

## Information of performance and safety

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FotoFinder products facilitates quick documentation in the areas

- Development documentation of illnesses
- Dermoscopy
- Trichoscopy
- Capillaroscopy and
- Inflammoscopy
- Aesthetics

This technical manual provides you with basic information on safe use and performance of the products.

### 1 Performance of the devices

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#### 1.1 Intended Use

The FotoFinder products 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 system is designed to be used for and can only be used in combination with the FotoFinder **Universe** software.

The products are designed for transient use with a maximum use of 60 minutes.

Do not use on injured skin, mucous membranes or in body orifices.

#### 1.2 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

#### 1.3 Use environment

The product is intended to be used in a professional healthcare environment (e.g. clinic, hospital) by the users described in the chapter User groups. The product is not intended for lay use.

Requirements for the physical as well as technical environment of use can be found in the corresponding chapter (1.10 Requirements for using the device).

There are no additional requirements to the social or clinical environment.

#### 1.4 Patient population

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

- General persons with skin lesions
- People with high risk of skin cancer / family history of skin cancer
- 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 FotoFinder software.

### 1.5 Indications and contraindications

The systems are intended for the conditions mentioned in chapter patient population. For a detailed list of ICD codes, please reach out to [info@fotofinder.de](mailto:info@fotofinder.de).

The following body parts are intended to be examined with the FotoFinder medicam 1000 and FotoFinder leviacam:

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

The devices are not intended to record images from mucosa, eyes and natural or artificial body orifices.  
The devices are not intended to record images from injured skin.  
The devices do not carry out a diagnosis. The diagnosis is in the responsibility of the medical professional!

### 1.6 Improper use

- Any use different to those contained in the *Intended use* and in these operating instructions and any additional use are considered unauthorized!
- 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 device in any form.
- It is prohibited to bypass the safety facilities when operating the device.

### 1.7 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
- 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

## 1.8 System components and technical data

### FotoFinder medicam



The video dermatoscope medicam 1000, together with the FotoFinder Universe software, enables both overview and microscopic images to be created. Depending on the image type, the medicam is used with or without the microscopic lens.

- The camera is designed with a built-in LED floodlight. This allows creating excellent overview images from up to 100 cm distance.
- The camera can be operated to a large extent via the control panel on the back and the shutter release in the camera handle, or optionally via the software.
- The **medicam 1000** is equipped with two distance holders for close-up overview images. The two fixed distances enable standardized close-up images and simplify subsequent image segmentation.

### Technical information

Model:	FotoFinder <b>medicam 1000</b>
Power supply:	12 V DC
Power consumption:	15 Watt
Protection class:	1
Classification of the application part:	B
IP Protection class:	IP20
Operating temperature:	0 - 25°C
Relative humidity*:	20-90%, noncondensing
Air pressure*:	min. 80 kPa to max. 107 kPa from -425m to 2000m a.s.l.
Transport and storage temperature:	0 – 40°C
Image caption element:	1/2.8 Type CMOS
Pixel count (effective):	approx. 2.000.000 pixels
S/N ratio:	more than 50dB
Minimum illumination:	min 0.1 lux/F1.6
Electronic shutter:	1/1 to 1/10.000 sec., 22 stages
Resolution:	1920 x 1080 pixel
Image format:	16:9
Closest distance without micro lens:	wide 1 cm, tele 120 cm
Zoom:	140x
Optical Zoom:	yes
Illumination:	LED
Connection:	Lemo Push-Pull Connector B Series
Cable length:	300 cm
Weight (without attachment):	approx. 0.7 kg
Transport/Packaging:	The device is shipped in a box with the following parameters: 44 x 32 x 28 cm, Total weight: max. 9 kg

\*valid for operation, transport and storage

### Accessories:

With FotoFinder medicam 1000 the following accessories can be used:

- |             |  |
|-------------|--|
| D-Scope III | <ul style="list-style-type: none"> <li>▪ Enables optical magnification up to 400x</li> </ul>   |
| D-Scope IV  | <ul style="list-style-type: none"> <li>▪ For polarized and unpolarized micro imaging</li> <li>▪ enables optical magnification up to 140x</li> <li>▪ different front caps: closed, open, conical</li> </ul> |

