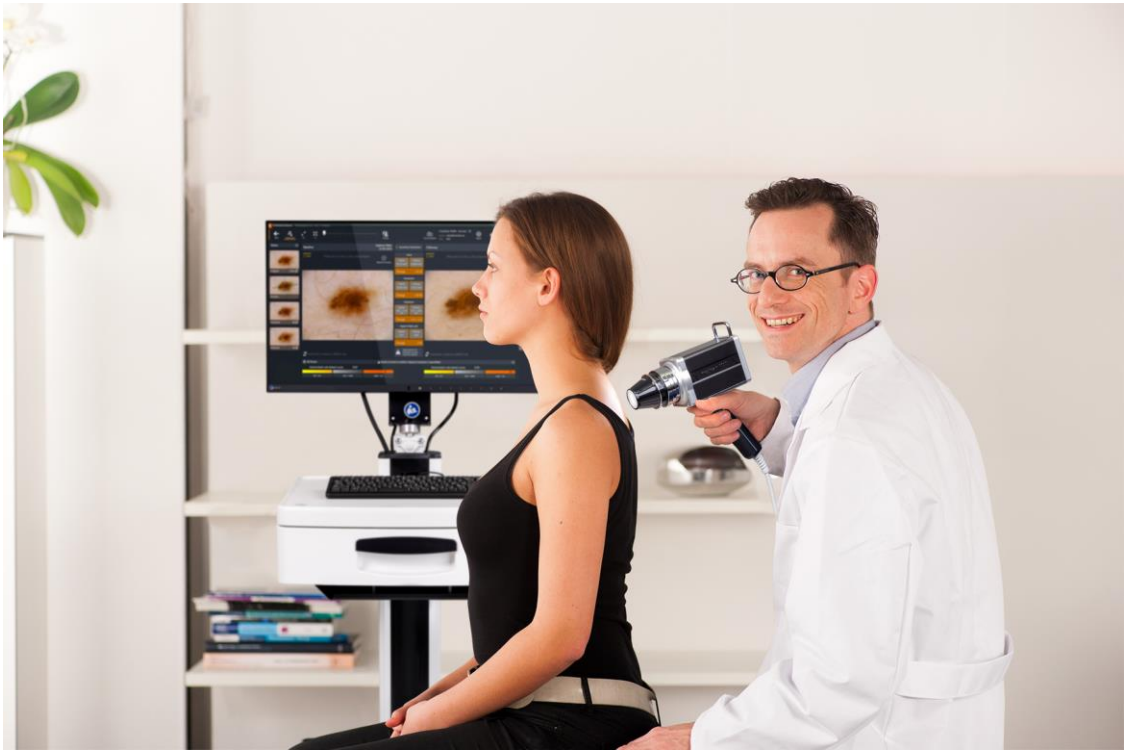


Fig. 1: medicam application example

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.

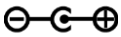
1.4 Information on the device label

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
	CE mark
	General warning
 eIFU indicator	Electronic user manual
	Observe the user manual
	Medical device
	Type B applied part
	Do not dispose of electrical and electronic devices with domestic waste
Type	Device type; describes the name of the device, e.g. FotoFinder medicam 1000
IP	IP protection class
	Month and year of manufacture
	Unique serial number of the device
Input	Compatible input voltage
Power	Nominal power
	UK Conformity Assessed Responsible Person for UK: FotoFinder Systems Ltd., 100 Addison Road, W148DD London, United Kingdom

Tab. 1: Explanations of the type plates, medicam 1000 and docking station

1.5 Explanation of the symbols

	Equipotential bonding
	System mode: Operating status of the device
	Coaxial power connector socket (power connection)
CH REP	Indicates the Swiss representative: Johner Medical Schweiz GmbH, Tafelstattstrasse 13a, 6415 Arth, Switzerland

Tab. 2: Further symbols on the device

2 Components and technical data

2.1 Product variants with the FotoFinder medicam 1000

Variant	Main components
FotoFinder component solution (cf. chapter Fehler! Verweisquelle konnte nicht gefunden werden. Fehler! Verweisquelle konnte nicht gefunden werden.)	■ FotoFinder medicam 1000 with docking station ■ Attachment lenses (D-Scope IV and/or D-Scope III) ■ Camera stand for the medicam 1000 ■ FotoFinder Universe* (software)
FotoFinder dermoscope desktop (cf. chapter 2.5 FotoFinder dermoscope desktop)	Like FotoFinder component solution, in addition: ■ FotoFinder Silent Medical Server (PC) ■ Isolating transformer ■ Monitor, mouse, keyboard
FotoFinder vexia*	Like FotoFinder dermoscope desktop without camera stand, in addition: ■ vexia system trolley
FotoFinder studio*	Like FotoFinder dermoscope desktop, in addition: ■ studio system trolley with – Lifting column – Portrait stand with head and chin support, digital SLR camera with PolFlash system
FotoFinder ATBM master*	Like FotoFinder dermoscope desktop without camera stand, in addition: ■ FotoFinder ATBM master system trolley with – Control unit – Linear drive with Canon camera and PolFlash XE – Laser Liner ■ Positioning mat

Tab. 3: Overview of medicam 1000 variants

NOTE

*There are separate instructions for use for this FotoFinder product.

