ATMOS
MedizinTechnik

English

Operating Instructions

ATMOS i View COLPO

CE

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1.0 Introduction

1.1 Notes on operating instructions

These operating instructions contain important notes on how to operate the ATMOS i View COLPO safely, correctly, and effectively. Their reading helps to avoid risks and also to reduce repair costs and down-times. This increases, among other things, the reliability and service-life of the colposcope.

These operating instructions serve not only for new operating personnel to be instructed in its use, but also for use as a reference manual. Reprints (also in extracts) only with permission in written form by ATMOS.

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

Care and safety inspections in conjunction with professional execution provide for operational safety and readiness for use of your ATMOS i View COLPO and are therefore a must besides regular cleaning.

Repair work and safety inspections may be carried out only by expert personnel authorized by ATMOS. By applying only original spare parts, you will have the guarantee that operational safety, readiness for work, and the value of your ATMOS i View COLPO will be preserved.

- This device bears the CE marking CE in accordance with the European Medical Device Regulation (MDR) 2017/745.
- The product ATMOS i View COLPO complies with all applicable requirements of Directive 2011/65/EU restricting the use of certain hazardous substances in electrical and electronic equipment (“RoHS”).
- The declarations of conformity and our general standard terms and conditions can be obtained on our website at www.atmosmed.com.
- The quality management system applied at ATMOS has been certified according to international standard EN ISO 13485.
- Prior to start-up, please peruse chapter 2.0 “For your safety” in order to be prepared for any possible dangerous situations.
- Report all serious incidents that have occurred in connection with this product to the manufacturer and your national competent authority.

These operating instructions are valid for the following devices:

ATMOS i View 21 COLPO REF 605.0000.0

Colposcope with an integrated, fanless, high-transmission, high-performance LED light in the colposcope head

ATMOS i View 31 COLPO REF 606.0000.0

Colposcope with an integrated, fanless, high-transmission, high-performance LED light in the colposcope head

Please keep this document for future consultation!

1.2 Intended use

Product name:	ATMOS i View 21 COLPO ATMOS i View 31 COLPO
Main functions:	The device is a colposcope intended to give a magnified illuminated spacial view on human tissue for diagnostic and treatment purposes.
Intended purpose:	Standard gynaecological examinations. Visual examination of the genital area
Intended Users / User profile:	Doctors and medical specialists
Intended Patient population:	All patients without any restrictions
Medical conditions to be diagnosed, treated or monitored:	Diagnostic examination of anatomy of all kinds
Application organ:	Natural orifices (portio and vulva)
Application time:	Short-term, under normal conditions for permanent use over a maximum up to 30 days
Application site:	Application sites are hospitals, doctor’s offices, ORs at gynaecologists.
Patient selection criteria:	None
Indications:	Standard gynaecological examination and / or therapy
Medical contra-indications:	None
Other contra-indications:	None
Warnings:	None
The product is:	active
Sterility/specific microbial status:	Not steril
Single use product / reprocessing:	Not a single use product. Reprocessing according to instructions for use.

1.3 Function

The ATMOS i View COLPO is a complete 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 best working quality.

The ergonomically arranged buttons, two selectable hand grip variants, and the integrated control panel provide the user with highest level of ergonomic comfort and suitability for daily use as well as outstanding and intuitive handling. Via the control panel, the individual options of the ATMOS i View COLPO can be activated. Besides triggering the camera (freeze frame) and starting/stopping possible video sequences, the operator is capable of manually switching the LED light source on and off despite the activated automatic light control. Due to the variety of options the ATMOS i View COLPO has to offer, the user is in a position to configure a colposcope to suit his requirements. The following functions can be chosen optionally:

- 4 lenses with different focal distances (200, 250, 300 and 400 mm) with or without fine focusing or VarioFocus (200 ... 500 mm) (easy exchange of lenses due to the respective thread on the colposcope head)
- 5-fold magnification changer. Exact adjustments via turning disks on both sides.
- Binocular tube, 0° or 45° angle
- Pivoting color 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 possibilities which can be individually adapted to suit the user’s environment.