### FotoFinder Docking Station



### Technical data

Model:	FotoFinder Docking Station 1000
Input power:	DC 12 V
Power consumption:	15 Watt
Protection class:	1
IP Protection class:	IP20
Power supply unit:	Manufacturer: Adapter Technology Co., Ltd., model: ATM036T-P120
Safety connection:	Equipotential bonding pin
Operating temperature:	0 - 25°C
Relative humidity*:	20-90 %, non-condensing
Air pressure*:	min. 80 kPA to max. 107 kPA from -425m to 2000m a.s.l.
Transport / storage temperature:	0 - 40°C
Transport/Storage:	dry room, do not subject to moisture, protect from dust
Compatibility with FotoFinder cameras:	medicam 1000
Weight (including USB cable)	1.3 kg
Required PC Hardware:	USB 3.0 Type-A

\*valid for operation, transport and storage

### **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.

## FotoFinder leviacam



Used together with the FotoFinder **Universe** Software, the **leviacam** camera can create overview and microscopic images.

- The camera is equipped with an integrated LED floodlight and LED micro-illumination (polarized and non-polarized) as default.
- Integrated floodlight illumination allows you to take excellent overview images at distances of up to 80 cm.
- The microscopic images made with the **leviacam** are created with 20x magnification.
- The camera can be controlled to a large extent via the buttons on the back, or optionally via the software.
- The leviacam is supplied with the **leviabase** camera mount for safe storage.

### Technical data

Model:	FotoFinder <b>leviacam</b>
Protection class:	1
Classification of the application part:	B
IP Protection class:	IP20
Operating temperature:	0 - 25°C
Relative humidity*:	20-90%, noncondensing
Air pressure*:	min. 80 kPA to max. 107 kPA from -425m to 2000m a.s.l.
Transport / Storage temperature:	0 - 40°C
Image pickup device	1/2.45 Type CMOS
Number of effective pixels:	approx. 13,190,000 pixels
S/N ratio:	more than 50dB
Minimum illumination:	min 6 lux
Electronic shutter:	1/25 to 1/5.000 sec., 24 stages
Resolution/Image format:	Full HD: 1920 x 1080 Pixel/ 16:9 5MP: 2592 x 1944 Pixel/ 4:3 8MP: 3264 x 2448 Pixel/ 4:3 13MP: 4128 x 3096 Pixel/ 4:3
Closest distance without micro lens:	100 cm
Zoom:	20x
Optical zoom:	no
Power supply:	5 V DC
Illumination:	LED
Connection:	USB 3.0 Type A
Weight with reflected-light microscope attachment (without cable):	approx. 220 g

\*valid for operation, transport and storage

### Beware of magnetic field

Never apply the **leviacam** without **levialens** directly on pacemakers or implanted cardioverter defibrillators (ICDs).

## FotoFinder vexia

The FotoFinder **vexia** is a flexible imaging system for dermoscopy and trichoscopy. It enables standardised patient images of skin, hair and nails in combination with the FotoFinder medicam 1000.



### Technical Information

<b>Model:</b>	FotoFinder <b>vexia</b>
<b>Supply voltage/Frequency:</b>	AC 115 V / 230 V / 47-63 Hz
<b>Power consumption:</b>	max. 350 Watt
<b>Protection class:</b>	1
<b>IP Protection class:</b>	IP20
<b>Operating temperature:</b>	0-25°C
<b>Relative humidity*:</b>	20-90%, non-condensing
<b>Air pressure*:</b>	min. 80 kPA to max. 107 kPA from -425m to 2000m a.s.l.
<b>Transport / Storage temperature:</b>	0 - 40°C
<b>Transport/ Packaging:</b>	The device is shipped upright on a pallet by a spedition company. The package has the following dimensions, including pallet: 85x80x140 cm Packet weight: 75 kg
<b>Transport/ Storage:</b>	dry room, do not subject to moisture, protect from dust
<b>Software requirement:</b>	FotoFinder Universe Software 2.0.41 or newer
<b>Compatibility with FotoFinder cameras:</b>	medicam 1000

\*valid for operation, transport and storage

## FotoFinder bodystudio ATBM



Automated Total Body Mapping with the **bodystudio ATBM®** tower allows the rapid, standardized documentation of the entire surface of the skin of patients at risk of developing skin cancer. The software guides the user through 20 specified positions. The system is further optimized to document psoriasis and aesthetic face and body treatments. This is made particularly easy with the camera's software control, a standardized distance with a laser line and the positioning mat.

