ATMOS
MedizinTechnik

Operating Instructions

ATMOS i View COLPO

English

GA1GB.420101.0
2025-02 Index: 27

CE

Table of contents

1 Introduction

1.1 Notes on the operating instructions

This operating information contains important notes on how to operate your product safely, appropriately and effectively.

This manual is used to train and instruct operating personnel and is also intended as a reference manual. It may be reprinted, either in part or in whole, only with the written permission of ATMOS.

These operating instructions must always be kept available near the product.

Care, period tests, regular cleaning and appropriate application are essential. They ensure the operational safety and usability of the product.

Maintenance, repairs and period tests may be carried out only by persons who have the appropriate technical knowledge and are familiar with the product. To carry out these measures, the person must have the necessary test devices and original spare parts.

This product bears the CE marking CE in accordance with the European Medical Device Regulation (MDR) no. 2017/745.

The product ATMOS i View COLPO complies with all applicable requirements of the directive 2011/65/EU restricting the use of certain hazardous substances in electrical and electronic equipment (“RoHS”).

You can find declarations of conformity and our general terms and conditions on our website at www.atmosmed.com.

The quality management system used at ATMOS has been certified according to the international standard EN ISO 13485.

Before putting the device into service for the first time, please read chapter 2.0 “For your safety” to avoid any dangerous situations.

Report any serious incidents that occur in connection with this product to the manufacturer and the national authority responsible for you.

These operating instructions apply to the following products:

ATMOS i View 21 COLPO	REF 605.0000.0
ATMOS i View 31 COLPO	REF 606.0000.0

1.2 Explanation of pictograms and symbols

In the operating instructions

⚠ DANGER Warning of a danger resulting directly in fatal or serious injury. Observe the necessary measures.
⚠ WARNING Warning of a danger of fatal or serious injuries. Observe the necessary measures.
⚠ CAUTION Warning of a danger of minor injuries. Observe the necessary measures.
ATTENTION Notice of a danger of damage to the product or other objects. Observe the necessary measures.

⚠	Warning of a danger of serious or fatal injury.
ⓘ	Notice of potential material damage that can be caused.
☞	Useful information on handling the device.
1.	Call for action. Proceed step by step.
»	Result of an action.
→	Move/plug in this direction.
click	Engage and check for tight fitting.

⚠ WARNING

On the device, type plate and packaging

	Follow the operating instructions (blue)
	Observe the operating instructions
	Warning! Pay special attention.
	Warning! Pay special attention (yellow).
	This product meets the relevant requirements of the EU regulations.
SN	Serial number
REF	Item number

	Manufacturer
	Manufacturing date
	Manufacturing date Country of manufacture: Germany
	This product meets the relevant requirements of the Eurasian Economic Union.
	Medical product
	Unique identifier of a medical product
	Weight setting for carrier arm
	No domestic waste
	Alternating current
	Fuse
	Do not reuse
	Do not look directly into the lighting of the ATMOS i View COLPO
	UL listing test mark
	Store in a dry place
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation
	This side up
	Fragile! Handle with care.
	Mobile stand transport position Do not lean against the device!

UDI application identifier

ATMOS i View 21 COLPO		ATMOS i View 31 COLPO	
(01)	04250365176162	(01)	04250365176179
(11)	210319	(11)	210319
(21)	11223344	(21)	11223344

Control panel buttons ATMOS i View 31 COLPO

	Light on/off (independent of automatic light control)
	Video recording (start/stop)
	Change between stroboscope and permanent light With built-in HD camera: camera light mode setting
	Freeze frame

ATMOS i View 21 COLPO control device

	Output of the power supply for the electronics in the colposcope
	Fuse
	Potential equalization according to IEC 60417-5021

ATMOS i View 31 COLPO control device

	Fuse
	Potential equalization according to IEC 60417-5021
	Colposcope
	Foot switch
	Record function
	Freeze
	Not in use
	Output signals of the tilt sensor in the carrier arm system

	USB port
	Internal/external video signal input (only with built-in HD camera)
	S video output (not with built-in HD camera)
	Video signal output (only with built-in HD camera)

1.3 Intended use

Product name: ATMOS i View 21 COLPO
ATMOS i View 31 COLPO

Main function: The device is a colposcope intended to give a magnified illuminated spatial view of human tissue for diagnostic and treatment purposes.

Intended use: Standard gynaecological examinations Visual examination of the genital area.

Intended users / user profile: Physicians and medical specialists

Intended patient group: All patients without any restrictions

Medical condition to be diagnosed, treated or monitored: Diagnostic examination of anatomy of any kind

Application organ: Natural orifices (portio and vulva)

Application time: “Short term” means intended for permanent use under normal conditions over a time of 60 minutes to 30 days.

Application site: Out-patient medical facilities, hospitals, medical care centres, operating theatres of gynaecologists.

Patient selection criteria: None

Indications: Standard gynaecological examination and/or therapy

Medical contraindications: None

Other contraindications: None

Warnings: None

The product is: Active

Sterility / specific microbial condition: Non sterile

Single-use product / re-sterilization: Not a single use product; re-sterilization according to operating instructions.

1.4 Function

The ATMOS i View COLPO is a comprehensive colposcope system, consisting of optics and lighting. It produces outstanding pictures for examination purposes with the use of latest LED technology and patent-registered optics. The interaction between the integrated fanless, high-transmission, high-performance LED, the apochromatic optics and the precisely adapted options offer the best working quality.

The ergonomically arranged function buttons, two freely selectable handle versions and the integrated control panel provide the user with maximum ergonomic comfort and suitability for daily use as well as outstanding and intuitive handling. The individual options of the ATMOS i View COLPO can be activated on the control panel. Besides triggering the camera (freeze frame) and starting/stopping possible video sequences, the user can use a mode knob to switch between the individual light functions and also switch the LED lighting on and off manually despite the activated automatic light control. Due to the number of options the ATMOS i View COLPO has to offer, the user is in a position to configure a colposcope adapted specifically to meet his requirements. The following functions can be chosen optionally:

- Four objective lenses with different focal distances (200, 250, 300 and 400 mm) with or without fine focusing or VarioFocus (200 ... 500 mm) (easy exchange of objective lenses due to the respective thread on the colposcope head)
- Five-fold magnification changer, exact setting due to locking screws on both sides.
- Binocular tube, 0° or 45° angle
- Pivoting colour filter
- Measuring scale
- Shadowless illumination

Due to the illumination and the integrable camera solution (integrated HD, or as HD or endoscope adapter for connection of an external camera), the ATMOS i View COLPO is a guarantor for best image quality.