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

1.4 Explanation of pictures and symbols

Short cuts / symbols contained in these operating instructions

→	Follow the arrows, sequence		Check
•	Please press where dot indicates		Move, plug ... in this direction
	Please read, important information		Turn, shift ... in this direction
■	General information		Replace
•	Numeration	click	Engage, check correct fit
	Warning, pay special attention		Important information

Symbols ATMOS i View COLPO

SN	Serial number	REF	Reference number
	Date of manufacture		Manufacturer
	Consult operating instructions		Follow operating instructions
MM6	Weight adjustment for the carrier arm		Professional disposal
~	Alternating current		Fuse
	Do not reuse. Exchange after use.	CE	This product complies with the relevant requirements of EU regulations.
	Do not look directly into the light source of the ATMOS i View	CLASSIFIED c UL us	UL Listing Mark
EAC	This device complies with the relevant requirements of the Eurasian Economic Union.	MD	Medical device
UDI	Unique Device Identifier of a medical device	%	Humidity limitation
	Atmospheric pressure limitation		Temperature limit
	This side up		Fragile, handle with care
	Keep dry	DE	Country of manufacture
			Mobile stand transport position Do not lean against the device

UDI application identifier

ATMOS i View COLPO 21		ATMOS i View COLPO 31	
(1)	04250365176162	(1)	04250365176179
(11)	210319	(11)	210319
(21)	11223344	(21)	11223344

Control panel buttons ATMOS i View 31


Light on/off (independent of automatic light control)


Video recording (start/stop)

Switch stroboscope – permanent light
With integrated HD camera: Adjusting of the light mode of the camera


Freeze frame

Only ATMOS i View 21 COLPO

Output of the power supply for the electronics in the colposcope


Potential equalization acc. to IEC 604175021


Fuse

Only ATMOS i View 31 COLPO


Fuse


Potential equalization acc. to IEC 604175021


Colposcope


Foot switch

Record function

Freeze

Not in use

Output signals of the tilt sensor in the carrier arm system

USB port

Input video signal internal/external (only with an integrated HD camera)

S-video output (not with an integrated HD camera)

Output video signal
(only with an integrated HD camera)

1.5 Scope of supply

- Prior to dispatch, the ATMOS i View COLPO was subjected to an extensive functional test and was carefully packed. Nevertheless, please compare the contents of the shipment on completeness immediately upon receipt (see delivery note).

1.6 Transport and storage

- After the transport of the ATMOS i View COLPO at temperatures below 0 °C, it should be kept at room temperature for at least six hours prior to first start-up. If the ATMOS i View COLPO is **not** acclimatized, it may **not** be used as damages to the electronic components may result.

Only transport the device in a shipping carton that is padded and offers sufficient protection.

If damage occurs during transport:

- Document and report the transport damage.
- Send the device to ATMOS (chapter “6.2 Sending in the device” on page 24).

Ambient conditions:

- Transport/storage:
  −10...+50 °C;
  30...95% humidity without condensation
  air pressure 500...1060 hPa
- Operation:
  +10...+35 °C;
  30...95% humidity without condensation
  air pressure 700...1060 hPa