2.2 General


Technical datasheet
medicam 1000
with Docking Station
Dimensions
33 cm
17 cm
25 cm
Optional: Spacer 63 mm / 28 mm
D-Scope IV
medicam holder
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FotoFinder®

Technical datasheet

medicam 1000
with Docking Station

Minimum & recommended system configuration:

The minimum computer requirements depend on the software used (e.g. FotoFinder Universe, 3.5). If you have any questions, please contact us.

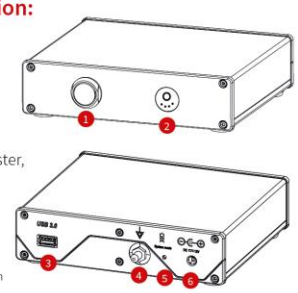
Attention!

Use only a PC or laptop which is powered by a medical isolating transformer or one that meets the IEC 60601-1 standards.
If you are using a medical isolation transformer then also connect the docking station to this isolation transformer.

Ports & Buttons of the Docking Station:

1. On/Off-Button
2. Push-Pull Connector
3. USB A 3.0
4. Potential Equalization
5. System Mode Button (activated with ATBM master, vexia oder studio)
6. Power supply

* Activating continuous mode by pressing with a narrow object prevents subsequent deactivation via the On/Off-Button.



Weight:

medicam 1000:	0.7 kg	
Docking Station:	1.3 kg	(including USB cable)
D-Scope IV:	0.2 kg	(including front caps)
medicam holder:	0.6 kg	(for desktop solution only)
Total:	**ca. 2.8 kg**	
Optional: D-Scope III	0.3 kg	(instead of D-Scope IV)
Total:	**ca. 2.9 kg**	

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. 80kPA to max. 107kPA from -425 m to 2000 m a. s. l.
Relative humidity*:	20 – 90 %, non-condensing
Power consumption:	15 watts
FotoFinder medicam 1000	
Supply voltage/frequency:	AC 115 V / 230 V / 50 – 60 Hz
Current consumption:	DC 12 V
Application part type:	Type B
Resolution:	1920 × 1080 Pixel
Zoom:	140 ×
Optical zoom:	Yes
Illumination:	LED
Connector:	Lemo Push-Pull connector B series
Number of effective pixels:	ca. 2.000.000 Pixel
Image format:	16 : 9
Minimal object distance without micro lens:	wide 1 cm, tele 120 cm
Cable length:	ca. 300 cm
FotoFinder Docking Station	
Supply voltage:	DC 12 V
Power adapter:	Manufacturer: Adapter Technology Co., Ltd., Model: ATM036T-P120
Safety connection:	Potential equalisation pin
PC hardware required:	USB 3.0 Type-A
Transport and storage:	The device is shipped in a box.
Dimensions product packaging:	ca. 60 × 40 × 40 cm
Packet weight:	ca. 10 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.

CE The device is manufactured in accordance with ISO 13485

* applicable for operation, transport and storage

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FotoFinder®

2.3 FotoFinder medicam®

Abb. 2: medicam 1000 with the D-Scope IV dermoscopy lens

1	Camera mount	4	Plug in distance holder
2	Bayonet fastener	5	Release button
3	D-Scope-IV Lens*	6	Operating light
		7	Back panel

**alternatively, other lenses and attachments can also be used, see in the following sections.*

■ The medicam LED is illuminate in green when the camera is connected to power.

Abb. 3: For Overview images: medicam 1000 without a microscopic lens

1 LED-Ring light
2 Contact pins for dermoscopy lens
3 optional Distance holder for close-up overview images

⚠ CAUTION

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

⚠ CAUTION

The LED floodlighting of the medicam can heat up to more than 40 °C during use. This has no impact on patients or users as they do not come into contact with this applied part during normal use: The medicam is not placed on the skin of the patient without an attachment lens. In order to prevent skin damage as a result of heat, ensure correct use and avoid any unnecessary skin contact with the LED floodlighting.

2.3.1 Spacers

The medicam 1000 can optionally be used with two different spacers for close-up overview images. These two fixed clearance distances enable standardisation of close-up images and make subsequent measuring of the images easier.

Fig. 4: Application example for the medicam 1000 with spacer

Fig. 5:medicam 1000 with spacer (1); in this case 63 mm

To attach the spacer:

1. Select one of the spacers (28 or 63 mm).
2. Insert the ends of the spacers into the designated openings at the front of the camera. No further fastening is required as the mount is magnetic.
3. Remember to attach the clips for the spacers.

Fig. 6: Clip for medicam spacer (2)

The scope of delivery of the optional spacers of the medicam 1000 includes black clips.

These clips must be fitted to the spacer with gentle pressure before it is placed on the skin of the patient.

Remove the clip for cleaning purposes after each use, and re-attach it for the next use.

