EN

FotoFinder®

vexia

Original user manual

Hardware

Setting the Pace in Skin Imaging Worldwide

www.fotofinder.de

FotoFinder vexia

Original user manual

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

CE

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1 About these operating instructions

1.1 Introduction

The FotoFinder vexia 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. chapter 11 Appendix)
- 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
info@fotofinder.de	Manufacturer's e-mail address
IP	IP protection class
	CE mark
	Observe the user manual
	Warning of dangerous electrical voltage
	Do not dispose of electrical and electronic devices with domestic waste
Type / Model	Device type; describes the name of the device, e.g. FotoFinder medicam 1000
Input	Compatible input voltage (if applicable: mains frequency)
Power	Nominal power
Frequency	Mains frequency
	Unique serial number of the device
	Month and year of manufacture
	UK Conformity Assessed Party responsible for UK: FotoFinder Systems Ltd., 100 Addison Road, W148DD London, United Kingdom
Output	Nominal voltage/nominal current at the isolating transformer output
	Safe working load
	Weight

 elFU indicator	Electronic user manual

1.5 Explanation of the symbols

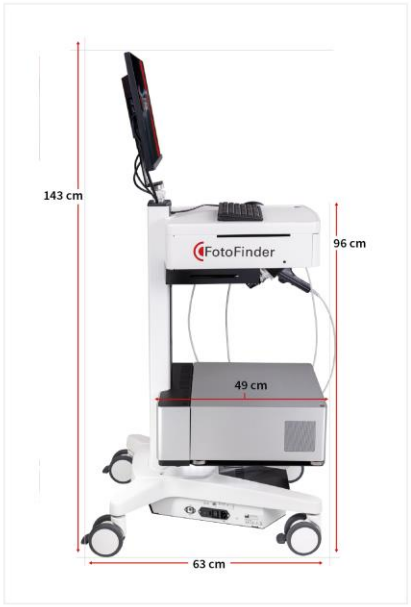
	Do not stand on surface
	Do not push this device component
	Equipotential bonding
CH REP	Indicates the Swiss representative: Johner Medical Schweiz GmbH, Tafelstattstrasse 13a, 6415 Arth, Switzerland

Tab. 1: Further symbols on the system

2 System components and technical data

FotoFinder **vexia**

Dimensions



Setting the Pace in Skin Imaging Worldwide

FotoFinder®

FotoFinder **vexia** Technical Data

System configuration Silent Medical Server:

- Intel CPU i5-13600 (2.7 GHz; 14 cores / 20 threads)
- 16384 MB (16 GB) RAM
- 1 × HDD-hard drive with min. 4 TB for database
- 1 × HDD-hard drive with min. 4 TB for backup
- 1 × SSD-hard drive with min. 1 TB
- Optional: external hard drive (USB 3.0) min. 2 TB
- Microsoft Windows© 10 Pro, 64-bit / Microsoft Windows© 11 Pro, 64-bit (as of FotoFinder Universe version 3.4.2)
- 8 USB ports (5 USB 2.0 and 3 USB 3.2)
- Potential equalization connector
- Internet connection for activation, software updates and remote support required

Monitor:

- 27" Monitor/LCD, 3840 × 2160 Pixel

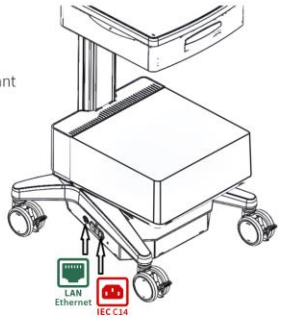
Existing ports vexia:

LAN / network port:

- RJ 45
- 10/100/1000 Mbit/s
- Network isolator compliant IEC 60601-1 (3rd Edition)

Electrical power supply:

- IEC C14 with V-Lock
  3 m-cable (V-Lock) included



Compatibility to FotoFinder dermatoscopes:

- FotoFinder medicam 1000(s)

Weight:

vexia cart:	42,0 kg	(without Silent Medical Server, monitor, keyboard, mouse, medicam)
Silent Medical Server:	11,0 kg	
Monitor:	5,0 kg	
medicam 1000:	1,0 kg	
Total:	**circa 59,0 kg**	

Specifications:

Manufacturer:	FotoFinder Systems GmbH
Address:	Industriestraße 12, 84364 Bad Birnbach, Germany
Model:	FotoFinder vexia
Supply voltage/frequency:	AC 115 V / 230 V / 50 – 60 Hz
Power consumption:	max. 350 Watt
Network isolator:	IEC 60601-1 compliant (3rd Edition)
Protection class:	I
IP protection class:	IP20
Ambient temperature:	0 – 25°C
Transport- and storage temperature:	0 – 40°C
Air pressure*:	min. 80 kPA to max. 107 kPA from -425 m to 2000 m above sea level
Relative humidity*:	20 – 90 %, non-condensing
Transport / Packaging:	The device is shipped standing upright on a wooden pallet by a professional company.
Dimensions of the packet: (incl. wooden pallet) (L × W × H)	90 × 90 × 177 cm
Packet weight:	ca. 93 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.

* applies to operation, transportation and storage

CE The device is manufactured in accordance with ISO 13485.

Setting the Pace in Skin Imaging Worldwide

FotoFinder®

The FotoFinder vexia comprises the following components:

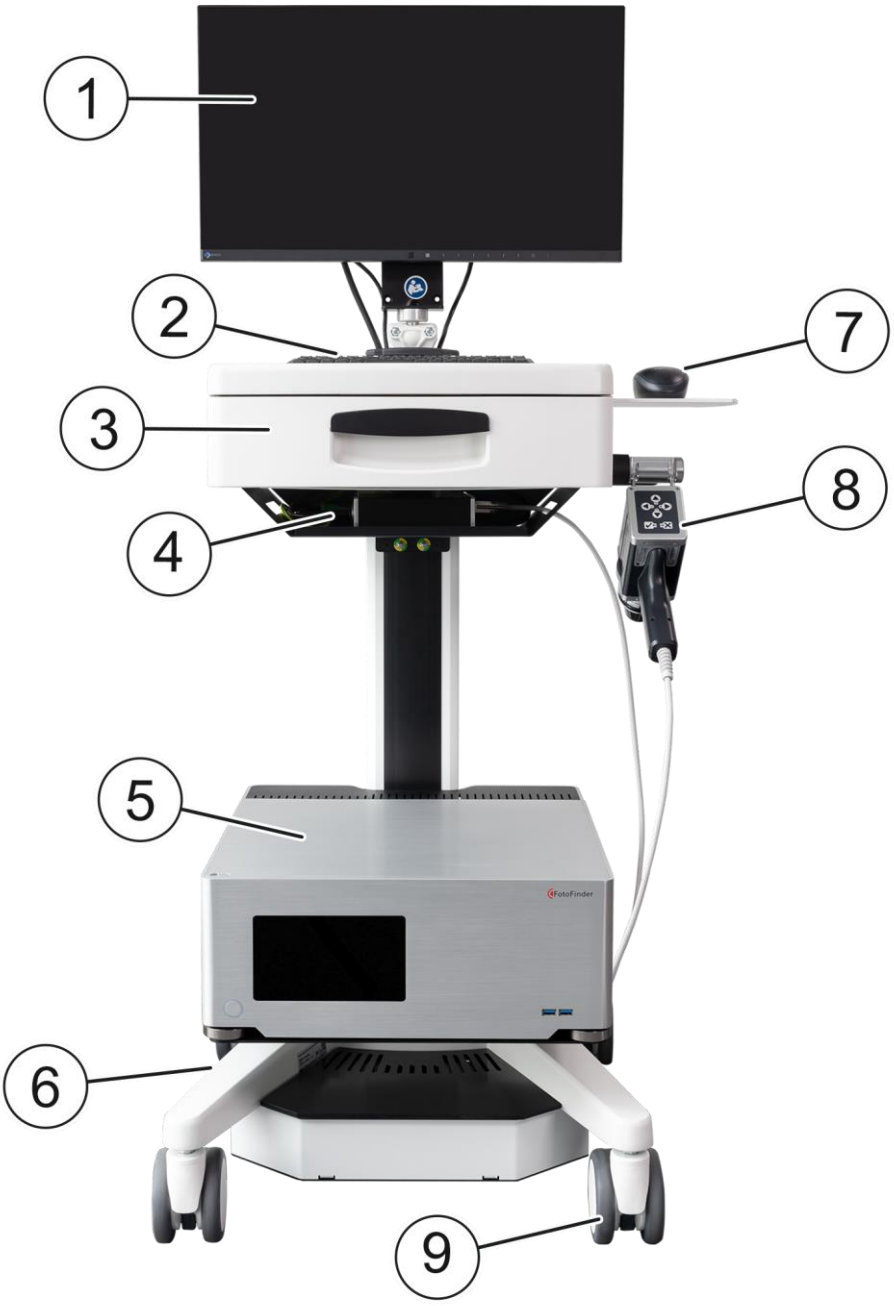


Fig. 1: FotoFinder vexia

1	Monitor
2	Keyboard
3	Drawer
4	Compartment with docking station
5	Silent Medical Server
6	Isolating transformer (with master switch and LAN port)
7	Mouse on extractable shelf
8	medicam 1000
9	Castors with locking brakes

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 dermoscope systems are intended for the non-invasive visual documentation of the surface of the skin by medical professionals. The system supports connection with the medicam or leviacam for digital non-invasive examination of intact skin (dermoscopy).

- The following applications are possible:
  - Imaging and documentation of the surface of the skin
  - Documentation of patient-relevant image data
  - Documentation of nevi
  - Non-invasive, short-term, digital dermoscopy of intact skin
- The system is designed to be used for and can only be used in combination with the FotoFinder Universe software.
- Only use the supported dermatoscopes medicam 1000 and leviacam.
- The product is intended for temporary use up to a maximum of 60 minutes per session.

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!

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

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.
- In the event of improper transport contrary to the instructions, the device may tip over or collide with other objects / persons and can cause injury to the person or operator, or result in damages to equipment and property.
- Moving parts on the system (e.g. monitor, camera positioning system, camera slide and drive belt) can cause 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 7 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.