2.0 For your safety

For your safety

- To safely disconnect the unit from the power supply, the power cable must be removed from the IEC connector of the control device!
- 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. In order to avoid the risk of electrical shock, this device may only be connected to a power supply with a properly installed earth conductor.
- Power cables, accessories, and access cables need to be checked for defects prior to setting up the ATMOS i View COLPO. 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. Explosion-hazardous areas may be caused by the use of flammable anesthetics, skin cleansing products, and skin disinfectants.
- If fluids have penetrated the ATMOS i View COLPO, it needs to be sent in and may only be used after being checked by a person authorized by ATMOS.
- After transport of the ATMOS i View COLPO at temperatures below 0 °C or prior to first start-up, it should be kept at room temperature for at least six hours. If the ATMOS i View COLPO is not acclimatized, it may not be used.
- Do not plug in electric connections (plug, socket) under the use of force. If this is not possible, check whether the plug fits the socket. If you should ascertain a defect in the connection, you should have it repaired by our service.
- Never look straight into the sun with lenses or eyepiece lenses.
- 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!
  > Damage to the eyes due to the strong glare.
- Please pay attention to the periodic tests in chapter 6 “Service and maintenance” on page 24.
- Prior to every use, the colposcope suspension (all joints included) need to be checked for safe connections.
- Take care that the patient does not touch the device or have any contact with it.
- Please observe the EMC Directives. Failure to follow this guideline can result in a hazard.
- Make sure that the unit is positioned so that all the controls and the on/off switch are always accessible.
- Dispose of wrappings accordingly.
- 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.
- Only proper and undamaged plugs and extension cables may be used.
- To disconnect the ATMOS i View COLPO from the power supply, first remove the plug from the wall outlet. Disconnect the connection line on the ATMOS i View COLPO afterwards only. Never touch plug or line with wet hands.
- Please observe the ambient conditions stated in the Technical Data (chapter 9.0).
- 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 is not liable for personal injury and damage to property if
  - no original ATMOS parts are being used,
  - the advice for use in these operating instructions is not being observed,
  - assembly, new settings, alterations, extensions, and repairs have been carried out by personnel not authorized by ATMOS.
- Unplug the device immediately if you observe fumes, sparks, or unusual noises.
- With every light source, a warming of tissue due to absorption may occur. Please make sure to reduce duration of use to a minimum, to switch off the light source when not in use, and to check heat development if necessary.
- The ATMOS i View COLPO may be operated only in rooms used for medical purposes, but not in areas subject to explosion hazards and in oxygen-rich environments.
- Take into consideration when setting up the colposcope that the elastic force of the arm – without colposcope head – is exceedingly strong. Operate the brake of the height adjustment carefully.
- Risk of injury! Take care not to roll the mobile stand over your feet when moving the stand.
- Please note 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, the user is obliged to regularly check the microscope for proper function. In the unlikely event of failure of the microscope, the user must take precautions to continue the treatment of the patient with suitable methods.

3.0 Setting up and starting up

3.1 Overview

	ATMOS i View 21 COLPO	ATMOS i View 31 COLPO
		
Description	Examination colposcope with an integrated, fanless, high-transmission, high-performance LED light in the colposcope head	Examination colposcope with an integrated, fanless, high-transmission, high-performance LED light in the colposcope head
Integrated high-performance white light LED	■	■
Automatic light control	■	■
Optimized stereo effect	■	■
Measuring scale	Optional	Optional
Integrated operating panel	Optional	Optional
Color filter H.A.S.I.	Optional	Optional
Integrated camera	-	Optional HD camera
HD adapter for an external camera	-	Optional
Endoscope adapter	-	Optional
Mains voltage	100–240 V	100–240 V
Light output	min. 120 klx (200 mm) min. 80 klx (250 mm) min. 55 klx (300 mm) min. 30 klx (400 mm)	min. 120 klx (200 mm) min. 80 klx (250 mm) min. 55 klx (300 mm) min. 30 klx (400 mm)
Operating life of the LED	50 000 hours	50 000 hours
Color temperature	See Technical Data	See Technical Data
Scope of delivery	Dust cover, operating instructions	Dust cover, operating instructions

3.2 Assembly

⚠ Please make sure that the static conditions stated by ATMOS MedizinTechnik are met (for details, see the separately enclosed document “Static requirements for installing the ATMOS i View”). The fulfilment of these requirements must be confirmed by an authorized expert.