In combination with the mechanical carrier arm and the numerous connection possibilities to the treatment chair or floor stand and ceiling mount, the ATMOS i View COLPO offers countless system options, which can be individually adapted to the user's environment.

☞ *These operating instructions describe all functions with a maximum configuration of the ATMOS i View 31 COLPO.*

1.5 Scope of delivery

The ATMOS i View COLPO has been subjected to an extensive functional test and was carefully packed prior to dispatch. Nevertheless, please check the contents of the shipment for completeness immediately upon receipt (see delivery note).

1.6 Transport and storage

After transporting the ATMOS i View COLPO at temperatures below 0 °C, it should be kept at room temperature for at least six hours before putting it into service for the first time. The ATMOS i View must not be operated if it is not acclimatized, because damage to the electronic components may occur.

Transport the device only in a padded shipping box that provides sufficient protection.

If you notice any transport damage:

- Document and report the transport damage and send the device to ATMOS; see chapter “6.2 Sending in the device” on page 32.

Ambient conditions for transport, storage and operation

See chapter “9 Technical data” on page 36.

2 Notes on your safety

2.1 General safety instructions

- To safely disconnect the device from the mains, the power cord must be removed from the IEC connector of the supply module!
- The ATMOS i View COLPO is a device designed in line with IEC 60601-1/EN 60601-1 and is a protection class I device. To avoid the risk of electrical shock, this device must be connected only to a power supply with properly installed earth conductor.
- Power cables, accessories and connection cables need to be checked for damage before putting the ATMOS i View COLPO into service. Damaged cables must be replaced immediately.
- The ATMOS i View COLPO may only be operated by qualified personnel.
- The ATMOS i View COLPO is not designed to be used in **explosion-hazardous** environments. Potentially explosive areas may be caused by using flammable anaesthetics, skin cleansing products and skin disinfectants.
- If fluid enters the ATMOS i View COLPO, the device must be sent in for inspection and may be restored to service only after being inspected by a person authorized by ATMOS.
- After transporting the ATMOS i View COLPO at temperatures below 0 °C, it must be kept at room temperature for at least six hours before putting it into service for the first time. The ATMOS i View COLPO must **not** be operated if it is **not** acclimatized.
- Do not plug in electric connections (plugs, jacks) with force. If this is not possible, check whether the plug fits the jack. If you notice damage to the connection, have it repaired by our service department.
- Never look straight into the sun with the objective lens or eyepiece lenses.

⚠ CAUTION

- Always make sure that you do not blind patients with the light source! Watch out that patients do not look directly into the light source! Never look directly into the light source yourself!
  >> Damage to the eyes due to the strong glare.
- Please observe the information on period tests in chapter “6 Maintenance and service” on page 32.
- The colposcope suspension (all joints included) must be checked for safe mounting each time before putting it into service.

⚠ WARNING

- Take care that the patient does not touch or come into contact with the device.
- Please observe the EMC directives. Failure to follow them can result in a hazard.
- Dispose of packaging material properly.
- Before connecting the ATMOS i View COLPO, check whether the line voltage and frequency specified on the ATMOS i View COLPO match the values of the power supply.
- Use only proper and undamaged power connections and extension cables.
- To disconnect the ATMOS i View COLPO from the power supply, first remove the plug from the wall outlet. Disconnect the connection line from the ATMOS i View COLPO only afterwards. Never touch the plug or line with wet hands.
- The ambient conditions specified in the technical data (see chapter “9 Technical data” on page 36) must be observed.

- The ATMOS i View COLPO meets the immunity to interference requirements of IEC 60601-1-2 / EN 60601-1-2 “Electromagnetic Compatibility – Medical Electrical Devices.”
- ATMOS are not liable for any personal injury and damage to property if:
  - No original ATMOS parts are used.
  - The instructions for use included in these operating instructions are disregarded.
  - Assembly work, new settings, alterations, extensions and repairs are carried out by persons not authorized by ATMOS.
- Pull the power plug immediately if you notice any fumes, sparks or unusual noises at your device.
- With any light source, tissue may be warmed due to absorption. Please make sure to reduce the duration of use to a minimum, switch off the light source when not in use and check any heat development of the light source if necessary.
- The ATMOS i View COLPO may be operated only in rooms used for medical purposes, but not in potentially explosive areas and oxygen-rich environments.

⚠ CAUTION

- Take into consideration when setting up the colposcope that the elastic force of the arm without the colposcope head is very strong. Operate the brake of the height adjustment carefully.

⚠ WARNING

- Please observe that only PCs and monitors with IEC 60601-1/EN 60601-1/EN 60950-1 approval may be connected to the video outlets of the ATMOS i View COLPO supply module!
- During operation of the colposcope, the user is obliged to regularly check that it is in working order. In the unlikely event of failure, the user must take precautions to continue the treatment of the patient with suitable means.

2.2 Danger to users, patients and third parties

⚠ CAUTION

Danger of injury!

- Take care not to roll the device over your feet when moving the mobile stand.

3 Setting up the device and putting it into service

3.1 Device overview

Description	ATMOS i View 21 COLPO	ATMOS i View 31 COLPO
	 Examination colposcope with integrated, fanless, high-transmission, high-performance LED lighting in the colposcope head	 Examination colposcope with integrated, fanless, high-transmission, high-performance LED lighting in the colposcope head
Integrated high-performance white light LED	✓	✓
Automatic light control	✓	✓
Optimized stereo effect	✓	✓
Measuring scale	Optional	Optional
Built-in operating panel	Optional	Optional
Colour filter H.A.S.I.	Optional	Optional
Built-in camera	X	Optional HD camera
Adapter for external camera	X	Optional
Endoscope adapter	X	Optional
LED lifespan	50 000 hours	50 000 hours
Scope of delivery	Dust cover, operating instructions	Dust cover, operating instructions

☞ You can find more technical data in chapter “9 Technical data” on page 36.

3.2 Setting up the device and putting it into service

⚠ The static conditions specified by ATMOS MedizinTechnik must be met (see separately supplied document “Static requirements for installing the ATMOS i View COLPO”) and confirmed by an authorised expert.

Mains voltage and fuse:

See chapter “9 Technical data” on page 36.

Please observe that only PCs and monitors with IEC 60601-1/EN 60601-1 approval may be connected to the video outlets of the ATMOS i View COLPO supply module!

3.2.1 Connecting to the mains supply

To safely disconnect the device from the mains supply, the power cord must be removed from the IEC connector of the supply module!