FotoFinder vexia

Cable	Type	Length
HDMI	Isolated	1,5 m
LAN (RJ45)	Isolated	0,5 m
USB	Isolated	< 1,8 m
Power input cable	V-Lock	< 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.

3.13 Moving the mounted device

Basically, the built-up device should not be moved unnecessarily, as it could get damaged. Should it nevertheless be necessary, please note the following:

The cart has a weight of 58 kg / 128 lbs. Therefore tilting and lifting for ergonomic reasons are out of the question. If the system needs to be lifted, several people are required and it can be lifted at the base (see red arrows on the image below).

⚠ WARNING

Only push the device by holding on to the front of the drawer, not by the monitor or monitor stand. Otherwise the structure might break.

⚠ WARNING

Make sure that the brakes are released on the wheels, otherwise the cart might tip over.

⚠ WARNING

Under no circumstances stand on top of the PC or PC stand. The structure might break.

Corresponding labels can also be found on your device (cf. chapter 1.5 Explanation of the symbols).

3.14 Maximum load of the components

The maximum load of the individual device components must not be exceeded, otherwise the device could be damaged. Please keep to the specified load limits. You will also find these on the corresponding labels on your device.

Keyboard tray	10 kg / 22 LB
Compartment	3 kg / 6,6 LB
Silent Medical Server	2 kg / 4,4 LB
Silent Medical Server tray	12 kg / 26,5 LB
Monitor bracket	14 kg / 30,8 LB
Camera mount for the medicam	8 kg / 17,6 LB
Cart base	65 kg / 143,3 LB

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.

⚠ WARNING

The individual components of the system must not be connected directly to a socket. The connection must only be made using the device power supply and the isolating transformer. Otherwise, there is a risk of electric shock.

⚠ 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

Only use power supply cables with V-Lock locking mechanism. This way any unintentional interruption of the power supply can be prevented.

⚠ 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.

ATTENTION

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

ATTENTION

Before commissioning, make sure that the locking mechanism on the castors (brakes) are working. When you have reached the park position and when stopping during transportation, all the brakes on the device trolley must be applied.

4.1 Delivery scope

Your FotoFinder product is dispatched as largely assembled. However, before commissioning, the following parts have to be attached and cabled. This task is performed by the respective FotoFinder consultant or the FotoFinder distributor.

