

Colposcopes and Stands



1E LED Light

1E LED

1D LED

1DW LED

1DS LED

3MVC LED USB

3MVCW LED USB

3ML LED

3MLW LED

3MLS LED 1"

3MLS LED 1/2"

3MVS LED Y/C NTSC

Instructions for Use

English



Imprint

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Please read the instructions and information in this manual carefully before using the device!

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1 Purpose

1.1 Intended use

Leisegang colposcopes are used in gynaecological examinations to provide enlarged, non-contact visualization of the female external genitalia (vulva, vagina, vaginal portion of cervix). The colposcopes can also be used for enlarged, non-contact visualization of other external organs.

Leisegang photo / video colposcopes with integrated or externally connected camera can also be used to document the findings.

Leisegang colposcopes are intended for diagnostic purposes only. Leisegang Feinmechanik-Optik GmbH recommends that further cytological examinations be carried out to confirm the diagnosis.

1.2 Indication and field of application

Leisegang colposcopes are used in gynaecological examinations to provide enlarged, non-contact visualization of the female external genitalia (vulva, vagina, vaginal portion of cervix).

Colposcopy - cytological findings:

- Suspected carcinoma
- Suspected low- or high-grade dysplasia (abnormal appearance of the tissue structure)
- Glandular atypia (glandular epithelial atypias (abnormalities) with or without inflammation that do not fulfil the criteria of a dysplasia)
- Unclear findings of cytological smear tests (pap smear test, liquid-based cytology)
- Abnormal smear test findings in patients who suffer from immunosuppression (suppression of the body's immune defences), for example due to HIV infection or after organ transplantation

Colposcopy - other findings:

- Proven infection with HPV (human papillomavirus: Viruses that can cause cervical cancer)
- Contact bleeding (bleeding due to contact with mucous membrane, e.g. after sexual intercourse)
- Persistent blenorrhea (persistent vaginal discharge)
- Macroscopically abnormal cervix (changes are visible with bare eyes)
- Cervical polyps (benign protrusions of the mucous membrane in the cervical canal)

1.3 User and application environment

User

User group	Qualification	Activity
End users: Doctors	Specialist in gynaecology	Operation of the device
End users: Medical staff	Professional training in healthcare	Device maintenance

Application environment

Leisegang colposcopes are exclusively intended for use at medical premises.



Consider the local requirements for the electrical installation.

1.4 Contraindications

There are no known contraindications to the use of Leisegang colposcopes.

1.5 Side effects

There are no known side effects to the use of Leisegang colposcopes.

1.6 General user instructions




This manual describes the intended use and operation of Leisegang colposcopes. Assembly and repair of the colposcopes are described in the Assembly and Repair Manual.

Highlighting


















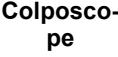



Highlighting	Function	Example
<i>Italics</i>	Reference to other sections or text passages	Please note the instructions as listed under <i>Chassis of colposcope head</i> .
Bold	Reference numbers for illustrations; for emphasis	(1)

1.7 Safety instructions

1.7.1 Meaning of symbols in this manual

Symbol	Meaning
	Necessary information for subsequent steps; notes and tips
	Safety notice 'Caution' Used to identify hazards which may result in minor personal injury or product and property damage.
	Safety notice 'Warning' Used to identify hazards which may result in serious personal injury or death.

1.7.2 Meaning of symbols on product and outer packaging

Symbol	Meaning	Symbol	Meaning
	The product complies with the regulations of the applicable EU directives (and national laws)		The product complies with US and Canadian safety requirements.
	Manufacturer's address		Date of manufacture
	Serial number of the product		Model number of the product
	Transport and store dry		Fragile; transport and store with care, do not stumble
	Permissible humidity range during transport and storage		Permissible temperature range during transport and storage
	Permissible pressure range during transport and storage		Type of protection; protection against harmful ingress of solids and water
	Transport and store with the arrows pointing up		Electromagnetic interference can occur in the vicinity of devices carrying this symbol
	Recycling of packaging materials		Separate disposal of waste electrical equipment
	Consult instructions for use		Generic device name in accordance with the Global Medical Device Nomenclature (GMDN)
	Alternating current		Direct current
	Protection class II		

1.7.3 Precautions and safety information

Read the following safety information carefully before installation and use:



- This manual is part of the device and should be kept for the entire life-time of the device.
- Keep this manual ready for consultation and pass it on to any subsequent user of the device.
- Observe the safety information related to the individual operations in the corresponding sections.
- Use the colposcope with Leisegang stands and Leisegang accessories only.
- Particles of dirt and dust may compromise the functionality of the device. Therefore, protect the device with the supplied dust cover when you are not using it. Make sure that the device is turned off before you cover it.
- There is risk of crushing when adjusting the height of the colposcope head and the swing-o-matic stand. Therefore, observe the safety instructions in the corresponding sections.
- The connecting rod of the colposcope must be inserted at least 20 cm deep into the stand frame to ensure a stable position.
- Do not dispose of your old electrical and electronic equipment with your household waste. Dispose of your old equipment in accordance with the relevant national regulations or return your old device either to your supplier or to Leisegang Feinmechanik-Optik GmbH.