- Analysis with **Bodyscan** is only permitted for adult patients, as it is otherwise not possible to guarantee correct documentation, due to changes in body height.
- The classification of the **Bodyscan** results is based on statistical analyses and does not replace an expert medical diagnosis. The diagnosis is the responsibility of the doctor.

### NOTE

You can use the following system components in the immediately vicinity of and in contact with the patient:

- medicam
- Positioning mat (patient positioning)

### Technical information

Model:	FotoFinder bodystudio ATBM master
Supply Voltage/Frequency:	AC 115 V / 230 V / 47-63 Hz
Power consumption:	max. 350 Watt
Protection class:	1
IP Protection class:	IP20
Operating temperature:	0-25°C
Relative humidity*:	20-90%, non-condensing
Air pressure*:	Min. 80 kPa to max. 107 kPa from -425m to 2000m a.s.l.
Transport / storage temperature:	0 – 40°C
Transport/ Packaging:	The device is shipped upright on a pallet by a freight company. The package has the following dimensions, including pallet: 90x90x210 cm Total weight: 125 kg

**Transport/ Storage:** dry room, do not subject to moisture, protect from dust  
**Software requirement:** FotoFinder Universe Software 3.1 and higher  
**Compatibility with Canon cameras:**

- Full-frame:**
- Canon EOS 6D Mark II
  - Canon EOS 5Ds
  - Canon EOS R
- Lens:**
- Sigma 50 mm F1.4 DG HSM | Art
  - Canon EF 24-105 mm f/3.5-5.6 IS STM
  - Canon RF 50 mm F1.8 STM
  - Canon RF 24-105 mm f/4L IS USM

\*valid for operation, transport and storage

### Laser Liner

The **Laser Liner** enables reproducible, exact patient positioning by projecting a red line on the floor.

#### Technical information

<b>Model:</b>	FotoFinder <b>Laser Liner</b> (USB)
<b>Wavelength:</b>	650 nm (visible)
<b>Output:</b>	5 mW
<b>Beam duration:</b>	<1.5mm@3m
<b>Laser class:</b>	Class 1 Laser Product according to DIN EN 60825-1:2008-05
<b>Angle of aperture:</b>	20 degrees
<b>Working range:</b>	5 m
<b>Thermal stability:</b>	0°- 50° celsius
<b>Input:</b>	5,0 Volt via USB
<b>Housing material:</b>	polyamide



**⚠ CAUTION**

Looking directly into the laser beam of the Laser Liner can lead to temporary irritation of the field of view.  
 Never look directly into the laser beam.

### PolFlash XE

The **PolFlash XE** is the flash unit on the FotoFinder **bodystudio ATBM master** system. It enables cross-polarized, reflection free images as well as non-polarized images with studio lighting.

**⚠ CAUTION**

The camera's flash may trigger seizures in people suffering from epilepsy or other light-sensitive ocular or nerve diseases.  
 People with these pre-existing conditions may not be subjected to the ATBM flash.

## FotoFinder studio

The FotoFinder **studio** is a turnkey imaging system for face and hair imaging with an electrically height-adjustable workstation. It enables standardized and comparable patient images in the areas Dermatoscopy, Aesthetics and Trichoscopy.



### The shiftable portrait stand

For images of the face and scalp area (aesthetics and trichoscopy), the system uses a moveable portrait stand with the PolFlash flash system and a head and chin support for the patient. These allow the user to take standardised images of the head and face area in a 180° degree radius.



On the stand base there are 5 grid positions (L90°, L45°, 0°, R45°, R90°). These enable standardized and therefore comparable patient imaging.

The use of the system is designed for the FotoFinder **Universe** or TrichoLAB software and can only be used with one of the software or a combination of both.

### Technical Information

Model:	FotoFinder <b>studio</b>
Supply voltage/Frequency:	AC 115 V / 230 V / 50-60 Hz
Power consumption:	max. 300 Watt
Protection class:	1
IP Protection class:	IP20
Operating temperature:	0-25°C
Relative humidity*:	20-90 % non-condensing
Air pressure*:	min. 80 kPA to max. 107 kPA from -425m to 2000m a.s.l.