2.3.2 D-Scope III

The D-Scope III is an optionally available attachment for your medicam. It allows optical magnifications up to 400x.

Fig. 7: D-Scope III

1 Focus ring
2 Colour markings to set an average focus value

2.3.3 D-Scope IV

The D-Scope IV lens for the medicam 1000 can be used for both polarized and non-polarized microimaging. It allows optical magnifications up to 140x.

For the D-Scope IV the following attachments are available:

- Lens attachment, closed
  for contact Dermoscopy

- Lens attachment, open
  for non-contact Dermoscopy

- Lens attachment, conical
  for lesions difficult to access

NOTE

When using the conical attachment, please make sure to always use an immersion liquid and non polarized lighting.

The D-Scope IV is equipped with LED illumination. Depending on the capturing mode (polarized – non-polarized), this switches to the appropriate mode as well. The Universe software shows which illumination is active at the moment in micro capturing mode. This can also be seen when the front cap is briefly removed.

NOTE

Image capturing with the D-Scope IV without the front cap is not possible! These images are only to visualize the built-in illumination!

CAUTION

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

Fig. 8: Visualization of the medicam 1000 with D-Scope IV with removed front cap and active LED light for polarized images.

Fig. 9: Visualization of the medicam 1000 with D-Scope IV with removed front cap and active LED light for non-polarized images.

2.3.4 Accessories for medicam®

Accessories	Item number
FotoFinder Cleaning Kit	FFS090400
D-Scope III Dermatoscopic attachment lens for up to 400x magnification	FFS009800
D-Scope IV Dermatoscopic attachment lens for polarised and non-polarised images	FFS000910
■ D-Scope IV attachment, closed	
– individual	FFS913030
– Pack of three	FFS912205
– Pack of ten	FFS913019
■ D-Scope IV attachment, open	
– Pack of three	FFS912204
■ D-Scope IV attachment, conical	
– individual	FFS000911
FotoFinder Docking Station	FFS000840
Power pack for FotoFinder Docking Station	DEH000002
USB 3.0 cable for Docking Station	TTL000011
USB 3.1 to USB C adapter	FFS000301
USB 3.0 cable (for component solution)	FFP910044
medicam camera stand	SED000006
Spacer for close-up overview images:	
■ Spacer 28 mm	ASD000314
■ Spacer 63 mm	ASD000315
■ Clip for spacer (pack of three)	THI000024

Tab. 4: List of medicam® *accessories*

Visit our webshop at www.fotofinder.de.

2.4 FotoFinder Docking Station

The FotoFinder docking station is the technical interface of the FotoFinder medicam to the connected computer.
The FotoFinder docking station is included with all FotoFinder systems with FotoFinder medicam (e.g. FotoFinder ATBM, FotoFinder vexia, FotoFinder studio).

Fig. 10: FotoFinder docking station

Front:		Rear:	
1	On/Off button	2	Switch for system mode

- You will find a description of the connections in the separate chapter (cf. chapter 4.2 Connections on the FotoFinder Docking Station).
- Standby light: The light on the power unit of the docking station lights up green when the device is connected to the power supply.
- The On/Off button lights up green when the docking station is on. Otherwise, it does not light up.
- *System mode*: If the docking station is installed in a system (FotoFinder ATBM, FotoFinder vexia, FotoFinder studio), the button for system mode is activated at the factory and the device is set to continuous operation. As a result, the docking station cannot be switched off manually using the On/Off button.

2.5 FotoFinder dermoscope desktop

The FotoFinder dermoscope desktop is a variant of the FotoFinder component solution (cf. 2.1).