- The device may only be operated in dry rooms and protected from spray water.
- The device must not be operated in an oxygen-saturated environment.
- Set up the device in a stable position.
- Do not roll the colposcope over cables or hoses on the floor.
- Do not connect any units to the device other than the intended.
- Do not lean on the device.
- Do not cover the cooling slots of the power supply unit or the cooling slots of the LED lighting. This can cause overheating and damage to the device.
- Position the device in a way to allow easy access to the power cable.
- When removing the power supply plug from the electrical outlet, pull it out by grasping the plug head.
- Do not remove the ferrite beads at the USB cables, since this may cause electromagnetic interference.
- Do not use colposcopes with defective power supply units, power cables, lamp cables or if any mechanical damage has occurred. Defective parts must be replaced by qualified and authorized service personnel. In this case please contact your supplier.
- Do not make any modifications to the device, since otherwise a safe operation of the device is no longer guaranteed and all guarantee and warranty claims against Leisegang Feinmechanik-Optik GmbH will expire.

- Always unplug the device from the electrical outlet before replacing the microfuse and before cleaning the device.
- The power supply unit is not drip or splash-proof. Penetrating water can result in electric shock. Therefore, you should take care that the power supply unit does not come into contact with dripping water while cleaning the device. Do not install any infusion devices, e.g. infusion bags, bottles and tubes above the colposcope that entail a risk of leakage.

2 Marketability

2.1 Medical device and placing onto market

According to Annex IX of the *93/42/EEC Medical Devices Directive*, Leisegang colposcopes are class I medical devices.

Leisegang Feinmechanik-Optik GmbH has provided evidence in a conformity assessment procedure according to Annex VII of the Medical Devices Directive that Leisegang colposcopes meet the essential requirements as in Annex I of this Directive.

All devices carry the CE mark, signifying compliance with these requirements. A copy of the declaration of conformity is provided with each colposcope when first delivered.

2.2 Warranty information

Leisegang Feinmechanik-Optik GmbH can only guarantee the safety, reliability and performance of Leisegang colposcopes if the user follows the instructions in this manual.

The warranty covers the repair or replacement of defective parts, as long as these defects are related to the manufacture or to the material.

The following actions will immediately void the warranty:

- Use of the colposcope other than for its intended purpose;
- Improper operation of the colposcope system;
- Defects or equipment failures that are caused by improper operation or normal wear and tear;
- Modifications or repairs of the colposcope performed by unauthorized persons;
- Non-compliance with applicable standards regarding electrical installations.

3 Device description

3.1 Essential features

All Leisegang colposcopes have the following features:

- Convergent beam path; the optical paths fall together in a working distance of 300 mm,
- 300 mm working distance,
- Green filter for observation of blood vessels(except angle devices),
- Ametropia compensation through adjustable eyepieces,
- LED lighting with an illumination intensity of 45.00052.000 lx¹ and a colour temperature between 5.7006.000 K,
- Leisegang colposcopes are designed for a service life of 10 years.

3.2 Colposcope

Front



1	Magnification changer
2	Horizontal drive
3	Connecting rod
4	Vertical drive
5	Thread for mounting plate
6	Front lenses
7	Lens

Back



8	LED lighting unit
9	Green filter
10	Clamp nut for tilt adjustment
11	Lamp cable
12	Eyepieces
13	Prism bodies

¹ 23.000-35.000 lx in S-devices (magnification: 3.75x/7.5x/15x)

Type plate of colposcope		
Model number		Device name
Serial number		CE-mark
Manufacturer		Date of manufacture
		Input
		Separate disposal Waste electrical devices

Power supply unit



- The power supply unit **REF BG / LED Y/C** is part of the following colposcope models: 1E LED Light, 1E LED, 1D LED, 1DW LED, 3ML LED, 3MLW LED, 3MVC LED USB, 3MVCW LED USB.
- The power supply unit **REF B 6400** is part of the following colposcope models: 1DS LED, 3MLS LED 1", 3MLS LED 1/2", 3MVS LED NTSC.



CAUTION

Injury due to electric shock




The use of a different power supply unit can result in electric shock.

► The above listed colposcope models may only be operated with the indicated power supply units!