<b>Transport/ Packaging:</b>	The delivery of the device is carried out by spedition, and it is laid on its side on a pallet. The package has the following external dimensions including pallet (LxWxH) [cm]: 120x80x120 Total weight: 150 kg
<b>Transport/ Storage:</b>	dry room, do not subject to moisture, protect from dust
<b>Compatibility with the Canon SLR cameras:</b>	Canon EOS 800D Canon EOS 850D Lens: Canon EF-S 18-55 mm 1:4 - 5.6 IS STM
<b>Compatibility with FotoFinder cameras:</b>	medicam 1000, leviacam

\*valid for operation, transport and storage

### NOTE

You may use the following system components in direct contact with the patient, if they are included in your system configuration:

- Chin rest and head stand
- medicam
- leviacam

## 1.9 Software

### FotoFinder Universe

FotoFinder **Universe** is a standalone software intended for:

- acquiring, processing, annotating, comparing and visualizing microscopic and macroscopic images of the human skin by medical professionals and dermatologists
- storing and managing images, patient and user data
- the standardized documentation of the intact skin surface and skin changes over time for pre-assessment and diagnosis support of skin conditions
- allowing the combination, communication and exchange of data with hardware devices and software manufactured by FotoFinder

### FotoFinder Moleanalyzer pro

FotoFinder Moleanalyzer pro is a software, which is intended to be used in addition to FotoFinder Universe. It is intended for the assessment of clinically atypical cutaneous pigmented lesions with one or more clinical or historical characteristics of melanoma. FotoFinder Moleanalyzer pro is designed to be used when a dermatologist chooses to obtain additional information for a decision to biopsy. FotoFinder Moleanalyzer pro should not be used to confirm a clinical diagnosis of melanoma. The Moleanalyzer pro offers assessments by indicating parameters for the commonly used 3-Point Checklist, 7-Point Checklist or ABCD rule to classify lesions (Asymmetry, Borders, Color and Structures).

Optionally, the software uses a convolutional neural network (CNN) algorithm to generate a risk score (AI Score). This AI Score indicates the similarity to malignant lesions by generating a value, which is assigned to different categories. In addition, the software generates a score which indicates the similarity to melanocytic skin lesions. This assessment supports dermatologists in the classification of different types of skin cancer. The accuracy of the algorithm is comparable to the performance of dermatologists.

The **Moleanalyzer pro** only supports microscopic images of a lesion. The software is not intended to support pre-assessment of images from acral skin, mucosa, eyes and natural or artificial body orifices.

The software does not diagnose a disease. This pre-assessment is only applicable to the diseases listed in the indications. Do not use the AI Score for assessment of lesions with a diameter of < 2 mm or > 20 mm.

Do not use the AI Score for the evaluation of lesion on hairy area or in locations near contaminations or markings (e.g. tattoos) within an area of 30 mm.

The algorithm was trained with images of Fitzpatrick skin type I-III. Do not use the AI Score on patients with skin type IV or higher, as the performance of the algorithm was not assessed and therefore the accuracy of the algorithm cannot be claimed.

**Moleanalyzer pro** is only intended to be used on lesions captured on intact skin. Do not assess lesions located in areas of psoriasis, eczema, acute sunburn or similar skin conditions.

Scale bars in micro images might have a negative effect on the CNN's accuracy.

## AI

The FotoFinder Moleanalyzer pro uses a Convolutional Neural Network (CNN) algorithm for the so-called AI-Score. The sensitivity as well as the specificity of the algorithm were proven in a clinical study.

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### NOTE

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The AI-Score can be requested for images with 20x magnification.  
The lesion must completely be in the image frame.  
For manually calibrated images the AI-Score result shall be considered with reservations.

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- The AI-Score is based on comparisons with images of malignant skin tumours (Melanoma, Basal Cell Carcinoma, Lentigo Maligna, Squamous Cell Carcinoma, Actinic Keratosis). The score indicates how similar a lesion to a typical malignant skin tumour is.
- The AI-Score does not assess the malignancy of the examined lesion! It only provides an estimate of whether a lesion is possibly malignant.

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### NOTE

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The AI-Score is based on statistics. The accuracy of the AI-Score can therefore not be guaranteed and it is intended only as an additional, supportive assessment tool for the physician.  
The AI-Score is not a substitute for the physician's overall clinical diagnosis!

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## FotoFinder mobile

FotoFinder mobile is a mobile application that works in conjunction with the FotoFinder Hub online cloud. The application is designed for patient management, standardized documentation of microscopic images, and to assist in the initial assessment of skin conditions. FotoFinder mobile enables digital documentation of intact human skin by healthcare professionals. The microscopic images are stored together with the relevant patient data, which makes it possible to visualize changes in lesions during subsequent follow-up examinations of the patient.