Mains voltage and fuse: Mains voltage: 100–240 V, 50/60 Hz; Fuse: 2 x T 3.15 A

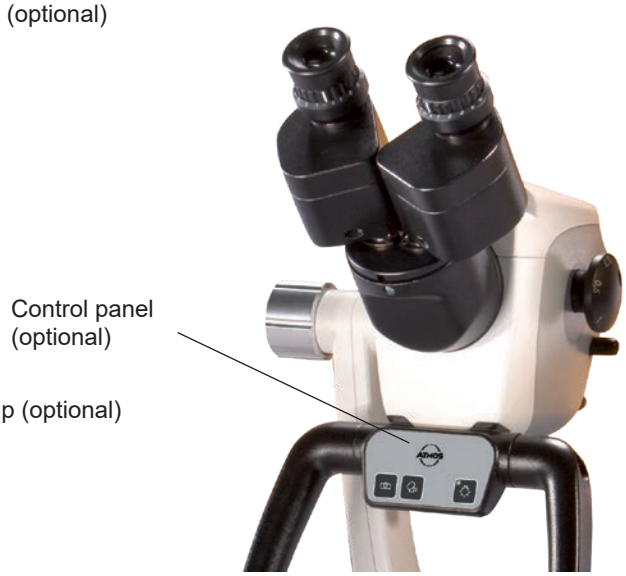
Please note that only PCs and monitors with IEC 60601-1/EN 60601-1 approval may be connected to the video outlets of the ATMOS i View COLPO supply module!

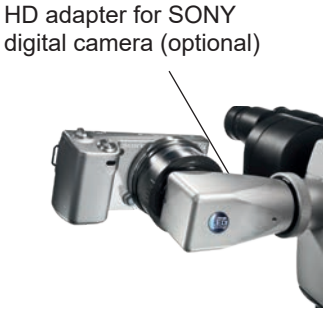
3.2.1 Connection to the power supply

Potential equalization:

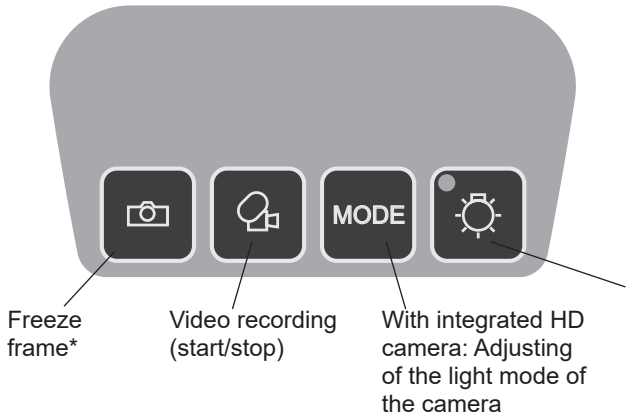
The ATMOS i View COLPO’s supply module has a rear connection for potential equalization which can be connected to the potential equalization rail in the room if need be. Hereby, user/patient safety can be increased especially in the case of a defective earth conductor. For connecting the device’s potential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