1	On/Off switch
2	Light intensity control
3	Connection for the power cable
4	Micro fuse holder
5	Connector socket with bayonet lock for the lamp cable

Type plate of power supply unit

	<p>POWER SUPPLY FOR COLPOSCOPE</p>		Device name
Model number	REF	BG / LED Y/C	
Serial number	SN	13-510000	CE-mark
Date of manufacture		2013-05	
Input	Input : 100-240V~ ,50/60Hz, 2A T		
Output	Output : 4V, 20W 5V, 0,8W 12V, 3W		
			Protection class II
	Leisegang GmbH Leibnizstr. 32, D-10625 Berlin LEISEGANG Made in Germany		Manufacturer
		IP30	Type of protection
Safety Information 'Caution'	 		Separate disposal of waste electrical devices

3.3 Stands

Swing-o-matic stand



1	Star knob screw
2	Post for roller base
3	Clamp flange
4	Supporting ring with latch pin
5	Conical insert
6	5-wheel spider base with counterweight
7	Frame
8	Clamp nut for clamp head
9	Power supply unit

Balance-o-matic stand



1	Circular level
2	Post for balance-o-matic stand
3	Spring shaft
4	Cable clamp
5	Adjusting collar for tension spring
6	5-wheel spider base with counterweight
7	Conical insert
8	Frame
9	Clamp nut for clamp head
10	Power supply unit
11	Locking lever

Upright stand







1	Clamp nut for clamp head
2	Power supply unit
3	Cable outlet
4	Stand pillar
5	5-wheel spider base

4 Technical data




4.1 General

Operational data	
Mode of use	Not suitable for use in an oxygen-enriched environment
Operating mode	Suitable for continuous operation
Applied parts	The device has no applied parts that come into direct contact with the patient
Working distance	300 mm
Environment and storage conditions	
Environment temperature	10-45 °C
Relative humidity	30-75 %, non-condensing
Air pressure	700-1.060 hPa
Storage	Dry, cool, protected from dripping water, protected from condensation

4.2 Devices with magnification 7.5x/15x/30x

Power supply unit REF BG LED Y/C	
Input	100-240 V ~, 2 A _{max} , 50/60 Hz
Output	4 V  20 W
	5 V  0.8 W
	12 V  3 W
Protection against electric shock	 Protection class II
Protection against harmful ingress of solids and liquids	IP 30
Integrated illumination	
LED	Light-emitting diode
Power consumption	10 W
Intensity of illumination E _v	45.000-52.000 lx (with a distance of 300 mm)
Colour temperature T _F	5.700-6.000 K
Light field diameter	58 mm
Field of view diameter	46/23/11.5 mm

4.3 Devices with magnification 3.75x/ 7.5x/ 15x

Power supply unit REF B 6400 / LED Y/C	
Input	100-240 V ~, 2 A _{max} , 50/60 Hz
Output	3.2 V  3 A _{max}
	5 V  600 mA _{max}
Protection against electric shock	 Protection class II
Protection against harmful ingress of solids and liquids	IP 30
Integrated illumination	
LED	Light-emitting diode
Power consumption	10 W
Intensity of illumination E_v	23.000-35.000 lx (with a distance of 300 mm)
Colour temperature T_F	5.700-6.000 K
Light field diameter	78 mm
Field of view diameter	76/38/19 mm

4.4 Standard colposcopes

1E LED light



1E LED



Model		1E LED light	1E LED
Mechanical data			
Weight		1.850 g	2.750 g
Dimensions H x W x D		564 x 125 x 205 mm	605 x 135 x 205 mm
Features			
Magnification	7.5x	—	—
	15x	●	●
	30x	—	—
Diopter adjustment (±7 diopter)		●	●
Horizontal and vertical fine adjustment		—	●
Green filter		●	●
45° angular insight		—	—

1D LED



1DW LED



Model		1D LED ²	1DW LED
Mechanical data			
Weight		3.000 g	3.100 g
Dimensions H x W x D		605 x 135 x 205 mm	640 x 135 x 245 mm
Features			
Magnification	7.5x	●	●
	15x	●	●
	30x	●	●
Diopter adjustment (±7 diopter)		●	●
Horizontal and vertical fine adjustment		●	●
Green filter		●	—
45° angular insight		—	●

² Also available as S-device: 1DS LED (magnification: 3.75x/7.5x/15x)

