



Instructions Manual



Capillaroscope

as supplied in Inspectis delivery kits DM-01, DM-02, MD-03 and DM-04

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General Product Information

The product is a USB3.0 digital microscope consisting of a camera unit, control electronics, illumination, optics, and mechanical parts. The product is designed to illuminate and image the intact skin for Capillaroscopy examinations.

Inspectis Digital Capillaroscope is intended for non-invasive examinations capillaries e. g. monitoring of small vessels of the microcirculation. The device is designed for use by professionals, i.e., doctors, physicians and other personnel dealing with health care.

There are no user serviceable components in the Capillaroscope. All assembly, adjustment, modification, maintenance, and/or repair must be carried out only by qualified personnel authorised by Inspectis AB.

The product must be used in accordance with this manual and all associated labelling and the Instructions for Use.

Any device that does not function as expected must be returned to Inspectis AB.

For additional information and questions, please contact Inspectis AB at +46-(0)8-270 191 or email to info@inspect-is.com.

Symbols Used in Manual

Warning, Safety hazard



This symbol indicates especially important information that is mandatory to read and observe.

Failure to comply can cause Hazards to personnel, Functional disturbances or damage to the instrument.

Dangerous optical radiation



This symbol warns against directly looking into the LED beam of the illumination equipment – either with or without optical instruments.

Failure to observe this notice poses a risk of eye damage.

Important information



This symbol indicates additional information or explanations that are intended to provide clarity.

General Instructions



Safety and Maintenance

- Avoid looking directly into the lenses when illumination is turned on.
- Do not scratch or hit optical surfaces of the device!
- Only use accessories provided or approved by Inspectis AB.
- Keep the equipment clean.
- Wipe inside and outside surfaces of the immersion oil contact adapter by a soft disinfection tissue to clean.
- Do not use alcohol to clean the immersion oil contact adapter.
- Never use Acetone or other similar strong solvents for cleaning.
- Keep the device away from direct sunlight, heat, and extreme humidity.
- Store the equipment inside its transport case when not used.



Cleaning procedures should not be performed when the device is connected to its power source. Disconnect the unit from the power source before cleaning or servicing.



This equipment is a precision optical device and shall be handled with great care!

Servicing

- Repairs may only be carried out by Inspectis or Inspectis-trained service technicians.
- Only original Inspectis spare parts may be used.

Intended Use

This product is intended for visual inspection and non-invasive examination of capillaries e. g. monitoring of small vessels of the microcirculation on intact human skin.

Transport

To prevent damage during transportation, pack the equipment and its accessories in their designated places inside the case.



Integration in third-party products

Consult Inspectis or an authorized Inspectis reseller if you intend to integrate the equipment into third-party products.

Health risks

Illumination system of the equipment is in risk group 1 according to EN 62471:2008 when used according to its intended use.



Don't look directly into the LED beam of the illumination – either with or without optical instruments for a long time. Failure to observe this notice poses a risk of eye damage.

Standard delivery kits

Nailfold Capillaroscopy System Basics DM-01:

- Capillaroscope, medical digital microscope USB3.0
- 200x High-resolution Lens with Built-in Illumination for Capillaroscope
- INSPECTIS© CAP Basics Software with report generator, unlimited use
- Immersion Oil Dropper
- Capillaroscope bench-top Holder
- Single-pedal Foot-switch for hand-free image capture
- Aluminium Carrying Case

Nailfold Capillaroscopy System Self-install DM-02:

- Capillaroscope, medical digital microscope USB3.0
- 200x High-resolution Lens with Built-in Illumination for Capillaroscope
- INSPECTIS© CAP Pro software with patient database
- Immersion Oil Dropper
- Tripple-pedal Foot-switch for hand-free image capture
- Capillaroscope bench-top Holder
- Aluminium Carrying Case

Nailfold Capillaroscopy System Pre-install DM-03:

- Capillaroscope, medical digital microscope USB3.0
- 200x High-resolution Lens with Built-in Illumination for Capillaroscope
- INSPECTIS© CAP Pro software with patient database
- Immersion Oil Dropper
- Tripple-pedal Foot-switch for hand-free image capture
- Capillaroscope bench-top Holder
- Notebook or PC, Win10/11 Professional, Turn-key
- Aluminium Carrying Case