Potential equalization:

The ATMOS i View COLPO’s supply module has a rear connection for potential equalization, which can be connected to the potential equalization rail in the room if necessary. This allows user/patient safety to be increased, especially in the case of a defective earth conductor. Use the potential equalization cord with REF 530.0030.0 to connect the device's potential equalization plug to the potential equalization rail of the room.

3.2.2 Colposcope overview

T-handle
(optional)

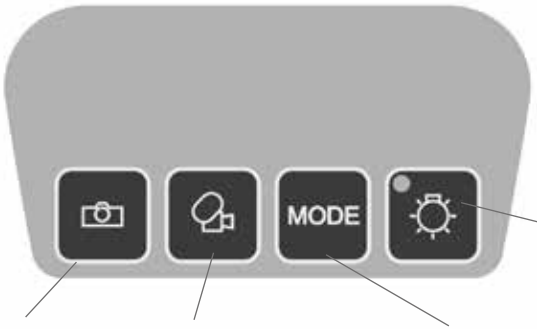
Adapter for SONY digital camera
(optional)

Endoscope adapter
(optional)

Control panel
(optional)

3.2.3 Operating elements on the colposcope

*When the button is pressed and held, you can switch between freeze frame and “Send trigger signal only” (for external image recording)!



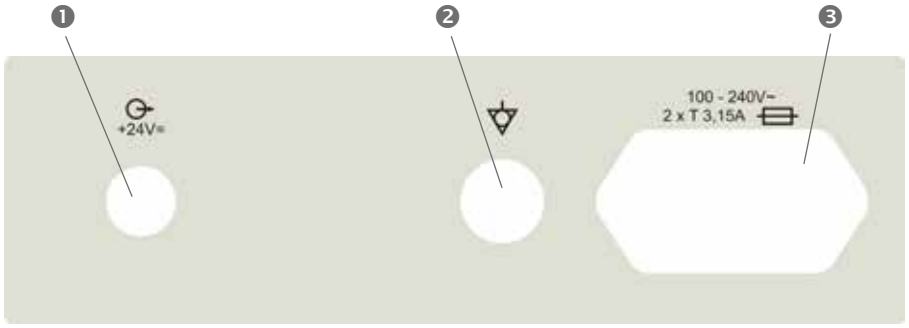
Light on/off (independent of automatic light control)

Freeze frame

Video recording (start/stop)

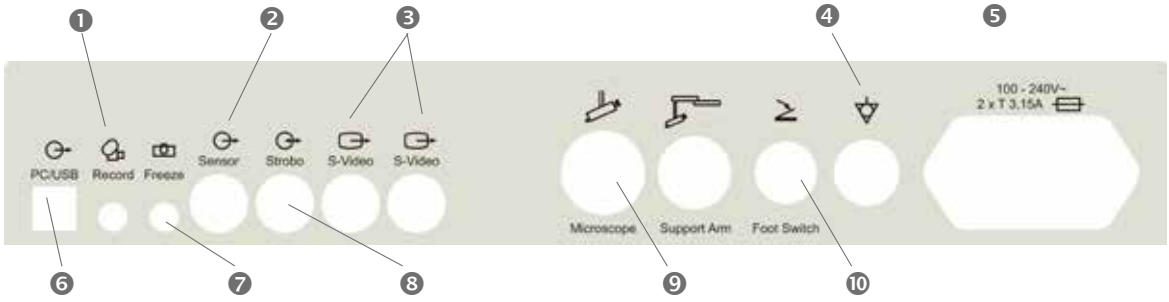
With built-in HD camera: camera light mode setting

3.2.4 Rear view of the ATMOS i View 21 COLPO control device



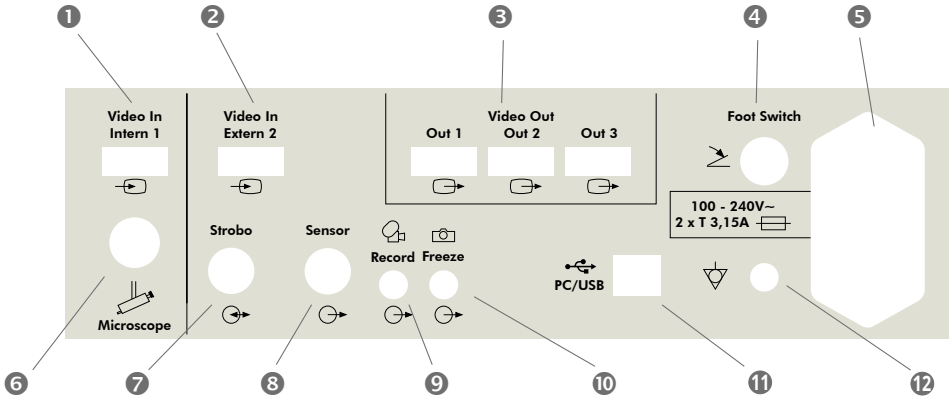
1. Output of the power supply for the electronics in the colposcope
2. Connection for potential equalization line in accordance with IEC 60417-5021
3. IEC power plug with fuse inlay for connection to the mains supply

3.2.5 Rear view of the ATMOS i View 31 COLPO control device (not with built-in HD camera)



1. Output signal of the video recording function
2. Output signals of the tilt sensor in the carrier arm system
3. S video outputs of the built-in SD camera
4. Connection for potential equalization line in accordance with IEC 60417-5021
5. IEC power plug with fuse inlay for connection to the mains supply
6. USB port for transfer of the button status of the freeze frame and video recording functions.
7. Output signal of the freeze frame function
8. Not assigned
9. Connection for the supply to the colposcope electronics and control line
10. Connection for the foot switch used to activate the image or video signal

3.2.6 Rear view of the ATMOS i View 31 COLPO control device with built-in HD camera



1. HD video input. Use only the HD built-in camera module.
2. HD video input of an external HD video source
3. HD video output of the internal 1 or external 2 video source
4. Connection for the foot switch used to activate the image or video signal
5. IEC power plug with fuse inlay for connection to the mains supply
6. Connection for the supply to the colposcope electronics and control line
7. Not assigned
8. Output signals of the tilt sensor in the carrier arm system
9. Output signal of the video recording function
10. Output signal of the freeze frame function
11. PC connection (optional)
12. Connection for potential equalization line in accordance with IEC 60417-5021

3.3 Integration options

☞ Observe the set-up instructions for the integration options.

3.3.1 Examination chair

For integration into GYN treatment units.