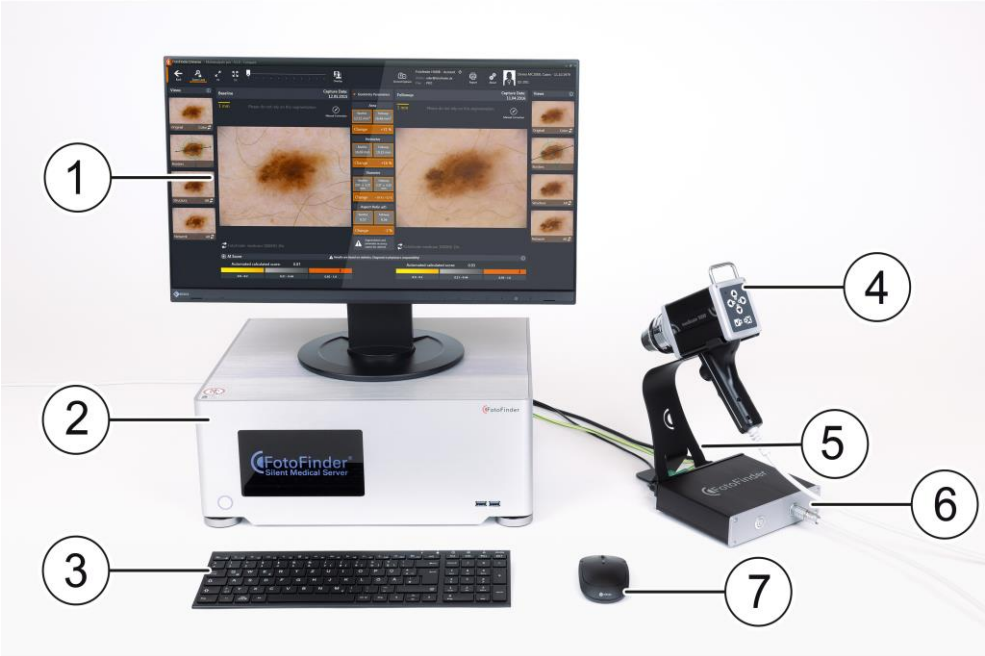


Fig. 11: FotoFinder dermoscope desktop

1	Screen	5	Camera stand
2	Silent Medical Server	6	Docking station
3	Keyboard	7	Mouse
4	medicam 1000*	8	Isolating transformer (not in the image)

(Illustrations partly serve as examples)

* Shown here with the optionally available D-Scope IV attachment lens. Alternatively, other attachments and other front caps can be used for micro capturing, see following pages.

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 medicam 1000 with Docking Station is an electrically operated and software controlled video dermatoscope intended for capturing microscopic and macroscopic images of the patient's intact skin surface by medical professionals.
The medicam 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 software 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 medicam disposes of an interface for lens attachments (D-Scope IV and D-Scope III) with different front caps, which support the recording of polarized and non-polarized microscopic images.
Contact with injured skin must be excluded.
The medicam including its accessories is intended to be used exclusively by medical professionals in a professional healthcare environment, e.g. clinics or hospitals.

The D-Scope IV is an accessory for the medicam. The intended purpose of the device is the standardized digital non-invasive examination and documentation of skin for dermatologic purposes. It allows the recording of microscopic images on intact skin with the medicam. The D-Scope IV can be used with different front caps in order to record more areas of intact skin. The LED illumination enables the user to switch between polarized and non-polarized imaging with immersion fluid.

The D-Scope III is an accessory for the medicam. The intended purpose of the device is the standardized digital non-invasive examination and documentation of skin for dermatologic purposes. It allows the recording of microscopic images with standardized illumination. The D-Scope III is only used on intact skin. The focus ring allows the user to make micro-adjustments in the focus level.

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:

- medicam®

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 Potential equalization

The equipment must be connected to the potential equalization network by plugs with angled sockets (cf. chapter 4.2.1 The potential equalization plug).

Additional equipment connected to a medical electric equipment must comply with the respective IEC or ISO standards (e.g. IEC, DIN EN 62368-1 Audio/video, information and communication technology equipment, IEC 60601-1/EN 60601-1 for medical devices). Furthermore, all components of the product must comply with the requirements for medical electric systems IEC 60601-1-2/EN 60601-1-2 standards. Any additionally connected equipment to any of the in- or outputs of the medical electric equipment must comply with the IEC 60601-1-2/EN 60601-1-2 standards.

ATTENTION

- The system has been designed for 115 VAC or 230 VAC. Before plugging in the power cable, check that the mains switch is set to your input voltage commonly used in your country.
- The additional power outlets of the device are designed for 230 VAC voltage and a maximum load of 350 Watt. Only use these power outlets for devices that are part of the system. Do not connect any additional power strips and extension cords.
- Do not connect any devices that are not listed in this manual and approved by the manufacturer to the additional power outlets of the system.

3.12.2 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.

3.12.3 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.

3.12.4 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.

3.12.5 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.

3.12.6 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.

medicam 1000

Cable	Type	Length
USB 3.0	Shielded	1.8 m
Power input cable	Power cable	< 3 m

3.12.7 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.

ATTENTION

The FotoFinder dermoscope component solution must only be operated with a medical isolating transformer as per EN 60601-1. The operator is responsible for adhering to this rule.
The isolating transformer can also be purchased from FotoFinder Systems.

ATTENTION

A galvanic isolator is required for use with Silent Medical Server. The operator is responsible for implementation.

ATTENTION

Incorrect power supply voltage could damage the device.
Use only the original power supply cable connected to the isolating transformer for power supply.

CAUTION

Risk of injury caused by tripping over the power cord or network cable!
The cables can create a tripping hazard if not organized well. This may result in injury caused by falling.
Always place supply cables away from walkways.

CAUTION

Give the power cord always some slack to avoid unintended disconnects from the wall outlet.

CAUTION

The power plug should be easily accessible in case of emergency. Set up your device so that you have direct access to the power plug.

4.1 Delivery scope

- medicam 1000
- Docking station (with camera stand as applicable)
- Power adapter with power cable
- USB 3.0 cable
- D-Scope IV (optionally D-Scope III)

The list can vary depending on the product variant (cf. chapter 2.5 FotoFinder dermoscope desktop).

NOTE

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

NOTE

Please note the medicam accessory list (cf. chapter 2.3 FotoFinder medicam®).