4.5 Photo/video colposcopes

3ML LED



3MVS LED Y/C NTSC



Model	3ML LED ³	3MLW LED	3MVS LED Y/C NTSC
Mechanical data			
Weight	3.900 g	4050 g	3500 g
Dimensions H x W x D	660 x 135 x 210 mm	675 x 135 x 240 mm	605 x 135 x 205 mm
Features			
Magnification	3.75x	—	—
	7.5x	●	●
	15x	●	●
	30x	●	—
Diopter adjustment (±7 diopter)	●	●	●
Horizontal and vertical fine adjustment	●	●	●
Green filter	●	—	●
45° angular insight	—	●	—
Video camera, in- tegrated	—	—	●
Video camera, external	●	●	—
DSLR camera (e.g. B. Canon EOS)	●	●	—

³ Also available as S-devices: 3MLS LED 1", 3MLS LED 1/2" (magnification: 3.75x/7.5x/15x)

3MVC LED USB



3MVCW LED USB



Model		3MVC LED USB	3MVCW LED USB
Mechanical data			
Weight		3.250 g	3.600 g
Dimensions H x W x D		625 x 135 x 195 mm	630 x 135 x 245 mm
Features			
Magnification	7.5x	●	●
	15x	●	●
	30x	●	●
Diopter adjustment (±7 diopter)		●	●
Horizontal and vertical fine adjustment		●	●
Green filter		●	—
45° angular insight		—	●
Video camera, in- tegrated		●	●
Video camera, external		—	—
DSLR camera (Canon EOS)		—	—

4.6 Stands

Upright stand



Swing-o-matic stand



Balance-o-matic stand



Model	Upright stand	Swing-o-matic stand	Balance-o-matic stand
Mechanical data			
Weight (without spider base)	1.750 g	5.000 g	7.900 g
Dimensions H x W_{max}	670 x 120 mm	680 x 640 mm	750 x 715 mm
Horizontal movement	– (rigid pillar)	swinging freely in a radius of 600 mm	swinging freely in a radius of 600 mm
Vertical movement	– (manually lockable)	– (manually lockable)	balanced zero-force- movement, lockable
Working height	907–1180 mm (manually lockable)	890–1290 mm (manually lockable)	840–1420 mm (two-stage locking mech- anism)
Features			
Chair assembly (right/left)	–	●	●
Assembly of the 5- wheel spider base	only with lightweight 5-wheel spider base (without counter- weight)	●	●

4.7 5-wheel spider base



Model	Heavyweight 5-wheel spider base
Weight	25 kg (incl. counterweight)
Diameter	650 mm
Wheels	Universal wheels for all floors, 5 lockable wheels

4.8 Model number

The model number (**REF**) consists of the following categories:

		Ocular view		Magnification			Head calibration		Lighting	Camera interface			Chip size				
Number		1		2			3		4	5			6				
	Model name	Straight	45° tilted	1 15x	D 7.5/15/30x	S 3.75/7.5/15x	Fine	Tilting only	LED	--	USB	Y/C NTSC	--	1/4"	1/3"	1/2"	1"
Code	XXX –	1	2	1	2	3	1	2	1	0	1	3	0	1	2	3	5

Example:	1D-121100	1			2		1		1		0			0			
----------	-----------	---	--	--	---	--	---	--	---	--	---	--	--	---	--	--	--

The example below shows the model name for a model 1D LED device with the following features:

Digit 1: straight insight

Digit 2: 7.5- / 15- / 30-fold magnification

Digit 3: Option to fine adjust height, tilt and sharpness

Digit 4: LED-Lighting

Digit 5: Without camera interface

Digit 6: Without chip

4.9 Electromagnetic compatibility

Leisegang colposcopes are intended for use in an environment, that meets the below-mentioned electromagnetic specifications.

Leisegang colposcopes have been designed to withstand the effects of EMI (electromagnetic interference) and meet the most current EMC standards. However, extremely high levels of electromagnetic energy (above the levels mentioned in IEC 60601-1-2) may still cause interference.

In order to reduce the risk of EMI, follow these recommendations:

- Do not turn on or use mobile communication devices, such as mobile two-way radios or cellular phones, in the proximity of the instrument. If the use of such equipment is required, please note the details on 'recommended distance' in the following tables.
- In the event of unexplained EMI, check if there are any transmitters, such as radio or TV stations, located nearby. Either the location of the device may need to be changed or shielding between the sender and the unit may need to be installed.
- We would like to point out that a change to the device or the addition of accessories or components could make the device more susceptible to the interference of radio waves.