- medicam
- Mouse and keyboard as required

NOTE

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

NOTE

Do not plug any additional device onto your system!
Please consult with the manufacturer if you wish to plug any additional devices.

4.2 Connections on the system cart

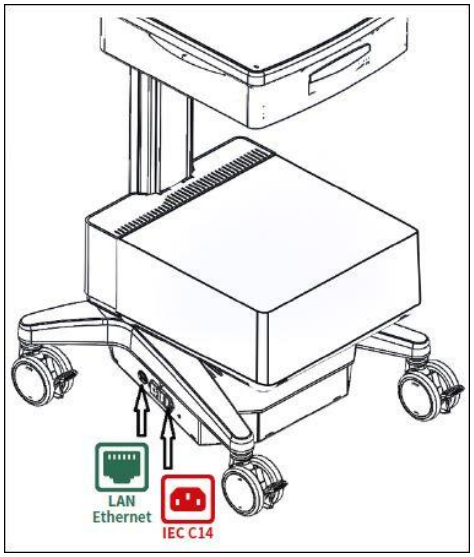


Fig. 2: Connections on the cart

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.

4.2.2 LAN connection

You will find the central Ethernet network port on the side of the device at the bottom, next to the master switch.

Please use this central network port on the device to connect external network cables. It is marked as *RJ45 LAN*. For reasons of electrical safety, never connect the network cable directly to the Silent Medical Server.

4.2.3 Power supply plug

The IEC C14 mains supply is on the side of the device on the bottom.

4.3 Main voltage settings on the system cart

The device can be operated with a supply voltage of 115 V or 230 V.

ATTENTION

Switch off the device and unplug the device's power cable before you change the supply voltage on the device.

The supply voltage can be set on the voltage selector on the isolating transformer.

The following fuses can be used:

Device	Fuse	
	115 V supply voltage	230 V supply voltage
FotoFinder vexia	T 4.0A	T 2.0A

4.4 Use in a network

- It is possible to operate the system in a network with several FotoFinder Universe clients.
- The FotoFinder vexia® includes a galvanic network isolator as per IEC 60601-1.

NOTE

For more information, please contact FotoFinder support: support@fotofinder.de.

5 Operation

ATTENTION

Under no circumstances stand on top of the PC or PC stand. The structure might break.

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.

ATTENTION

Do not use the USB connection to charge mobile phones, Smartphones and Tablets.
Only use the USB connection for updates and reading out log files.

5.1 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. Also check the castors on the device to make sure they run freely.
7. Check the system regularly according to the valid rules of technology, but at least every 12 months.

5.2 Switching on the device

1. Connect the device to the power supply.
2. Switch the master switch at the bottom left of the system trolley to *On*.

The indicator lamp for the voltage supply above the master switch now lights up in green.

3. Press the On/Off button at the front of the Silent Medical Server (computer).

The computer boots. You can tell this by the active logo on the front on the computer monitor.

4. Start FotoFinder Universe*.

NOTE

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

5.3 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.

6 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.

6.1 Cleaning the device

- Before cleaning, disconnect the entire system from the power supply.
- Clean the case, control panels, control elements and the screen with a soft cloth moistened slightly with a mild detergent.

6.2 Disinfection of the device

- Commercially available disinfectants that are approved for surface disinfection or disinfection wipes can be used. The disinfectants must be applied and used as pure wipe disinfection according to the manufacturer's instructions.
- If a complete disinfection is necessary, the mounted parts can be disassembled by a specialist and disinfected in this state by wiping.

7 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.
- The FotoFinder vexia® is equipped with dual swivel castors and brakes. These must be checked every 12 months to ensure that they are safe, and that the castor fastening bolt is firmly in place without a gap.
- 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.

8 Malfunction and troubleshooting

NOTE

Please always observe all safety instructions in this manual!

8.1 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.

NOTE

For replacements or for repairs parts and necessary documents are available on request from the manufacturer.

8.2 Problems with the hardware

8.2.1 **Computer won’t start**

- Check the power switch on the rear.
- Check the plug connection of the power cable for correct fit.
- Press the power switch on the front (the indicator light should be blue).
- To minimise power problems, plug the system directly into a fixed power outlet.