Nailfold Capillaroscopy System Extensive DM-04:

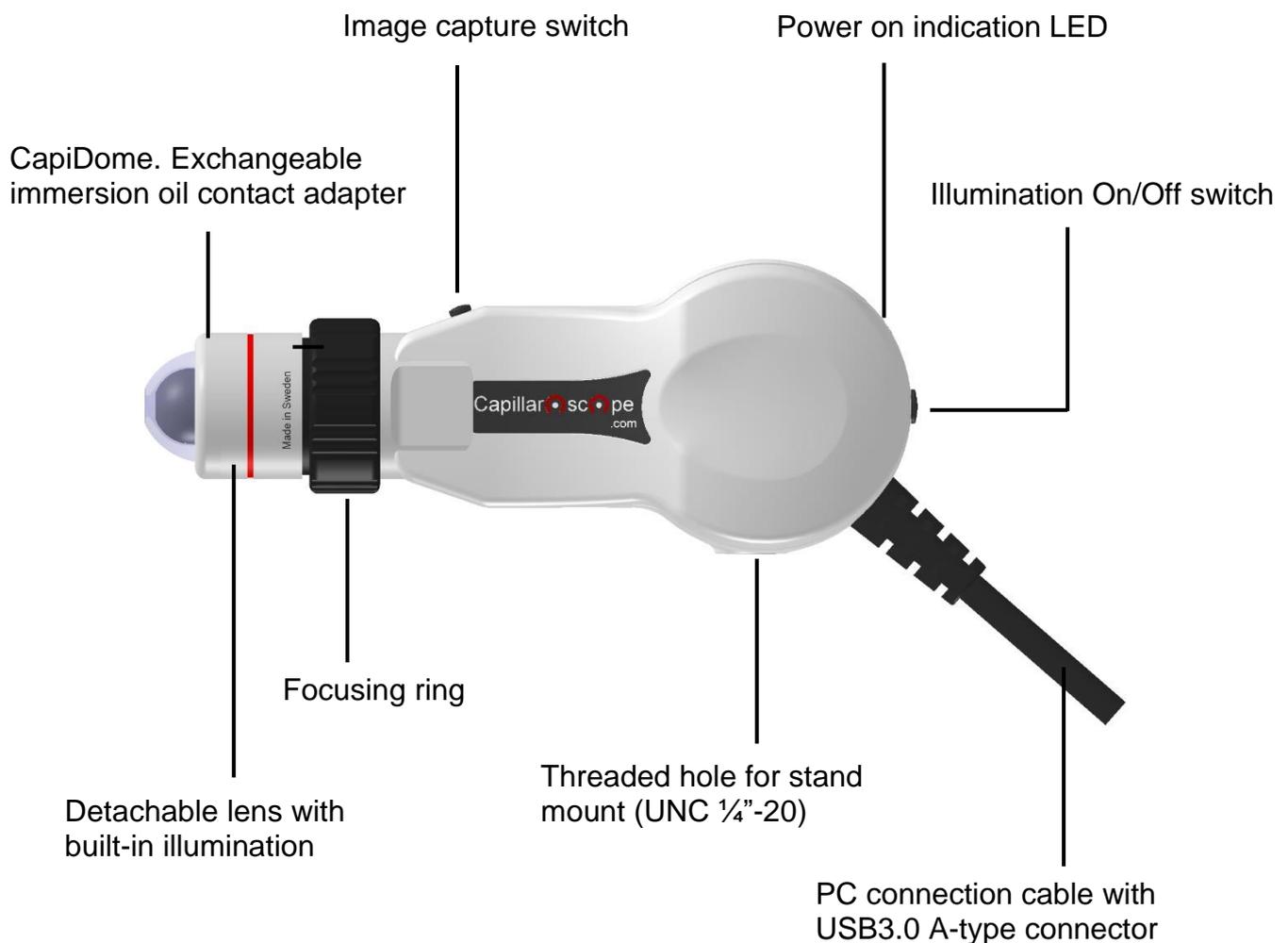
- Capillaroscope, medical digital microscope USB3.0
- 200x High-resolution Lens with Built-in Illumination for Capillaroscope
- INSPECTIS© CAP Pro software with patient database
- Immersion Oil Dropper
- Tripple-pedal Foot-switch for hand-free image capture
- Capillaroscope bench-top Holder
- Notebook or PC, Win10/11 Professional, Turn-key
- Aluminium Carrying Case
- Healthcare Cart, medical grade

Product Description

The Inspectis Capillaroscope is a hand-held digital video microscope equipped with a removable high-definition lens and built-in lighting for non-invasive capillaroscopy examinations, e.g. visual inspection and documentation of small vessels in the microcirculation.