Table 1:
Guidance and manufacturer's declaration - electromagnetic radiation

Leisegang colposcopes are intended for use in the electromagnetic environment specified below. The user of a Leisegang colposcope must ensure that the device is being operated in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	Leisegang colposcopes use RF energy only for its internal function. Therefore, the RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	Leisegang colposcopes are suitable for use in all environments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 2:

Guidance and manufacturer's declaration - electromagnetic immunity

Leisegang colposcopes are intended for use in the electromagnetic environment specified below. The user of a Leisegang colposcope must ensure that the device is being operated in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD)	±6 kV contact	±6 kV contact	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
IEC 61000-4-2	±8 kV air	±8 kV air	
Fast electrical transient/burst	±2 kV for power supply lines	±2 kV for power supply lines	The main power supply should be equal to that of a typical commercial facility or a hospital.
IEC 61000-4-4	±1 kV for input/output lines	±1 kV for input/output lines	
Surge	±1 kV differential mode	±1 kV differential mode	The main power supply should be equal to that of a typical commercial facility or a hospital.
IEC 61000-4-5	±2 kV normal mode	±2 kV normal mode	
Voltage dips, short interruptions and voltage variations at power supply input lines IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0,5 cycles	<5 % UT (>95 % dip in UT) for 0,5 cycles	The main power supply should be equal to that of a typical commercial facility or a hospital. If the user of a Leisegang colposcope requires continued operation during power mains interruptions, it is recommended that the Leisegang colposcope is powered by an uninterruptible power supply or a battery.
	<40 % UT (>60 % dip in UT) for 5 cycles.	<40 % UT (>60 % dip in UT) for 5 cycles.	
	<70 % UT (>30 % dip in UT) for 25 cycles.	<70 % UT (>30 % dip in UT) for 25 cycles.	
	<5 % UT (>95 % dip in UT) for 5 seconds	<5 % UT (>95 % dip in UT) for 5 seconds	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	The magnetic fields of the power frequency should be within a range that is characteristic for a typical commercial environment or in the environment of a hospital.

Note: UT is the AC voltage prior to the application of the test level.

Table 3:
Guidance and manufacturer's declaration - electromagnetic immunity

Leisegang colposcopes are intended for use in the electromagnetic environment specified below. The user of a Leisegang colposcope must ensure that the device is being operated in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted HF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 V 3 V /m	<p>Portable and mobile RF communications equipment should not be used closer to parts of the Leisegang colposcope, including cables, as specified in the recommended distance. This is based on the valid formula for the frequency of the transmitter.</p> <p>Recommended separation distance:</p> $d = [3.5 / 3] \sqrt{P}$ $d = [3.5 / 3] \sqrt{P} \text{ 80 MHz to 800 MHz}$ $d = [7 / 3] \sqrt{P} \text{ 800 MHz to 2,5 GHz}$ <p>In this case, P is the maximum output power rating of the transmitter in watts (W) according to the manufacturer of the transmitter; <i>d</i> is the recommended separation distance in meters (m).</p> <p>The field strength of the fixed RF transmitters, as determined by an electromagnetic site survey ^(a) should lie below the compliance level in each frequency range ^(b).</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol: </p>
Note 1:	At 80 MHz and 800 MHz, the higher frequency applies.		
Note 2:	These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.		
a)	The field strength of fixed transmitters, such as base stations for (mobile/cordless) phones and public land mobile radios, amateur radio, AM and FM-radio stations and TV-transmissions can, in theory, not be predicted accurately. In order to assess the electromagnetic environment due to fixed RF transmitters, a factory-made electromagnetic site survey is recommended. If the measured field strength in the location, in which the Leisegang colposcope is being operated, exceeds the above-mentioned RF compliance level, particular attention must be paid in order to guarantee a normal operation of the Leisegang colposcope. If an incorrect operation is observed, additional measures may be required, such as the realignment or relocation of the Leisegang colposcope.		
b)	Above the frequency range of 150 kHz to 80 MHz, the field strength should be less than 3 V/m.		

Table 4:
Recommended separation distance between portable/mobile RF communications device and a Leisegang colposcope - valid for equipment and systems not intended for life-sustaining applications

Leisegang colposcopes are for use in an electromagnetic environment in which radiated RF disturbances are monitored. The user of a Leisegang colposcope can help prevent electromagnetic interference by maintaining a minimum distance between the portable/mobile RF communications device (transmitter) and the Leisegang colposcope as recommended below; this minimum distance is determined by the maximum output power of the communications device.

Maximum output power of transmitter W	Distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = [3.5 / 3] \sqrt{P}$	80 MHz to 800 MHz $d = [3.5 / 3] \sqrt{P}$	800 MHz to 2.5 GHz $d = [7 / 3] \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
Note 1:	At 80 MHz and 800 MHz, the higher frequency applies.		
Note 2:	These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.		

5 Transport and storage

5.1 Storage



- If the boxes are stored for a longer period of time, attention needs to be paid, that the environmental conditions are dry, cool and non condensing. The boxes must be stored drip-proof.
- Store the boxes on the right side, according to the inscription 'Top'.

5.2 Disposal of packaging material



The packaging is made from recyclable materials and can be recycled. Use the country-specific waste disposal system.