8.2.2 Monitor has a black screen

- Check the ON switch on the front and rear of the monitor
- Check the cable and the connections between the monitor and the computer
- Check the signal (DVI, VGA or Display Port), press the "S" button on the front of the monitor several times until it is set correctly
- To minimize power problems, connect the vexia system directly with an installed power socket

8.2.3 The isolating transformer when the system has no power

- Check the following points one after the other:
  - the green control light on the isolating transformer is on
  - the switch on the isolating transformer is on
  - all cables are correctly plugged in on both ends
  - the wall / floor socket has electricity (e.g. check with another device)
- Check or replace the two fuses on the isolating transformer if necessary. Replace the fuses with equivalent replacement fuses. Such fuses are enclosed on the isolating transformer under the black plastic cover. Contact a qualified personnel for this purpose. The fuse holder may only be removed when the mains plug is disconnected.
- Try an alternative connection cable with V-Lock locking system (against unintentional pull-out of the C13 plug).

9 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.

10 Glossary

FotoFinder leviacam*	FotoFinder's USB camera for capture and examination of lesions
FotoFinder medicam*	FotoFinder's digital video camera for capture and examination of lesions
FotoFinder Universe*	FotoFinder user software
HD	High definition
ID	Identification number for the TeamViewer software

NOTE

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

11 Appendix

FotoFinder

Die einzelnen Produkte, sowie das gesamte System sind nicht steril, weswegen keine Sterilisierungs-Prozesse anwendbar sind.

The individual devices, as well as the system are non-sterile, which is why no sterilization procedures are applicable.

FotoFinder Systems GmbH Industriestr. 12 84364 Bad Birnbach Germany

Bad Birnbach, 01.06.2021

Julian Mayer, Authorized Officer

FotoFinder

SYSTEMERKLÄRUNG
SYSTEM DECLARATION

FotoFinder Systems GmbH
Industriestraße 12
84364 Bad Birnbach
Deutschland

SRN: DE-MF-000007084

Wir erklären hiermit, dass nachstehende medizinische und nicht-medizinische Produkte

We declare that the following medical and non-medical devices

Gerät / Device	Basic UDI-DI (if applicable)
Medizinischer / Medical PC "FotoFinder Silent Medical Server"	*Nicht anwendbar / not applicable*
FotoFinder medicam 1000s mit Zubehör / including accessories	426015845MC001WG
FotoFinder Universe (Version 3)	426015845FFU001XY
Gerätewagen / mobile cart "vexia"	*Nicht anwendbar / not applicable*
Bildschirm / Monitor	*Nicht anwendbar / not applicable*
Trenntransformator / Isolating Transformer	*Nicht anwendbar / not applicable*

zu einem medizinisch elektrischen System in einer Weise, die mit der Zweckbestimmung der Produkte kompatibel ist, gemäß Art. 22 (EU) 2017/745 kombiniert werden:

are combined to a medical electrical system in a manner that is compatible with the intended purpose of the devices by means of Art. 22 (EU) 2017/745:

"FotoFinder vexia"

Basic UDI-DI: 426015845FFS001XJ

Um die Konformität dieser Kombination zu beweisen, haben wir

In order to prove conformity of this combination, we

1. die gegenseitige Vereinbarkeit der Medizin- und gegebenenfalls sonstigen Produkte entsprechend den Hinweisen der Hersteller geprüft und ihre Tätigkeiten entsprechend diesen Hinweisen durchgeführt
   verified the mutual compatibility of the devices and, if applicable other products, in accordance with the manufacturers' instructions and have carried out their activities in accordance with those instructions;
2. das System verpackt und die einschlägigen Benutzerhinweise angegeben, unter Einbeziehung der Informationen, die vom Hersteller der Medizin- und sonstigen zusammengestellten Produkte bereitzustellen sind,
   packaged the system and supplied relevant information to users incorporating the information to be supplied by the manufacturers of the devices or other products which have been put together
3. die Zusammenstellung von Medizin- und gegebenenfalls sonstigen Produkten zu einem System unter Anwendung geeigneter Methoden der internen Überwachung, Überprüfung und Validierung vorgenommen.
   verified and validated the activity of combining devices and, if applicable, other products as a system by appropriate methods