The device is designed for use by professionals, i.e. doctors, physicians and other personnel dealing with health care.

Device structure



Cleaning after Examination

It is recommended to clean and disinfect the contact adapter (CapiDome) after each patient examination.

Unscrew the CapiDome from tip of the lens and wipe inner and outer surfaces of the contact adapter by a soft disinfection tissue.

Turn the CapiDome counterclockwise to unscrew it from the lens.



Other surfaces of the digital microscope and the lens can also be cleaned by a soft disinfection tissue.



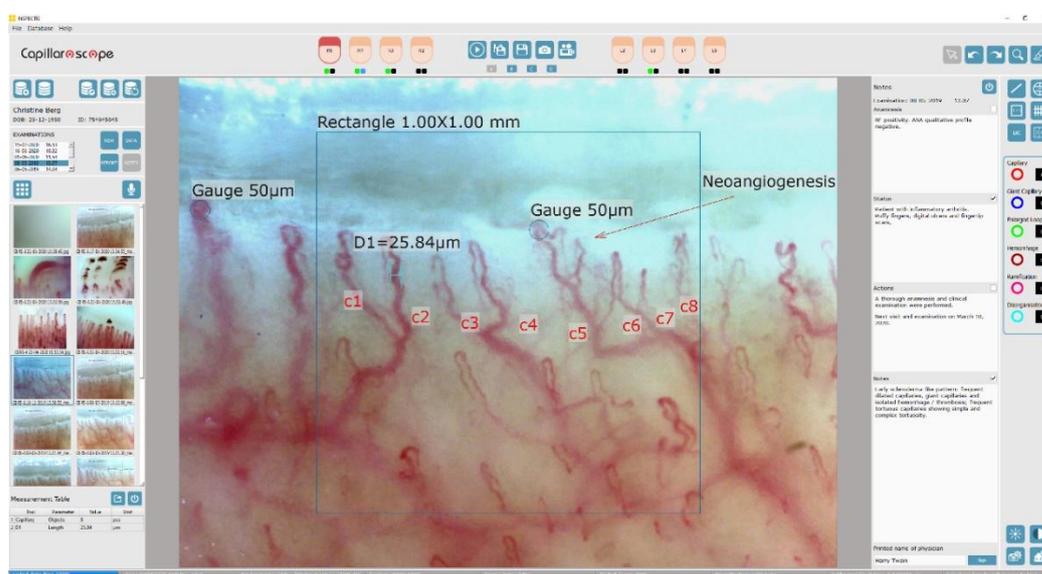
Cleaning procedures should not be performed when the device is connected to its power source. Disconnect the unit from the power source before cleaning.



Alcohol-based (isopropanol 45%) surface disinfectant with surfactant and water can be used to clean the CapiDome. The plastic material of the contact adapter will however degrade over time and CapiDome must be replaced with a new one.

Installation and Connections

- Before connecting the Capillaroscope to the computer, make sure the provided camera drivers and INSPECTIS© software are installed.
- Remove the protection caps from the Lens and the Microscope device and gently push the Lens inwards to click onto the Digital Microscope.
- Plug the Capillaroscope to an available USB3.0 port of the computer. Make sure bandwidth of the USB port is 5Gbit/s.
- Press the On/Off switch to turn on the lens light.
- On INSPECTIS©, select Capillaroscope as input device to display the live image. Use quick-access camera settings P1 or P2 for best image.
- Refer to INSPECTIS CAP Software instructions Manual for how to use the software.



For more information on how to use the INSPECTIS© software and perform patient examinations, read the software's instruction manual.

Using Capillaroscope

Apply a few drops of the supplied immersion oil to nailfold of the desired finger of the patient to be examined.

Hold the Capillaroscope as a pencil and place the lens tip on the patient's nailbed slightly angled as it shown the image below.



Focusing can be fine-tuned by adjusting the focusing ring or by angling the device towards/backwards relative to the patients nailfold.