We recommend storing the original box and packing material. If necessary, the device can be transported well protected at a later point in time.

6 Operation

6.1 Preparing the colposcopy



The installation and initial start-up of the colposcope should only be performed by a qualified technician. Please contact your supplier.

Before starting the set-up, please check that the power cord is plugged in and that the power supply is turned on.

6.1.1 Performing height adjustments

The general working height is set during the assembly of the device. However, if needed, you can adjust the height:

Swing-o-matic stand



CAUTION

Risk of crushing through weight

The stand is heavy and can cause crush injuries if dropped.

- Hold the stand frame when adjusting the working height until the retaining ring is locked in place.

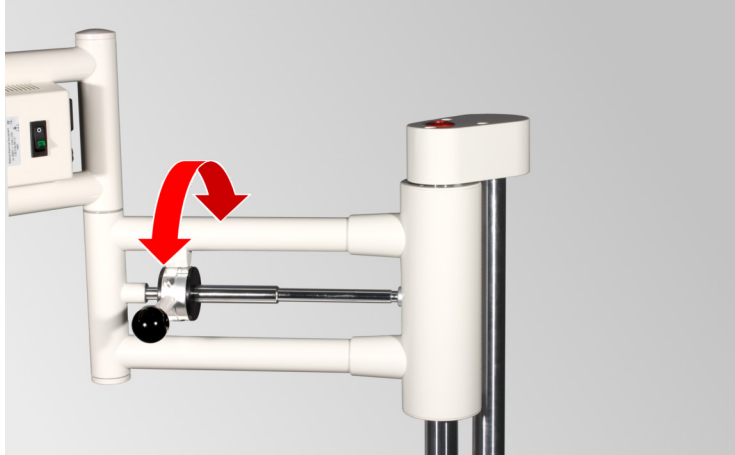
1. Hold the stand frame and pull out the latch pin of the retaining ring (1). Move the retaining ring to the desired height and release the latch pin into the appropriate hole (2):



2. Carefully put the stand frame back on.
 - The rough working height is set.

Balance-o-matic stand

Release the locking lever, move the stand frame to the desired height and slide the locking lever back to hold position:



Connecting rod of the colposcope



CAUTION

Risk of crushing due to a sudden lowering of the colposcope

The colposcope is heavy and can cause crushing injuries.

- Hold the colposcope when releasing the clamping nut and set it to the lowest position.



CAUTION

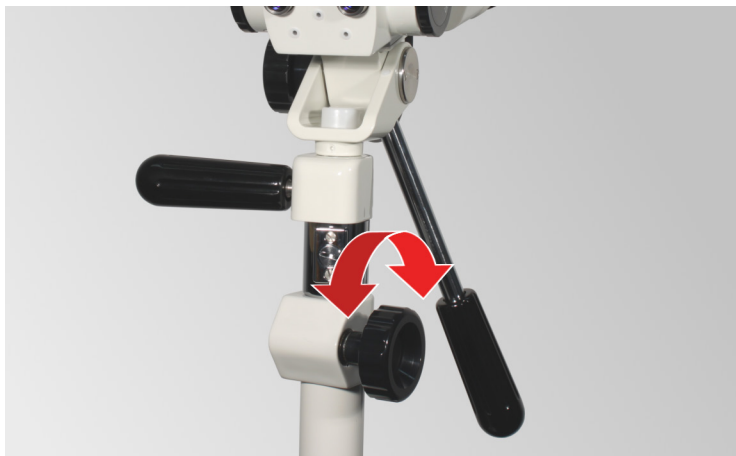
Risk of injury, damage to the device

If the connecting rod is not inserted deep enough into the stand frame, personal injury or equipment damage may occur.

- The connecting rod of the colposcope must be inserted **at least 20 cm** deep into the stand frame to ensure a stable position.

Prerequisite (for balance-o-matic stand):

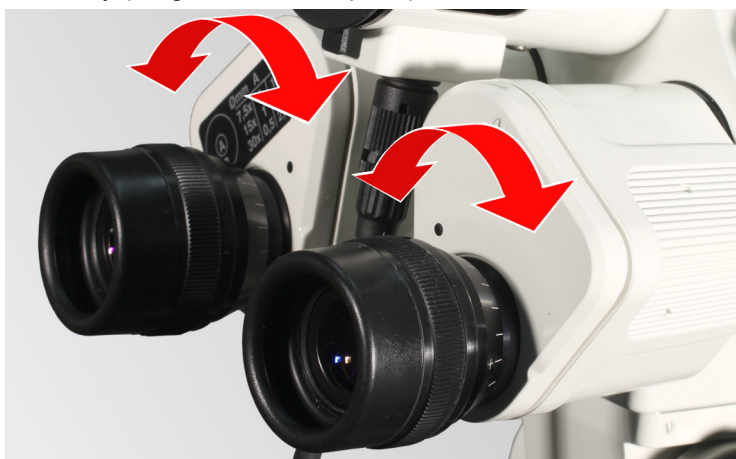
- The balance-o-matic stand is in a locked position.
1. Hold the colposcope head firmly and loosen the clamping nut on the clamp head:



2. Move the colposcope to the desired height and tighten the clamping nut again. Please note the minimum insertion depth of 20 cm.
 - The rough working height is set.