Your ATMOS sales and service partner will be happy to inform you about any adapting options for examination chairs.

3.3.2 Mobile stand

⚠ WARNING

When transporting the roller stand, please make sure you always leave the colposcope arm in a retracted position and tighten the screws.

⚠ WARNING

Danger of injury!

Take care not to roll the device over your feet when moving the mobile stand.

☞ The brakes must be locked on the rolling stand when the device is in working position.

3.3.3 Wall stand

⚠ CAUTION

Mount on the wall by means of a rail. The attachment of the colposcope head is height-adjustable.

☞ Please use a water level to align the wall stand!

3.4 Putting the device into service

☞ Check whether the voltage values on the type plate match the mains supply.

☞ Check the scope of delivery.

☞ Make sure you observe the safety information in chapter “2.1 General safety instructions” on page 11 before putting the device into service for the first time.

☞ After transporting the colposcope at low temperatures, it must be kept at room temperature for at least six hours before putting it into service for the first time. The colposcope may not be used if it is not acclimatized.

☞ Take into consideration that the elastic force of the arm without the colposcope head is very high when putting the device into service. Operate the brake for the height adjustment carefully.

☞ To activate the ATMOS i View COLPO, please press the on/off switch on the front side of the control device.

3.5 Operating requirements

Make sure the following requirements are met for the further operation of the device after installing the device:

- All joints and connection parts that are responsible for the safety of the device are securely mounted and fit properly.
- All electronic connections (cables, plugs, power cables etc.) are in perfect condition.
- The mains voltage and frequency specified on the colposcope match the values of the supply network.
- The colposcope is connected to a safety connection socket with the provided power cable.

ATTENTION

Please make sure you never point or direct the beam into the patient’s eyes. Do not look directly into the light source.

☞ With every light source, the biological tissue may be warmed and, under certain circumstances, damaged by radiation and absorption. Please make sure you keep the luminosity and duration of use to a minimum, switch off the light source when not in use and check the heat development if necessary.

3.6 Setting up the device at a glance

1. Use the fixing wheel on the colposcope suspension to move the colposcope into its initial position.
2. Adjust the colposcope vertically and horizontally.
3. Set all the clamps on the carrier and float arm to ensure the arm meets the requirements for ease of movement!
4. Swing in the colposcope into the working space.
5. Adjust the interocular distance by pressing the lens tubes together or pulling them apart.

☞ The interocular distance is set correctly when you see a single circular picture with both eyes!

3.6.1 Adjusting the eyepiece lenses

Persons without glasses:

1. The eyepiece lenses remain in their initial position (eyepiece lenses are pulled out). Set the dioptre scale to zero.

Persons with glasses – People with defective vision and glasses:

1. Keep your glasses on and push the eyepiece lenses in the direction of the lens tube until you hear them engage.
2. Set the dioptre scale to zero.

Persons with glasses – People with defective vision but without glasses (refraction values known):

1. Take off your glasses.
2. Set the dioptre scale to the respective number on the eyepiece lenses (eyepiece lenses are pulled out).

Persons with glasses – People with defective vision but without glasses (refraction values not known):

1. Take off your glasses.
2. Set both eyepiece lenses to +5 dpt.
3. Remove the lens tube from the colposcope head and focus on an object* in the distance.

☞ The object still looks blurred.

4. Turn the dioptre ring of the first eyepiece lens slowly clockwise until the object is sharp. Keep your other eye closed in the process. Repeat this procedure a couple of times to determine the average value.
5. Set the second eyepiece lens with the same procedure and attach the lens tubes with the fastening screw to the colposcope head (eyepiece lenses pulled out).

☞ Never use the sun as an object!

General information:

☞ Set the fivefold magnification changer to maximum magnification (2.0). Approach the object with the colposcope (according to the chosen focal distance) until the image is sharp. The grade of sharpness is retained when the magnification level is changed.

☞ The brightness can be adjusted with the locking screw on the bottom of the device if necessary.

4 Operation

4.1 Colposcope suspension

- The colposcope head is connected laterally to the colposcope arm by means of the corresponding suspension.
- All connection cables run through the suspension – therefore no disturbing cables are visible from the outside (with the exception of the attachment of the option of an external camera and direct connection to a monitor).
- Due to a locking screw attached to the suspension, the colposcope can be adjusted vertically to meet the individual requirements of the user.

1. To fix the colposcope head, turn the locking screw clockwise away from you.
2. To loosen the colposcope head, turn the locking screw anti-clockwise towards you.

ATTENTION

Check the secure mounting of the colposcope to the suspension each time before putting it into service!

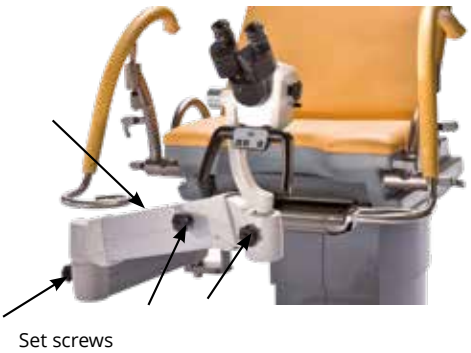
4.2 Mechanical arm

- The mechanical colposcope arm can be adjusted with four set screws to meet individual requirements.
- Choose the strength of the clamping so that the free movement of the arm meets your requirements.
- Turn the set screw clockwise to fix the arm.
- To loosen the arm, turn the set screw anti-clockwise.
- To align the arm, please observe the set-up instructions for the integration options.

⚠ CAUTION

Prior to use, ensure that the brakes of the arm system are set correctly.

Automatic light switching: The LED light of the colposcope is switched off automatically once the arm is in the lower position.



4.3 Handles

☞ You can choose between two versions of handles when purchasing the ATMOS i View COLPO.

4.3.1 T handle

4.3.2 Lateral double handle

The position of the lateral double handle can be gradually adjusted by simultaneously pulling it laterally and turning it.

☞

4.4 Adjusting the interocular distance

The interocular distance can be set to 50 – 75 mm.

1. Swivel the colposcope into the work space.
2. Look through the eyepiece lenses and push the eye lens tubes together or pull them apart with both hands.

The correct interocular distance is set when you look through with both eyes and a single circular picture is visible!

4.5 Adjusting the eyepiece lenses

Persons without glasses:

- The eyepiece lenses remain in their initial position.
  Initial position = eye guidance of the eyepiece lenses pulled out.
- Make sure the zero of the dioptre scale matches the index line of the eyepiece lenses.