The FotoFinder application is used in combination with hardware imaging devices, which allow to capture microscopic images using a mobile device.

The following features are available:

- ⇒ Acquisition and management of patient data
- ⇒ Capturing and managing microscopic images
- ⇒ Documentation of patient examinations
- ⇒ Assigning images to a patient
- ⇒ Assigning a localization to an image
- ⇒ Requesting a second opinion (Second Opinion) from experts (not for all variants)
- ⇒ Request AI score (Artificial Intelligence)

FotoFinder mobile connects online with the Moleanalyzer pro algorithms to generate the AI score.

The connection to the FotoFinder Hub allows to use a second opinion service (not for all variants). These functions are only accessible via paid subscriptions. Subscription management is only available through a FotoFinder Hub account. The app data is synchronized, stored and managed via this cloud solution.

FotoFinder mobile is intended for the documentation of skin lesions. The app must not be used to make or confirm a clinical diagnosis of melanoma, any other skin disease or skin cancer.

The application does not provide a diagnosis. The AI score is based on statistics. The diagnosis and therapy decision are the responsibility of the physician!

The application is intended for transient use. In combination with the hardware imaging device, the product is in continuous use for less than 60 minutes during a diagnosis session.

## NOTE

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FotoFinder mobile is a product group which includes different mobile applications, such as the handyscope pro application or the skreen software.

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## FotoFinder Hub

FotoFinder Hub is a cloud-based image storage platform for mobile dermatoscopes. The purpose of FotoFinder Hub is to store and display images, patient information and analysis results. FotoFinder Hub is intended for the documentation of microscopic and macroscopic images of the intact human skin and to visualize skin changes over time. The FotoFinder Hub is not intended to provide a diagnosis, as it is the responsibility of the physician. FotoFinder Hub is intended to communicate with other FotoFinder software and exchange data. The FotoFinder Hub is intended to administer subscription and user management.

## 1.10 Requirements for using the device

### Minimum configuration of the computer

The system is delivered with a perfectly configured **Silent Medical Server** as standard. The recommended configuration for a self-acquired system is specified below.

- CPU
  - 2.50 Ghz
  - Quad-Core (4 cores / 8 threads)
  - CPU-Generation not older than 5 years
  - x86-64 architecture
- RAM
  - 16384 MB (16 GB) RAM
- Graphic card (only for ATBM master and studio)
  - integrated graphic card
  - 1 GB RAM
- Hard drive
  - 500 MB/s, e.g. M.2 SSD with 6 Gbit/s for Operating System
  - 500 GB free memory space
- Monitor
  - 1920 x 1080 px, 24"
  - 3840 x 2160 px, 27"
- Operating system
  - Microsoft® Windows® 10 Pro, 64 bit
  - Microsoft® Windows® 11 Pro, 64 bit
- Protection e.g. malware, firewall

### 1.11 Requirements for the recording room

**General requirements:**

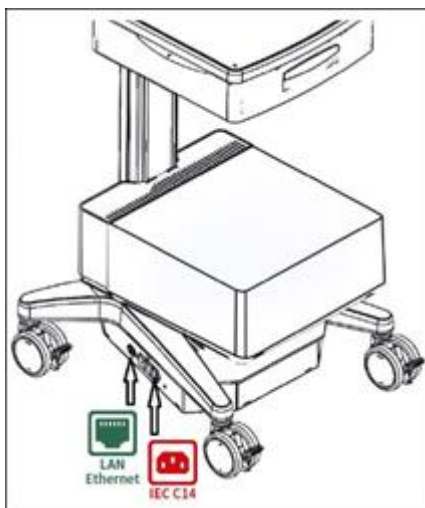
- Only use the device in bright and well illuminated rooms. Avoid direct sun light.