NOTE

Please also refer to the separately available installation instructions.

4.2 Connections on the FotoFinder Docking Station

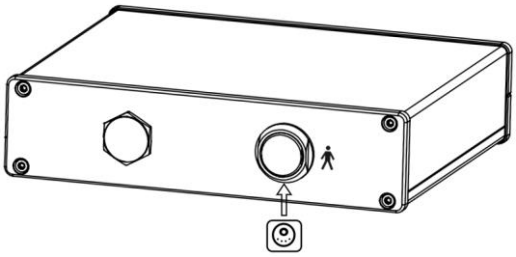


Fig. 12: FotoFinder Docking Station *front side*

Push-Pull round plug:
Socket for the medicam 1000 outlet

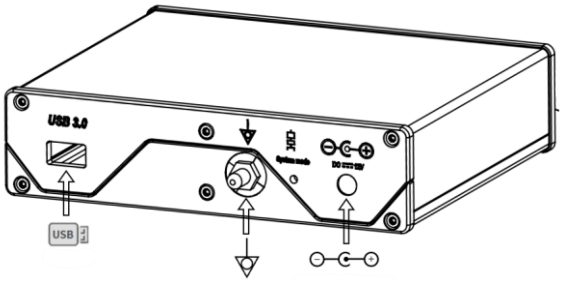
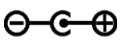


Fig. 13: FotoFinder Docking Station *back side*

USB A 3.0 port:
Cable port to connect with the PC

Connector for equipotential bonding (EB)



Hollow plug socket:
Power mains outlet

ATTENTION

The USB A 3.0 port is not symmetrical; therefore the cable can only fit into the port in one orientation.
If you plug in the cable using the wrong orientation, the port can be damaged.
Please pay attention to always use the correct orientation when installing the medicam and Docking Station.

4.2.1 The potential equalization plug

Before you start up the device and connect the mains plug, first connect the potential equalization cable connected through the main potential equalization rail to the designated socket for potential equalization (POAG) (cf. chapter 3.12.1 Potential equalization).

The requirements for medical electrical equipment with a connector for potential equalization are described in the EN 60601-1 standard.

4.3 Connecting the camera to the computer

Connecting the medicam to the Docking Station:

Fig. 14: Push-Pull round plug connection with the medicam *cable on the* Docking Station

1. On the front of the Docking Station there is a Push-Pull round plug connection (cf. chapter 4.2 Connections on the FotoFinder Docking Station). Connect the cable of the medicam here. When connecting, make sure that the red dot on the plug is at the top and thus matches the red dot of the round plug connection (see photo).

The push-pull plug prevents from unintentionally plugging the cable out.

2. To disconnect, hold the plug at the ridged part of the plug and pull it straight out, away from the device.

4.4 Mounting the lens

- The lens for microscopic images can be attached to the camera via a bayonet fastener:

  1. Simply place the lens on the contact area at the front of the camera and press lightly against the lens.
  2. Then turn it clockwise until it locks.
  3. The lens can be easily removed by turning it counterclockwise.

- The lens attachment can be removed for maintenance and cleaning by turning it counterclockwise.
- The integrated micro illumination can be turned on and off with the button on the back panel of the camera. As soon as the micro lens is attached, the floodlight automatically turns off.

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 medicam

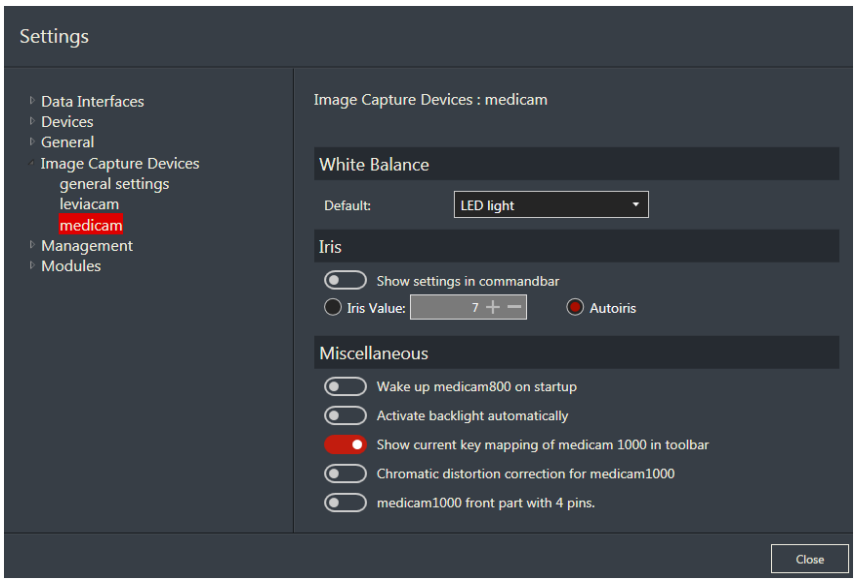


Fig. 15

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

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

Fig. 16

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 medicam

6.2.1 General

- The camera is already preset by the manufacturer.
- The camera is controlled by the FotoFinder Universe software and can only be used in combination with this software (or, if applicable, with the software from TrichoLAB).
- Depending on the capturing mode (overview or micro image), the camera must be used with or without an reflected light microscope attachment lens.
- The camera is equipped with an integrated LED floodlight for overview images from a distance of up to 120 cm. This LED floodlight turns on automatically as soon as the overview capturing mode is started in Universe. The LED floodlight can only be operated in this overview mode in Universe.
- The attachment lens of the medicam (e.g. the D-Scope IV) are equipped with illumination. This illumination switches on automatically as soon as you start the micro capturing mode in Universe. The illumination can only be operated in this micro capturing mode in Universe.
- The shutter release is integrated in the camera handle.