Persons with glasses:

- People with defective vision and glasses on push the eyepiece lenses in the direction of the lens tube until they hear them engage and set the dioptre ring to zero.
- People with defective vision but without glasses (with known refraction values) take off their glasses and set the dioptre scale on the eyepiece lenses to the matching number (eye guidance of the eyepiece lenses pulled out). The focussing process is described in chapter 4.10.
- People with defective vision but without glasses (with unknown refraction values) set both eyepiece lenses to +5 dpt. Remove the binocular tube, incl. the eyepiece lenses, from the colposcope head and focus on a distant object*. At this point of time the object still looks blurred. Slowly turn the dioptre ring of the first eyepiece lens clockwise until the object appears sharp. Keep your other eye closed in the process. Repeat this procedure a few times to determine an average value. Use the same procedure for the second eyepiece lens. Reattach the lens tubes with the eyepiece lenses to the colposcope head with the fastening screw. The focussing process is described in chapter 4.10.
- *Never use the sun as an object!

4.6 Exchanging the objective lenses

The designated thread on the colposcope head allows the different objective lenses to be easily exchanged and fixated.

Due to the integrated thread, the objective lenses can be loosened by turning them anti-clockwise and fastened by turning them clockwise.

4.7 Exchanging the objective lenses with manual fine focussing

Screw on the objective lens as previously described and lock it with the intermediate screwed ring.

4.8 Exchanging the VarioFocus objective lens

To loosen the VarioFocus objective lens from the colposcope head, turn it anti-clockwise. To mount the VarioFocus objective lens on the colposcope head, turn it clockwise onto the thread.

Positioning the setting dial

The setting dial can be positioned on either side of the VarioFocus objective lens.

Attention! Firmly hold the VarioFocus objective lens during the entire process to prevent it from coming loose from the colposcope head and falling off.

Loosen the three grub screws on the objective lens. Continue to hold the objective lens and turn the setting dial into the desired position. Fixate the three grub screws.

4.9 Setting the fivefold magnification changer

The fivefold magnification changer from ATMOS allows the magnification to be changed between 0.5x and 2.0x.

- Select the desired zoom factor on one of the lateral locking screws.
- Make sure you hear the chosen magnification factor engage in the respective groove.
- The magnification factors: 2.0 – 1.4 – 1.0 – 0.7 – 0.5 are freely selectable.
- The magnification which points in the direction of the eyepiece lenses is the current magnification.

4.10 Focussing

- Set the maximum magnification factor (2.0) on the magnification unit.
- Approach the object with the colposcope until the image is sharp.
- If the magnification factor is then changed, the pre-set degree of sharpness of the image will be maintained.

4.10.1 Fine focussing

The optional fine focussing allows for sensitive and precise focussing within a 17 mm range. Fine focussing is necessary to focus accurately at a high zoom factor.

- Replace the respective objective lens with fine focussing with the objective lens already installed (simply unscrew and screw on using the thread on the colposcope head and secure with intermediate screwed ring).
- Conduct the focussing as described before.
- Adjust the focus with the adjusting disk mounted on the side of the objective lens.

Fine focussing

4.11 Exchanging the lens tube

The tube's focal distance of 160 mm allows comfortable and fatigue-proof observation of the object with both eyes. Work is made considerably easier by the exceptionally large exit pupil and an increased stereo base of 24 mm.

Please hold the tube tight with one hand while undoing the screw. Otherwise the tube could fall down.

- Undo the screw on top of the lens tube and remove the tube from the colposcope head.
- Make sure the gudgeons and grooves of the dove tail fixation engage and the lens tube lies flat.
- Then tighten the screw again.
- Check for secure fitting.

4.12 Pivoting H.A.S.I. filter

The pivoting H.A.S.I. filter gives a more contrasting and clearer view of the mucosa.

- Turn the function knob 90° clockwise to swivel in the colour filter.
- The filter is removed from the optical beam path of the colposcope by turning the knob 90° anti-clockwise.

4.13 Shadowless illumination

The shadowless illumination option prevents instruments from causing shadows in the field of view. This option cannot be retrofitted.

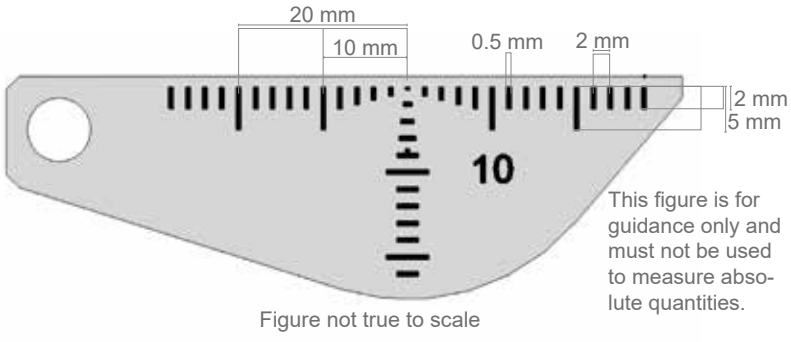
- No operating steps are required for the shadowless illumination.

4.14 Colposcope magnifications and object field sizes

Objective lens f in mm is equivalent to the approximate working distance	Factor display on magnification unit					Eyepiece lenses with tube f = 160 mm
	0.5	0.7	1.0*	1.4	2.0	
	Total magnification / visual field Ø in mm					
200	6.4 / 31	9 / 22	12.8 / 16	18 / 11	25.6 / 8	16x
250	5.1 / 39	7.2 / 28	10.2 / 20	14.3 / 14	20.5 / 10	16 x
300	4.3 / 47	6 / 33	8.5 / 23	12 / 17	17 / 12	16 x
400	3.2 / 62	4.5 / 44	6.4 / 32	9 / 22	12.8 / 15	16 x

* Read off at factor 1 if magnification is used without the zoom unit on the colposcope.

4.15 Measuring scale



A true-to-scale dimension scale can be faded into the field of the illumination light path using a small locking screw beneath the objective lens. This documentation-capable display enables the measurement of objects regardless of the selected magnification factor. The scale is displayed in both the 3D picture and all camera pictures and can be faded out at any time if necessary.

- To show the scale, turn the function knob 45° clockwise.
- The measuring scale can be swivelled out of the illumination path again by turning it 45° anti-clockwise.