**FotoFinder bodystudio ATBM master:**

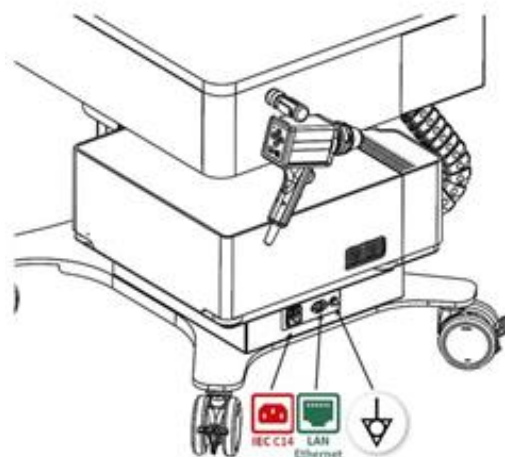
- As background for the photo documentation, you should only use monochrome, non-reflecting and the smoothest possible surfaces (monochrome dark blue photography canvas provided by FotoFinder, RAL 5022).
- The distance between the persons and the background should be as close as possible. The distance to the background should be the same during follow ups.
- It is only possible to scan patients with a height of 130cm – 200cm. Complete scanning with taller or shorter persons is not supported (irrelevant for facial imaging with the portrait stand).

### 1.12 Connection plugs on the device

FotoFinder vevia / bodystudio ATBM master



FotoFinder studio



**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)

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

**LAN plug**



The central Ethernet network plug (LAN RJ45) is located at the bottom of the device, directly next to the main switch.

### Power supply plug



**IEC C14**

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

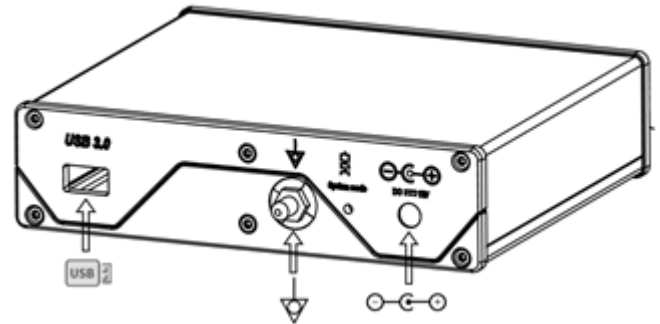
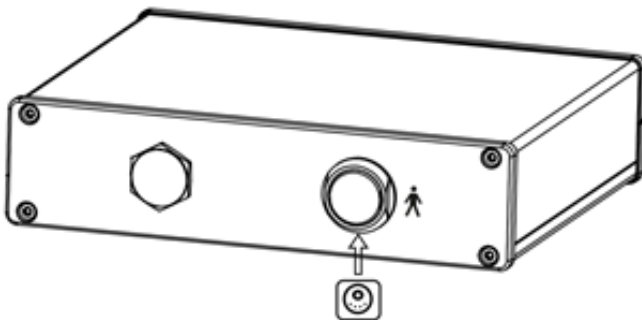
LAN / network plugs:

- RJ 45
- 10/100/1000 Mbit/s
- Networkisolator conform to IEC 60601-1 (3rd Edition)

Electrical power supply:

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

### Docking Station 1000



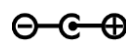
Push-Pull round plug connection:  
Socket for the connection of **medicam 1000**  
(MC1000-4)



USB A 3.0 port:  
Cable connection for connection to the PC



Connectors for potential equalization  
(POAG)



Hollow plug socket:  
Power connection

## 2 Safety of the device

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### 2.1 General

- The device is designed and constructed as state-of-the-art and in accordance with recognized guidelines and standards.
- The manufacturing of all devices is according to actual state of ISO 13485
- However, the device may be hazardous under the following circumstances, if
  - the device is not used as intended.
  - the device is improperly operated by untrained or uninstructed personnel.
  - the device is improperly repaired or maintained.
  - the safety instructions and warnings in these operating instructions are not observed.
  - the device is improperly modified or converted.
  - prescribed maintenance is not conducted in due course.

### 2.2 Notes on the use

- The device should only be operated by qualified and instructed persons.
- The unit can only be used, operated and maintained properly and safely with the help of the operating instructions. These are enclosed with the product.
- The product must be visually inspected for damage before each use
- All devices with an earthing bolt (e.g. **Docking Station**, isolating transformer, FotoFinder **vexia**, **Tower Station**, **Silent Medical Server**) must be earthed to the potential equation rail on the system and to the domestic or industrial earth in accordance with EN 60601-1.
- Work on the unit may only be carried out by the manufacturer
- The unit may only be used in the configuration as supplied by the manufacturer.

#### WARNING

All **application parts** must be cleaned after each patient, otherwise there is a risk of infection due to poor hygiene

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### 2.3 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 products are listed below.