6.1.2 Performing a diopter adjustment

Adjustment for near- or far-sightedness can be made at the two eyepieces. The adjustment can be made for each eye individually (range: +7 to -7 diopters):



Emmetropia	Both eyepieces are set to 0 .
With glasses	Both eyepieces are set to 0 .
No glasses	The eyepieces are adjusted individually.

The diopter adjustment is made while setting the focus at the eyepieces (see section 6.1.4 *Adjusting focus of eyepieces*).

6.1.3 Using a colposcope with spectacles

1. Remove the two upper eyepiece cups:



2. Continue as described in section 6.1.4 *Adjusting focus of eyepieces*.

6.1.4 Adjusting focus of eyepieces

1. Turn the horizontal drive so that the colposcope head is in the centre position.
2. Position the colposcope horizontally at a distance of 300 mm and in front of an even object (such as a wall with patterns).
3. Set the magnification drum changer to the maximum magnification level 30x (S-devices: 15x):



4. Turn the prism bodies so far apart that you can easily see the same image.

5. Set the diopter rings of both eyepieces to 0:



6. With your left eye, look through the left eyepiece. The two displayed concentric circles must be in focus. If this is not the case, turn the diopter ring until you can see the two circles sharp and clear.
7. Now turn the horizontal drive until you can clearly see the object with your left eye.
8. Then, look through the right eyepiece with your right eye. Turn the diopter ring until you can clearly see the object with the right eye.
- The colposcope is now set so that it is always in focus for both eyes and all magnification levels.
 - At the same time, a connected camera now also shows a sharp image on all magnification levels.

6.1.5 Set up working distance

The working distance is 300 mm, measured from the front edge of the front lens up to the surface of the tissue.

Position the colposcope within this distance, before you begin working with the colposcope.

6.2 Using a colposcope



CAUTION

Risk of injury in the event of a faulty device

A faulty device can cause injuries.

- If it can be assumed that the device can no longer be operated safely, take it out of service, secure it against further use and contact your supplier.



We recommend that when not in use, the device is being switched off and covered with the dust cover.

6.2.1 Performing fine adjustments

Fine adjustment drives

Both the fine adjustments in horizontal and vertical direction and the angle can be carried out via the two fine adjustment drives:



- | | |
|----------|---|
| 1 | Vertical drive
Moves the colposcope head up and down (max. 80 mm). |
| 2 | Horizontal drive- Focus
Moves the colposcope head back and forth (max. 40 mm). |
| 3 | Horizontal drive- Tilt
The colposcope head can be tilted by raising or lowering the horizontal drive. |



The model 1E LED light features only the tilt function.

6.2.2 Swing in green filter

For a differentiated view of the tissue you can swing in the green filter:



- | | |
|---|------------------------|
| 1 | Swing in green filter |
| 2 | Swing out green filter |



Models with a 45° angular insight (1DW LED, 3MLW LED, 3MVCW USB LED) do not have a green filter.

6.2.3 Adjust magnifications

The magnifications can be set via the magnification drum changer:



6.2.4 Determining the lesion size

There are two concentric measuring rings integrated into the left eyepiece, an inner circle **A** and an outer circle **B**. With the help of these measuring rings, the size of the observed object can be estimated. There is a legend on the left-hand prism body, which specifies the size of the two circle diameters in mm for each magnification level:



Please note that determining the lesion size is no precise measurement method and is only a subjective assessment.

7 Care, maintenance, inspection

7.1 Care and disinfection



CAUTION

Injury due to electric shock

The power supply unit is not protected against the ingress of water. Penetrating fluid can result in electric shock.

- Always unplug the device before cleaning.

Colposcope, stand



CAUTION

Damage to the device

To avoid damage to the device, observe the following instructions for cleaning and disinfection:

Cleaning

- Wipe the colposcope and the stand with a damp (not wet!) cloth regularly. Standard detergents should be used at suitable dilution. Afterwards, wipe with a dry, non-fuzzing cloth.
- Do not use harsh or corrosive cleaning agents! They can cause damage to the surface.
- Avoid splashing water, as this could damage the device.