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.

NOTE

The camera casing of the medicam 1000 may become slightly warm if it is used for longer periods.

NOTE

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

6.2.2 Control panel of the medicam

Fig. 17: Rear and control panel of the medicam 1000

- The camera can largely be operated using the rear control panel or, in part, using the software.
- You can display an overview of the respective key configuration in the software. Activate this additional user help in the settings of the software.

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

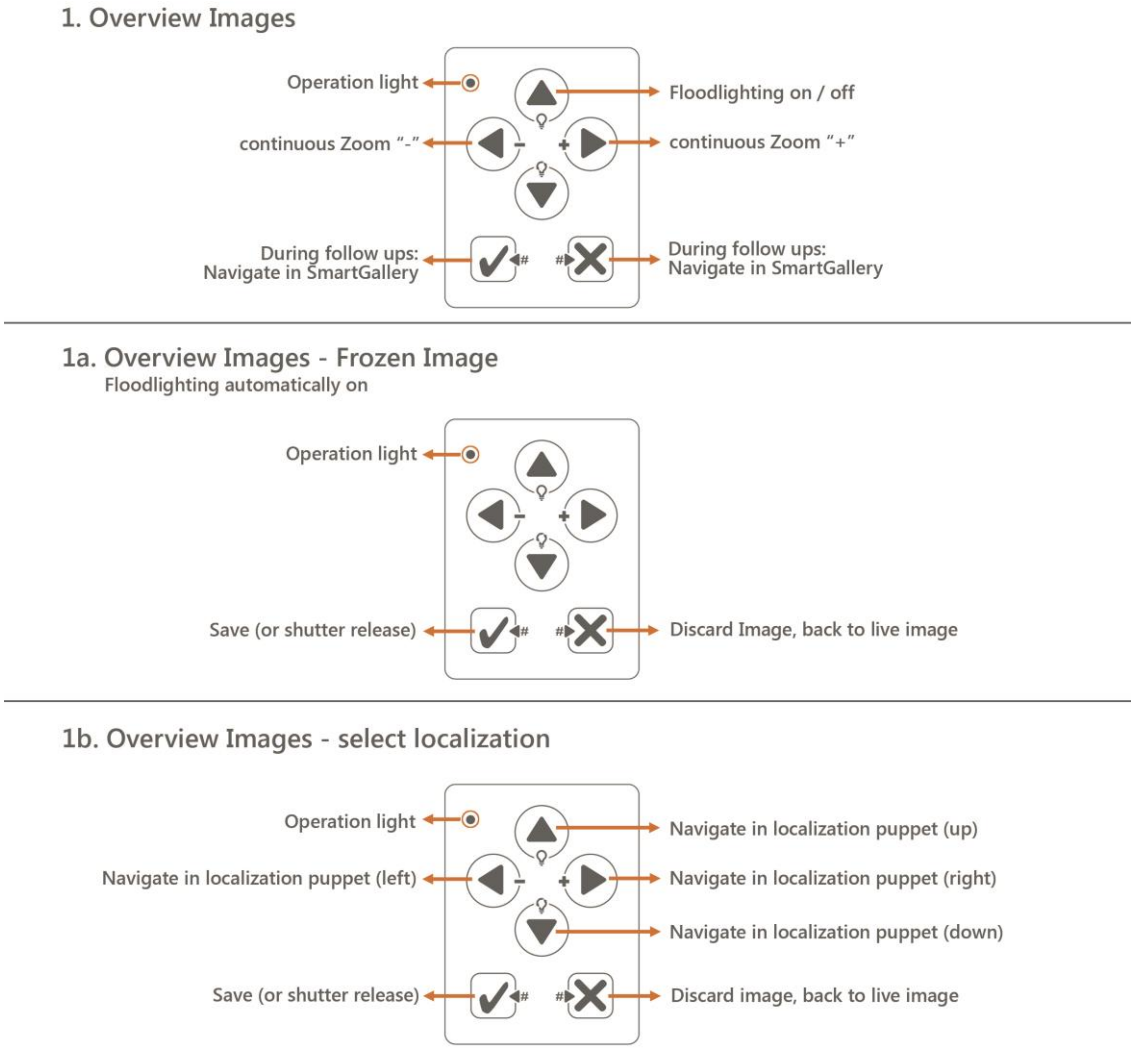