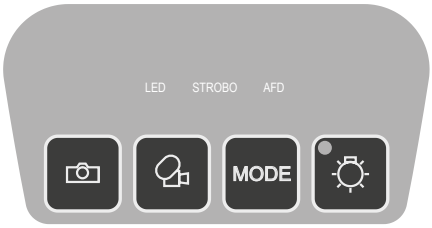
☞ The following dimensions must be observed:
- Distance of 2 mm,
- Line width of 0.5 mm.

Please observe that these specifications apply only to the following combinations: Measuring scale for 300 mm objective lens or 300 mm objective lens with fine focussing and 16x wide-angle eyepiece lens.

4.16 Image and video recording

Built-in camera: Optionally, an HD camera can be integrated in the ATMOS i View 31 COLPO.

External video sources: External video sources can be controlled with the control panel buttons if they are connected to the “Freeze” and “Record” jack plugs.



Control panel buttons:

- Save the image.
- Start/stop recording a video frequency
- MODE Set the light mode of the built-in HD camera.

The data are transmitted to a connected PC (USB interface). The ATMOSoft software can process the data.

Only with built-in HD camera:

You can change between the built-in HD camera and external video source by switching the LED light on or off. As soon as the LED light goes off, the built-in camera is switched off and the data from the external video source are displayed (Video Out 1 – 3).

☞ Observe this also with the automatic light switching.

4.16.1 Setting the light mode of the built-in HD camera

The current light mode of the built-in HD camera is displayed on the monitor by pressing the MODE button once. The light mode can be changed by pressing the MODE button again.

Light mode	Display on the monitor
Standard	• The LED light remains unchanged • The default setting is automatically selected by switching on the power
Center	• The LED light is displayed with fewer reflections • Suitable for recordings through an ear speculum
Warm	• The LED light appears warmer

4.17 Endoscope adapter

The standardized endoscope adapter allows for an easy connection of an external ATMOS cam or other external endoscope camera to the colposcope. The ATMOS cam can be easily and swiftly connected to the endoscope adapter by means of a special clamping lock. Other endoscope cameras with a standardized connection interface can also be adapted without any difficulty.

4.18 Adapter for external camera

Due to the specially developed adapter, you can adapt a SONY digital camera with e-mount connector to the ATMOS i View COLPO. This camera enables you to take and archive HD-resolution pictures.

The adapter is covered with a cover cap when supplied. This cap is used to protect against dirt and must be re-attached whenever the camera is removed or the adapter is not used.

⚠ WARNING

Please make sure the weight of externally connected cameras does not exceed 300 g.

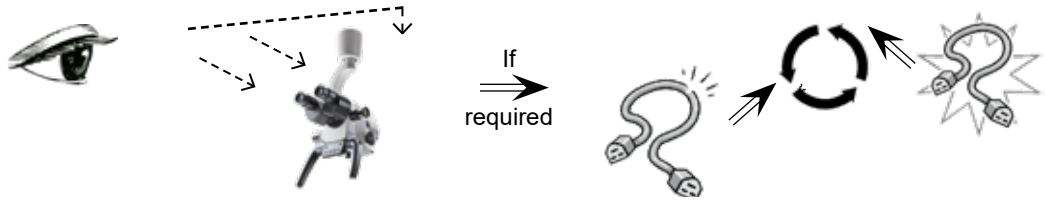
5 Sterilization

⚠ WARNING

5.1 General information on cleaning and disinfection

Prior to cleaning

Medical colposcopes like the ATMOS i View COLPO need to be fail-safe at all times. Therefore, we recommend the following prior to each use:



- ☞ The described measures relating to cleaning and disinfection are no replacement for the valid regulations for operation!
- ☞ All disinfectants used for the disinfection of the ATMOS i View COLPO must be approved.
- ☞ Always observe the concentration specifications and instructions by the respective manufacturer!

5.2 Cleaning the mechanical colposcope surface

All mechanical surfaces of the ATMOS i View COLPO must be wipe-cleaned and disinfected each time after use.

- ☞ Do not use any aggressive or abrasive cleansing agents.

Remove any residue with a mixture of equal parts of ethyl alcohol and distilled water to which a drop of standard washing-up liquid is added.

⚠ If fluid has entered the ATMOS i View COLPO, the device must be sent in for inspection and must not be put back into service until it has been inspected by a person authorized by ATMOS.

⚠ Disconnect the power plug from the mains before cleaning and disinfecting the colposcope surface.

The sterilization drapes may be used for the sterile covering of the device. Use the sterilization drapes only once. Affix the cover loosely so that there is enough room left for the colposcope support and the device. The drapes must be especially loose around the handle because the surgeon must use the colposcope though the drapes.

5.3 Cleaning the objective/eyepiece lenses

The article REF 538.4400.0 (eyepiece lens cups, soft) is not permanently resistant to disinfectants and cleaning agents. The aging of the eyepiece lens cups is accelerated by using these agents! Replace the eyepiece lens cups if they exhibit signs of wear.

5.3.1 Cleaning optical surfaces

Optimum image quality is achieved by the multilayer T* coating of the optical components (e.g. eyepiece lenses, objective lenses).

The image quality could be impaired even by the slightest contamination such as fingerprints. The internal optics of the colposcope can be protected from dust by never storing it without a protective cover, adapter for external cameras, objective lens, lens tube or eyepiece lenses.

You can cover the colposcope to protect it from dust after using it. Always store objective lenses, eyepiece lenses and optical accessories that are not required in clean, dust-free cases.

The external surfaces of optical device components should be cleaned only if necessary.

☞ Any dust that accumulates on the objective lens surfaces can be blown away or removed with a soft, clean brush.

5.3.2 Cleaning the optical surface of the endoscope mounting

The endoscope mounting is protected against dirt and moisture by a glass cover. For cleaning and care of this glass cover, proceed in the same way as with the other optical surfaces of the ATMOS i View COLPO. This can be done by following the same principle as when cleaning optical surfaces.

The endoscope mounting is protected with a cover when supplied to prevent dirt and moisture from entering it.

5.3.3 Fogging of optical surfaces

To prevent the eyepiece lens optics from fogging, we recommend using a standard anti-fogging agent.

☞ Anti-fogging agents provided by eyecare professionals for use with eyeglass lenses are also suitable for the eyepiece lens optics of the ATMOS i View COLPO.

☞ Please observe the operating instructions supplied with the respective anti-fogging agent.

☞ Anti-fogging agents not only ensure fog-free optics, they also clean and protect them against dirt, grease, dust, fluff and fingerprints.

5.4 Recommended surface disinfectants

ℹ Changes in colour may occur if disinfectants containing aldehyde and amine are used on the same object.