Disinfection

- Disinfect the device using disinfectants according to your internal hygiene plan.
- The solutions applied for the manual cleaning and disinfection need to be used according to the manufacturer's instructions and their specified exposure time must be observed.

Germany:

- When choosing a disinfectant, please follow the recommendations of the *Kommission für Krankenhaushygiene und Infektionsprävention (Commission for hospital hygiene and infection control)* issued by the German Robert Koch Institute (RKI) and the Bundesinstitut für Arzneimittel und Medizinprodukte (Federal German Institute for Drugs and Medical Devices).

Countries outside Germany:

- When choosing a disinfectant, please follow the recommendations of your national hygiene standards.

Lenses



CAUTION

Damage to the device

To avoid damage to the equipment, observe the following cleaning instructions:

- You can use a watery soap solution for cleaning the lenses. Use special lens cloths to wipe the lens dry.
- Do not use harsh or corrosive cleaning agents! They can cause damage to the surface.

Power supply unit



CAUTION

Injury due to electric shock

The power supply unit is not protected against the ingress of liquids. Penetrating fluid can result in electric shock.

- Avoid drips and splashes.
- Do not spray cleaning or disinfecting solutions on the power supply unit.

Other components (photo/video adapter, photo equipment, cameras)



CAUTION

Damage to the device

To avoid damage to the equipment, observe the following cleaning instructions:

- Observe the same instructions as listed under *Colposcope*, *stand* and *Lenses*.
- Do not attempt to clean the lenses **within** the adapter or camera! This will cause damage to the equipment.

7.2 Maintenance



Leisegang colposcopes are low-maintenance, free of wear parts and do not require preventive maintenance within the specified expected service life.

7.3 Inspection



Before each use, the user should check the device for any visible damage. An inspection of the electrical safety, in connection with a functionality test in accordance with the information provided by the standard IEC 62353, should be carried out after each repair and at least every **3 years**.

Leisegang Feinmechanik-Optik GmbH recommends a regular inspection of the device every **3 years**. For further information, please contact your supplier.

8 Repair



- Repairs may only be carried out by authorized persons or organizations. In the event of a necessary repair, please contact your supplier.
- Send the device in a cleaned and disinfected condition. Please follow the instructions in section 7 *Care, maintenance, inspection*. Please enclose documented proof that the device has been cleaned and disinfected.
- The device must be packed shock and shatter-proof. Use original packaging if possible.

9 Customer care

In case of technical problems, questions or complaints, please contact your supplier.

In case of complaints please always provide the following information:

- Order number,
- Model number (**REF**) and
- Serial number (SN) of the components.

The serial numbers are provided on the respective plates:



The shown name plates are exemplary figures!

10 Disposal of waste equipment



Countries of the European Union

According to the EU directive on waste electrical and electronic equipment (WEEE) (2002/96/EC), waste electrical and electronic equipment must be disposed separately. Therefore, do not dispose your old equipment with your normal household waste, but take it to your local collection site or contact your supplier.

Countries outside of the European Union

Other rules may apply in countries outside of the European Union, please note the regional regulations.

11 Glossary

Ametropia compensation	Compensation of short- or far-sightedness. This can be done for each eye individually by means of the two eyepieces (range: +7 to -7 diopters).
Working distance	Distance front lens to object level (= 300 mm).
Colour temperature T_F	Specifies the colour impression of a light source. Using colour temperature, one can set the colour of a light source in relation ('hot' or 'cold' light) with the colour of natural light (sunlight). The unit of measurement for colour temperature is Kelvin (K).
Light field diameter	The size of the field, which is illuminated at a distance of 300 mm.
Field of view diameter	The visible area of an object that can be seen through the colposcope. The greater the magnification level, the smaller the field of view and vice versa.
Green filter	A colour filter that darkens red and blue light and brightens green light. Thus, the contrast of the image is increased, blood vessels are shown more clearly.
Intensity of Illumination E_v	Specifies the luminous flux from a light source onto a certain area. The unit of measurement for illumination intensity is lux (Abbrev.: lx).
LED	L ight E mitting D iode. Electronic semiconductor device that emits light when an electrical current passes through.
Eyepiece	The optical portion facing towards the eyes, with which the enlarged image produced by the colposcope can be viewed.
Beam path, convergent	The two light beams for the eyes run together in a point that lies at a distance of 300 mm in front of the front lens. This distance is in accordance with the working distance. This way, the eye does not have to focus on this point on its own, as it is the case with a parallel beam path, therefore fatigue-free work is ensured.
White Balance	White balance is used to calibrate the camera to the colour temperature of the light at the location. This will ensure that the camera displays white - and thus all other shades - correctly.

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