Fig. 18: *medicam 1000* panel functions for overview images

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

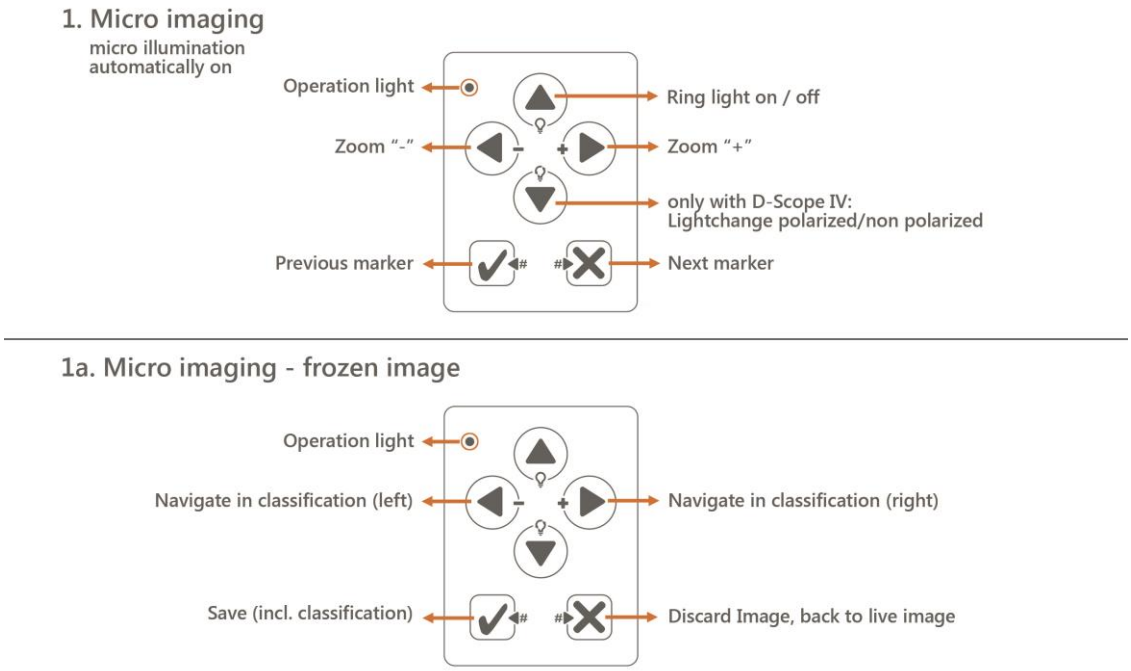


Fig. 19: *medicam 1000* panel functions for micro images

An overview of the medicam 1000 panel functions relevant in the Screening module is provided below:

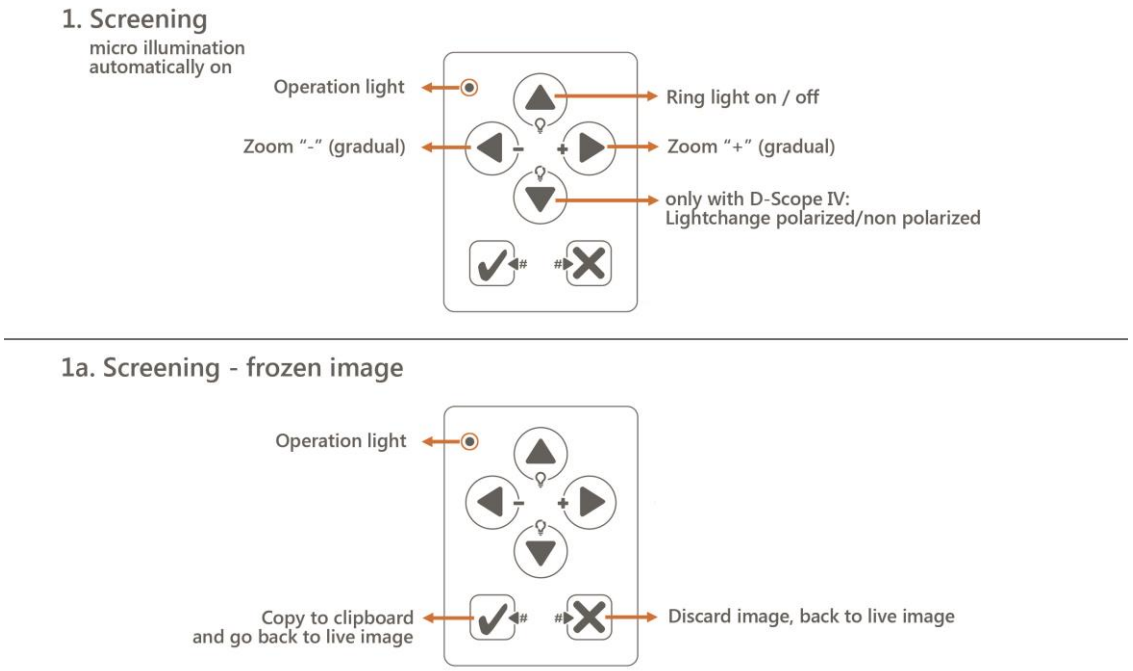


Fig. 20

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

For cleaning, we recommend the FotoFinder Cleaning Kit (cf. 2.3), consisting of the FotoFinder Cleaning Solution and the FotoFinder Cleaning Wipes.
The Cleaning Kit is suitable for all FotoFinder camera models and lenses.