*Do **not** use any*

- Disinfectants that contain organic or inorganic acids or bases because they could cause corrosion damage.
- Disinfectants that contain chloramines or phenol derivatives because they could cause stress cracks in the material used for the housing.

Disinfectant	Suitable for				
	Colposcope	Handle	Control unit	Other mechanical surfaces	Optical surfaces
Green & Clean SK				x	x
Bacillol® 30 Foam				x	

Disinfectant	Suitable for				
	Colposcope	Handle	Control unit	Other mechanical surfaces	Optical surfaces
Kohrsolin® FF (application concentrate)	x	x		x	
Kohrsolin® extra (application concentrate)	x			x	x
Mikrobac® forte (application concentrate)	x	x		x	
mikrozid® sensitive wipes			x	x	
SaniCloth® Active	x			x	

5.5 Hygiene plan

WHAT	HOW			WHEN				NOTICES
	C	D	S	Each time after use	Daily	Weekly	Monthly	
Housing	X	X		X				Manual wipe cleaning and disinfection
Lens/optics	X	X			X			Manual wipe cleaning and disinfection
Applied parts*	X	X		X				Manual wipe cleaning and disinfection
Protective covers (disposable products)				X				Disposable product -> Not suitable for re-sterilization; exchange after use
Handles	X	X		X				Manual wipe cleaning and disinfection

C = cleaning, D = disinfection, S = sterilization

* Applied parts

Setting knob (colour filter, measuring scale, fivefold magnification changer, control panel, set screws on the arm).

6 Maintenance and service

⚠ WARNING

6.1 Basic instructions

- Prior to each use, a visual inspection of the colposcope and colposcope connection line must be performed. **Damaged cables must be replaced immediately!**
- Maintenance, repairs, and period tests must **not** be carried out while the product is being used on the patient.
- Maintenance, repairs and period tests may be carried out only by persons who have the appropriate technical knowledge and are familiar with the product. To carry out these measures, the person must have the necessary test devices and original spare parts.
  ATMOS recommend commissioning an authorized ATMOS service partner. This will ensure that the repairs and tests are carried out appropriately, original spare parts are used and any warranty claims remain unaffected.
- Conduct a repeat test of the electrical safety in accordance with IEC 62353 at least every 24 months. ATMOS recommend conducting an inspection within this framework in accordance with the manufacturer's specifications.
- No warranty rights shall exist in the event of damage or malfunctions caused by using non-ATMOS accessories or consumables.
- The instructions and regulations for the respective field of application should be observed.

ATMOS neither guarantee fault-free operation nor assume any liability for personal injuries and damage to property if:

- No original ATMOS parts are used.
- The instructions for use included in these operating instructions are disregarded.
- Assembly, new settings, alterations, extensions and repairs have not been executed by personnel authorized by ATMOS.

6.2 Sending in the device

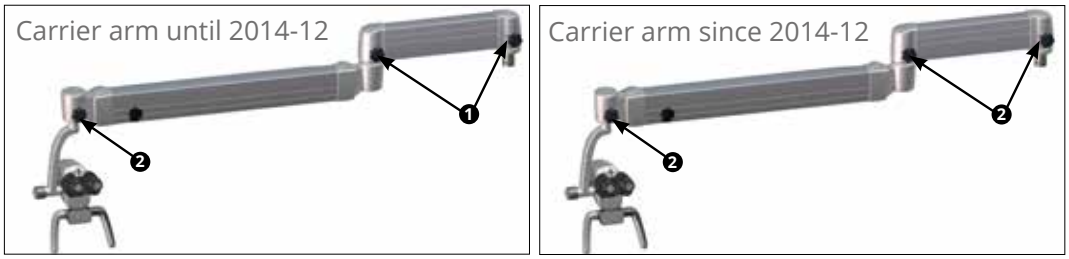
- Remove all consumables and dispose of them properly.
- Clean and disinfect the product and accessories in accordance with the operating instructions.
- Enclose any accessories used with the product.
- Fill in the QD 434 form "Delivery Complaint / Return Shipment" and the corresponding **decontamination certificate**.

☞ This form is enclosed with each delivery and can be found at www.atmosmed.com.

- Pack the device well padded in suitable packaging.
- Place the QD 434 form "Delivery Complaint / Return Shipment" and the corresponding **decontamination certificate** in an envelope.
- Affix the envelope to the outside of the package.
- Send the product to ATMOS or your dealer.

6.3 Exchanging spare parts

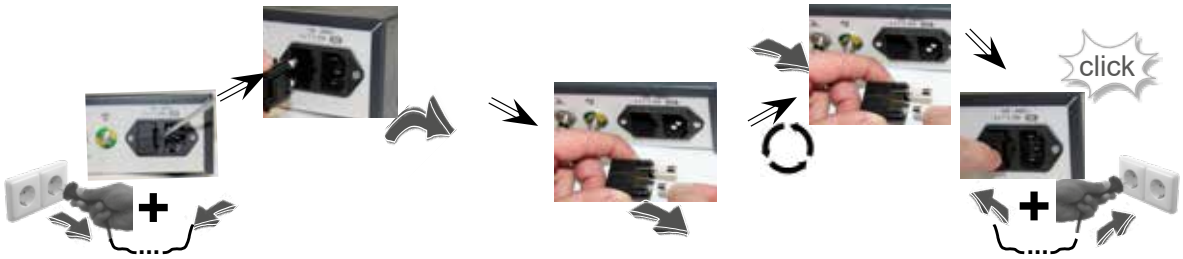
❶	Brake, star grip, copper insert	REF 538.2013.0
❷	Brake, star grip, POM	REF 538.2015.0



Fuse T 3.15 A/H 250 V: REF 008.0751.0

The system must be disconnected from the mains supply before exchanging the main fuse. For this purpose it is necessary to pull the plug of the power cable from the power outlet.

6.4 Changing the fuse



7 Troubleshooting

Description	Possible causes	Measures
ATMOS i View COLPO cannot be switched on	• Power cable not connected. • Defective fuse.	• Connect the power cable. • Exchange the fuse.
ATMOS i View COLPO is hot		• Please ensure sufficient air ventilation. • Switch off and allow to cool down for 2 – 3 hours
ATMOS i View COLPO is overheated		Please notify ATMOS's service department.
No function whatsoever	ATMOS i View COLPO is switched off.	Switch on AMTOS i View COLPO at the connection box
Fivefold magnification changer is defective		Notify ATMOS's service department.
Arm lags behind	Column is not vertically aligned.	Adjust the column.
Insufficient light or no light at all	The ATMOS i View COLPO was swung into "parking position" and thereby the light was switched off	Pull ATMOS i View COLPO into working position
	Failure of the LED light source.	Notify ATMOS's service department.
	Extreme decline in the LED light source.	
	The light source is dimmed down too low.	Increase the brightness of the light source.