Position numbers are printed on the focusing ring to remember the best focus next time.

Capture still images with the snap switch, by footswitch or via software.



For more information on how to use the INSPECTIS® software and perform patient examinations, read the software's instruction manual.

Specifications

Camera

#	Component	Dimension/details
1	OS compatibility	Windows 10/11
2	Video output	USB 3.0
3	Frame rate	For 15 fps: 2592x1944 (5 MP) For 22 fps: 2000 x 1500 (3MP) For 30 fps: 1920 x 1080 (Full HD) For 57 fps: 640 x 480
4	Image sensor	1/2.5" CMOS, 2592H x 1944V Pixels, 5.0 Mp (5 million pixels)
5	Resolution and formats	Default format 2000 x 1500 (3MP), 4:3 2592 x 1944 (5 MP), 4:3 2000 x 1500 (3MP), 4:3 (default format) 1920 x 1080 (Full HD), 16:9 640 x 480, (VGA) 4:3
6	Pixel size (sensor)	2.2 μm x 2.2 μm
7	Field of View 200x lens	1.68 x 1.26 mm \pm 0.05mm (HxV) at 2000x1500
8	Field of View 300x lens	1.31 x 0.98 mm \pm 0.05mm (HxV) at 2000x1500
9	Power source	The microscope takes the necessary current from USB port of the computer. Maximum 500mA.
10	Size (with lens)	135 x 50 x 37 mm
11	Weight	205 g
12	Cable length	1.8 m
13	Operational conditions	Operational temperature 5°C to 40° C Humidity 20 to 90% rH – non-condensing
14	Storage conditions	Storage temperature is -10° to 60° C Humidity 20 to 80% rH – non-condensing

Optics

#	Component	Dimension/details
1	Lens	Exchangeable 100x, 200x and 300x with LED light
2	Illumination	Integrated pure white LED ring light. Light emitted from the tip of the light guide: 1.0 \pm 0.25 lm
3	Color temperature	5800K
4	Illumination lifetime	2 years illumination warranty
5	Light safety	LED light sources do not contain ultraviolet wavelengths λ 250 to λ 400nm nor infrared wavelengths λ >770 nm. Light Intensity Safety Statement according to DOC_1832_A.

Explanation of Device Symbols



Device On/Off



Snap Image



Lot/Batch Number



Manufacturer



Waste Electrical and Electronic Equipment.



Conforms with the Medical device Directive (93/42/EEC) and has been subject to the conformity procedures laid down in the council directive.

Declaration of Conformity

Manufacturer: : Inspectis AB
Address: : Torshamnsgatan 35, SE-164 40 Kista, Sweden
Telephone no: : +46-(0)8-270 191
E-mail address: : Info@inspect-is.com
Web: : www.inspect-is.com

Type of equipment: : Digital USB Microscope
Product name: : Digital Capillaroscope
Product No: : N-001 with Lenses IN-010/IN-011/IN-012/IN-013
Basic UDI-DI No: : 735015075IN-001TW
Product Classification: : Class I
Classification Rule: : Annex VIII, Chapter III, rule 1 of the Medical Device Regulation (MDR)

Inspectis AB declares under our sole responsibility that this product meets the requirements of the Swedish law regarding medical devices and the regulations LVFS 2003:11.

The product therefore meets the requirement of the EU Medical Devices Regulation (2017/745).



System Requirements

Minimum System requirements:

Component	Minimum specification
CPU	Intel Core i5, CPU @ 2.5 GHz or faster
Operating System	Windows 10/11 (x64 version Professional, Enterprise)
Memory	16 GB or higher of RAM
Hard disk	200 GB of Free Space
Display	Laptop: 15.6" / 1920 x 1080 (Full HD) PC: 24"-27" / 3840 x 2160 (4K)
Ports	One USB 3.0 or USB3.1 or USB3.2 port (5Gbit/s) Two USB 2.0 port

Recommended computers by Inspectis:

- **Station:** HP Workstation Z2, Intel Core i7, 16 GB RAM
- **Laptop:** DELL Latitude 3520, Intel Core i7, @ 4.8 GHz, 15.6", Full HD
HP EliteBook, Intel Core i7, @ 4.2 GHz, 15.6", Full HD

Inspectis Capillaroscope is a CLASS 1 medical device.