1. Carefully remove the dermoscopic lens from your medicam camera.
2. Take off the lens attachment (front cap) by turning the attachment ring counterclockwise.
3. To prepare for cleaning, apply the Cleaning Solution to your Cleaning Wipes.
4. Clean the inside and outside of the lens attachment (front cap) with the moistened wipe. Don‘t forget to disinfect the front surface that is in direct contact with your patient.
5. Apply the Cleaning Solution to a fresh wipe and clean the two lenses at the front and the back of the dermoscopy lens. With a circular motion, gently remove oil, fingerprints and grime from the lens surfaces, working from the centre outward.
6. If necessary, also clean the lens at the front of the camera where the dermoscopic lens is attached.
7. Again, take a fresh, dry wipe to remove the residue of the cleaning solution and polish the lenses.
8. When attaching the front cap to the dermoscopic lens, please ensure that it snaps into place completely. Otherwise the camera auto focus will not work correctly.

7.2 Disinfection

- The medicam and its accessories (e.g. front caps, distance holders) must be cleaned and disinfected before each use on a patient.
- To disinfect the medicam and its accessories, use alcohol-free quick disinfection wipes, e.g. mikrozid® sensitive wipes from Schülke. The disinfection wipes should be suitable for disinfecting ultrasound heads.

Specific notes for the D-Scope IV attachments:

The D-Scope IV lens attachment (cf. chapter 2.3.3 D-Scope IV) can be cleaned in an ultrasound bath (tested with Podolock Sonic, manufacturer: Ruck) with for example the Endozime® Dual Enzymatic Detergent disinfection liquid (manufacturer: Ruhof Corporation).

Fig. 21: D-Scope IV attachment

To disinfect the D-Scope IV attachment the following cleaning materials are suitable:
Disinfection sprays:

- Incidin™ OxyFoam or Incidin™ OxyFoam S (manufacturer: Ecolab Engineering GmbH)
- Kodan Tinktur forte, colorless (manufacturer: Schülke & Mayr GmbH)

Disinfection foams:

- Tristel Duo pour Ophtalmologie (manufacturer: Tristel GmbH)

Disinfection wipes for quick cleansing:

- Cleanisept® Wipes (manufacturer: Dr. Schumacher GmbH)

Disinfection wipes:

- Cidalkan Wipes (manufacturer: Alkapharm)
- Incidin™ OxyWipe or Incidin™ OxyWipe S (manufacturer: Ecolab Engineering GmbH)
- Sani-Cloth AF3 Germicidal Disposable Wipe (manufacturer: PDI, Inc.)

ATTENTION

The front caps are not sterile. The front caps must not be cleaned in autoclaves. This could cause damage to the material.

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.

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.

- The FotoFinder medicam should be returned to the manufacturer for servicing at least once per year. A replacement camera is available to be borrowed for the duration of the servicing work. For this purpose, contact your FotoFinder distributor. He/she will inform you of the procedure and the costs.

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 software

9.2.1 Live image display of medicam® 1000 is delayed

- Check the computer's utilisation. Anti-virus software may affect the operation of the FotoFinder medicam 1000.
- Check the utilisation of the USB 3.0 ports. No other device or USB hub may be operated on the same USB 3.0 port as the medicam 1000.

9.3 Problems with the hardware

9.3.1 medicam® does not react or is not recognised

- Check the green operating light on the back of the FotoFinder medicam.
- Check all connections to the computer and to the FotoFinder Docking Station for correct connection.
- Check whether the FotoFinder Docking Station is switched on.
- Shut down the computer, disconnect and reconnect the camera plug and restart the computer.

9.3.2 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.

11 Appendix

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 medicam 1000s
Artikelnr. / *Product code:* FFS010001, FFS010004, FFS010040

Mit folgendem Zubehör
With the following accessories

FotoFinder Docking Station (mini)
D-Scope IV mit Vorsatzkappen (offen, geschlossen, konisch) / *with front caps (open, closed, conical)*
D-Scope III mit Vorsatzkappe / *with front cap*
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:* 426015845MC001WG

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

Wir erklären Konformität zu folgenden angewandten Spezifikationen / *We declare conformity to the following common specifications:*

Verordnung / *Regulation* (EG) 1907/2006
Richtlinie / *Directive* (EU) 2011/65
Annex IX, (EU) 2017/745

Konformitätsbewertungsverfahren / *Conformity assessment*

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

FotoFinder Systems GmbH Industriestr. 12 84364 Bad Birnbach Germany

Bad Birnbach, 26.11.2022

Julian Mayer, Authorized Officer

11 Appendix