8 Options and accessories

Options	REF
200 mm objective lens	538.1000.0
250 mm objective lens	538.1100.0
300 mm objective lens	538.1200.0
400 mm objective lens	538.1300.0
200 mm objective lens with manual fine focussing (17 mm)	539.1700.0
250 mm objective lens with manual fine focussing (17mm)	539.1800.0
300 mm objective lens with manual fine focussing (17 mm)	539.1900.0
400 mm objective lens with manual fine focussing (17 mm)	539.2000.0
VarioFocus objective lens, 200 - 500 mm	538.4500.0
Fivefold magnification changer	538.1700.0
Variozoom	539.2400.0
PLUS depth of field	538.4100.0
Binocular straight tube, 10 times, f = 160 mm	538.3900.0
Binocular straight tube, 16 times, f = 160 mm	605.2000.0
45° adaption for binocular tubes	606.1106.0
Binocular rotary disk	538.3300.0
Eyepiece lens cups, soft	538.4400.0
Shadowless illumination	538.4300.0
Colour filter, green	539.1300.0
Endoscope camera adapter	538.1800.0
Adapter SONY ALPHA camera	539.2300.0
Built-in full HD camera	539.1500.0
Measuring scale (200 mm)	539.1200.0
Measuring scale (300 mm)	606.1200.0
H.A.S.I. filter	605.2200.0
T handle	538.1500.0
Double handle	538.1600.0
Splash protection	538.3700.0
Cover cap set	538.3800.0
Interface micro manipulator	605.2100.0
Colposcope holder (ATMOS i View, Kaps & Zeiss)	503.0553.0
Colposcope holder (Schmitz Gynstuhl)	606.0020.0
Colposcope arm	605.1500.0

Accessories (ATMOS MedizinTechnik)	REF
Mobile stand GYN	605.1200.0
Monitor support for colposcope mobile stand	605.1250.0

Additional accessories	REF
Colposcope holder (gMotio)	503.1035.0

9 Technical data

Voltage	100 - 240 V~ ± 10%; 50/60 Hz
Power consumption	Max. 45 VA
Fuses	2 x T 3.15 A / H 250 V
Operating time	Continuous operation
Light intensity F 200 F 250 F 300 F 400	 Min. 120 klux Min. 80 klux Min. 55 klux Min. 30 klux
Colour temperature	5000 ± 500 K
Cooling	Fanless/passive
Protective earth conductor resistance	Max. 0.1 Ω
Earth leakage current	Max. 5 mA
Housing leakage current	Max. 0.1 mA
Patient leakage current	Max. 0.1 mA
Ambient conditions for transport/storage - Temperature - Humidity without condensation - Pressure	 -10...+50°C 30...95 % 500...1060 hPa
Ambient conditions for operation - Temperature - Humidity without condensation - Pressure	 +10...+35°C 30...95 % 700...1060 hPa
Maximum operating altitude	≤ 3000 m
Contamination level	2
Overvoltage category	II
Weight	3.65 – 5.6 kg
Period tests	Repeat the electrical safety test every 24 months.
Protection class (EN 60601-1)	Recommended: inspection according to manufacturer's specifications.
Degree of protection	I
Type of protection	No applied parts present
CE mark	IP X0
ID no. (REF)	605.0000.0 ATMOS i View 21 COLPO 606.0000.0 ATMOS i View 31 COLPO

Issue of technical data: June 2021

10 Disposal

- The ATMOS i View COLPO does not contain any hazardous materials.
- The housing material is fully recyclable.
- Pay attention to careful separation of the different materials.
- Observe the national disposal regulations (e.g. waste incineration).

Disposal within the EU

The device described above is a high-quality medical product with a long service life. The colposcope must be disposed of professionally at the end of its life cycle. According to the EU directives (WEEE and RoHS), the device must not be disposed of with domestic waste. Please observe the applicable laws and regulations for the disposal of old devices in the respective country.

Disposal within the Federal Republic of Germany

In the Federal Republic of Germany the law for electrical devices (ElektroG) regulates the disposal of electrical devices. It must be assumed that these devices could be contaminated. Therefore, according to the regulations of the EAR (Stiftung Elektro-Altgeräte Register), this type of device is excluded from the ElektroG regulations. To guarantee proper disposal of your old device, please either pass on your old device to your specialized dealer or send it directly to ATMOS MedizinTechnik for professional disposal.

The device surface must be disinfected before disposal or transport.

11 Notes on EMC

☞ Medical electrical devices are subject to special precautions with regard to EMC and must be installed according to the EMC instructions described in the following.

Guidelines and manufacturer's declaration – Ambient conditions

The ATMOS i View 21 / 31 COLPO is suitable for use in the following environments:

- In professional healthcare facilities, such as medical practices, clinics, first aid facilities and operating theatres.

The following environments are not suitable:

- Within the vicinity of HF surgical devices and in settings outside of an HF-shielded room of a magnetic resonance imaging system.
- The customer or user of the ATMOS i View 21/31 COLPO must ensure that the device is used in the prescribed environment.

Guidelines and manufacturer's declaration – Key features

☞ Observe the respective technical data in this manual. The essential key features are fully usable even in the presence of electromagnetic disturbances.

Guidelines and manufacturer's declaration – Removable components that can be replaced by the operating company

The ATMOS i View 21/31 COLPO has the following removable components that can be replaced by the operator:

Type	REF	Max. cable length
Power cable	507.0859.0	3.0 m

Guidelines and manufacturer's declaration – Warnings

⚠ WARNING

The use of electrical components and accessories other than those specified or provided by the manufacturer can cause increased electromagnetic interference or reduced immunity to electromagnetic interference, resulting in faulty operation of the device.

⚠ WARNING

Portable RF communications equipment (e.g. radios, antenna cables) must not be used any closer than 30 cm* to any parts of the colposcope, including cables, specified by the manufacturer. Otherwise, this could result in degradation of the key features of the device.

☞ *The distance may be reduced at higher immunity test levels.

12 Notes

MedizinTechnik

ATMOS MedizinTechnik GmbH & Co. KG
Ludwig-Kegel-Str. 16
79853 Lenzkirch / Germany
Phone: +49 7653 689-0
info@atmosmed.com