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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 disturbed by the emission of electromagnetic radiation from other electrical devices, or by electrostatic discharge, so that the live image is interrupted or, in the worst case, 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, this can lead to infections due to poor hygiene.

Any accessories that are not intended for the product or the modification of the system, e.g. by conversion, can lead to the device no longer being functional or being able to be used in accordance with the intended use.

During longer operation, the surface of the device may heat up.

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 patient or operator, or result in damage.

Moving parts on the system (e.g. portrait stand, monitor, camera positioning system, lifting column) can cause injuries to persons.

### **ATBM**

The laser radiation of the laser optics may cause impairment of eyesight.

For individuals with epilepsy or other light-sensitive eye and nerve disorders, the camera flash may trigger seizures.

Covering the Polflash XE flash unit with flammable materials can cause the unit to heat up and, in the worst case, cause a fire.

### **medicam / leviacam**

The magnets used in the medicam or leviacam may affect sensitive devices, e.g. pacemakers.

The use of damaged attachment caps, e.g. breakage or cracks in the material can lead to injury to the skin.

### **Software**

Improper operation by untrained personnel may result in harm to the patient.

Incorrect entry of information in the software, or incorrect assignment of patients or images by the operator, can lead to a misinterpretation. The consequences can be an unnecessary or delayed treatment of a skin condition.

Installing additional software on the PC may, in rare cases, cause the FotoFinder Universe software to stop working. If you have any questions about compatibility, please contact our FotoFinder support.

Misuse by the user cannot be ruled out despite the provision of usage information.

### **Moleanalyzer pro**

If the user bases the diagnosis solely on the results of the software (incl. AI score), it may lead to unnecessary or delayed treatment of a skin condition.

Misinterpretation of the algorithm cannot be ruled out.

### **IT Security**

The following residual risks regarding IT Security cannot be ruled out completely despite the implementation of risk control measures:

- Accessing and using another user's credentials, such as username and password (Spoofing)
- Maliciously changing or modifying persistent data and the alteration of data in transit (Tampering)
- Performing prohibited operations in a system that lacks the ability to trace the operations (Repudiation)
- Reading a file that one was not granted access to, or reading data in transit (Information disclosure)
- Attempting to deny access to valid users, such as by making a web server temporarily unavailable or unusable (Denial of Service)
- Gaining privileged access to resources in order to gain unauthorized access to information or to compromise a system (Elevation of privilege)

Those residual risks may lead to therapeutic patient data being published along with the name of the patient in the worst case.

## 2.4 Environmental conditions

- Only use the device indoors. The system must not be exposed to extreme humidity.
- When setting up the system, please ensure sufficient air supply in order to avoid an accumulation of heat in the devices. Do not close or cover the ventilation slots of the **Silent Medical Server**.
- Do not place the devices near sources of heat like radiators or in places where they are exposed to direct sunlight, unusually high dust, mechanical vibrations or shocks.
- Do not place the system near other devices which generate a strong magnetic field, such as converters or high-voltage power lines.

### CAUTION

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

## 2.5 Electrical safety

### DANGER

A device of Protection Class 1 resp. 2 - Danger of injury due to electric shock.  
Connect the device to an earthed power supply.

### DANGER

**Mortal danger due to electric current**  
**Mortal danger when in contact with live components. Results in severe injury or death.**  
Work on electrical systems may only be conducted by authorized electricians.  
Disconnect the power supply and secure against reactivation before starting any work.

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.

### WARNING

- An electric shock may occur if the system, including all externally connected devices, is not properly grounded.
- The system must only be connected to a power supply outlet that has a proper grounding conductor to avoid electric shock.

## ESD

Electrostatic discharge (ESD), commonly referred to as a static shock, is a naturally occurring phenomenon. ESD occurs most often during low humidity, whereby persons can create static electricity. 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.

## 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). This IEC standard complies with the European norm (EN 60601-1-2).

**⚠ 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.

**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.

## 2.6 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 find these in the instructions for use and on the corresponding labels on your device.

## 2.7 Maintenance

To ensure proper functioning of the system, it should be inspected by a service technician at periodic intervals to check its operational safety and functionality. The intervals should be based on the valid guidelines for safety inspections of active medical devices and is recommended to take place every 12 months.

## 2.8 Disposal

The appliance must not be disposed of in household waste. Please dispose of the product in a professional and environmentally friendly way. The respective country-specific disposal regulations must be observed.