3.2.2 Colposcope overview



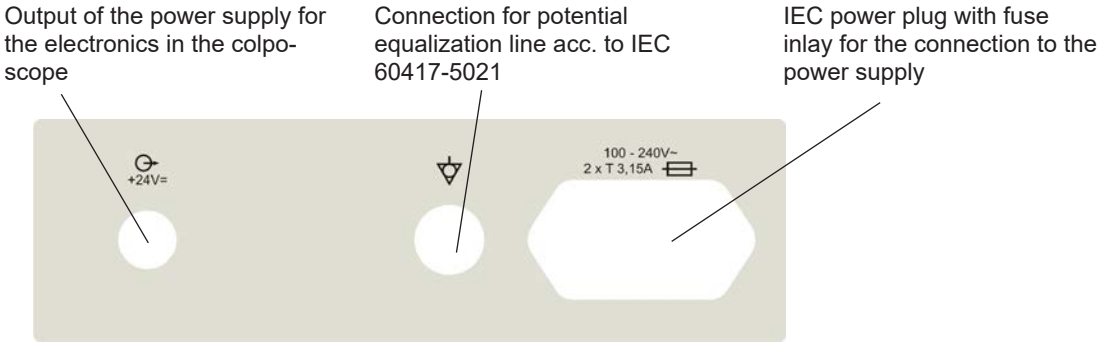


3.2.3 Operating elements on the colposcope

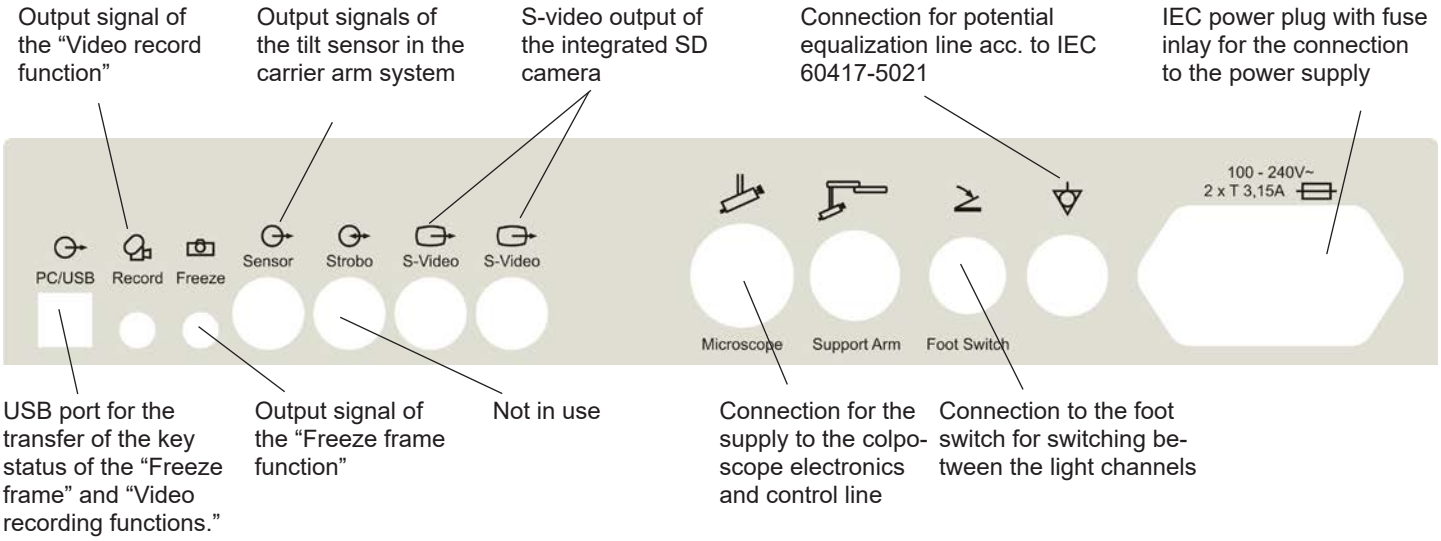


*With a long press, you can switch between the still image and the “Send only trigger signal” (for external image recordings).

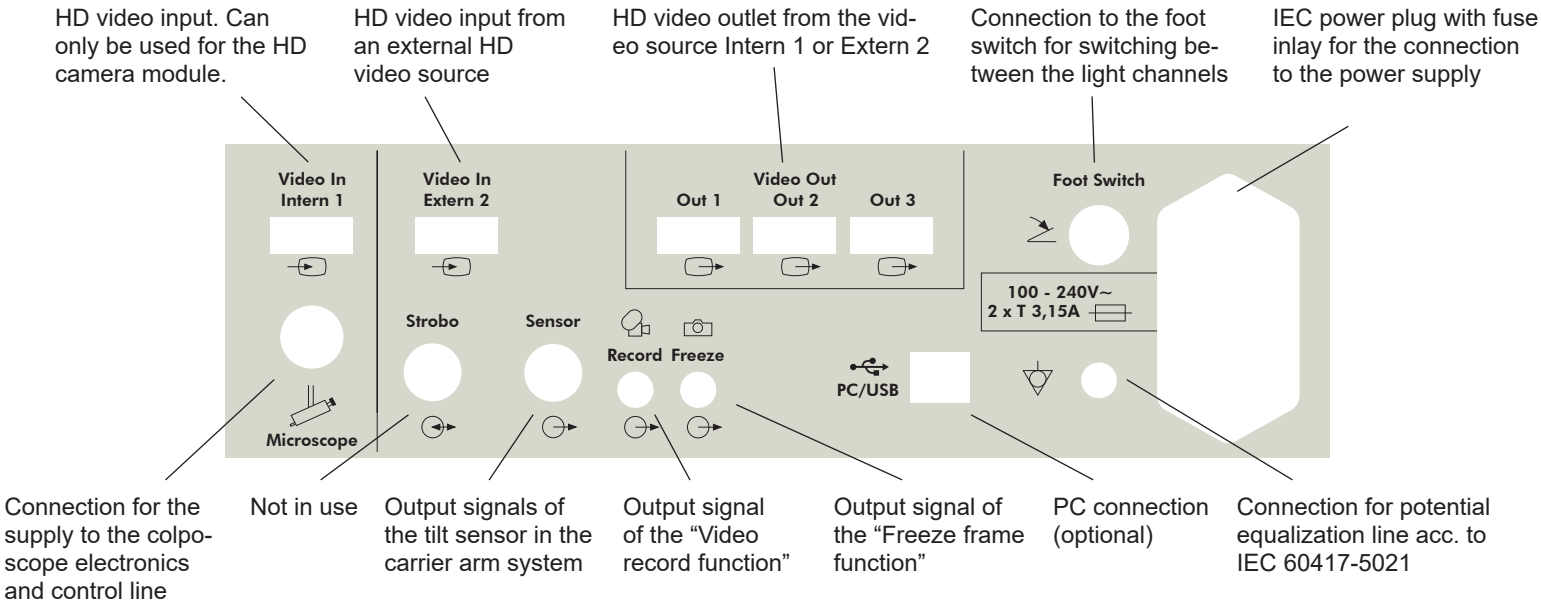
3.2.4 Rear view of the control device of the ATMOS i View 21 COLPO



3.2.5 Rear view of the control device of the ATMOS i View 31 COLPO (not with an integrated HD camera)



3.2.6 Rear view of the control device of the ATMOS i View 31 COLPO with an integrated HD camera



3.3 Integration options

Please note the assembly instructions for the integration options.

Examination chair

Your ATMOS Sales and Service partner will be happy to inform you about options for adapting the colposcope to examination chairs.

Mobile stand

When moving the roller stand, please make sure that the colposcope arm is in a retracted position and the screws are tightened.

⚠ **Risk of injury!** Take care not to roll the mobile stand over your feet when moving the stand.

When the device is placed in working position, the brakes must be locked.

3.4 Starting up

- Check whether the voltage values on the type plate correspond to the line voltage provided.
- Peruse the safety information in part 2.0 prior to starting up the device for the first time.
- Check the scope of delivery.
- After transporting the colposcope at low temperatures, it must be kept at room temperature for at least six hours. If the colposcope is not acclimatized, it must not be used.
- Take into consideration when setting up the colposcope that the elastic force of the arm – without colposcope head – is exceedingly strong. Operate the brake of 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

Please note that the following requirements must be adhered to for further operation after installing the device:

- All joints and connection parts which are responsible for the safety of the device are securely fastened.
- All electronic connections (cables, plugs, power cables, etc.) are in good order and condition.
- The line voltage and frequency specified on the colposcope correspond to the values of the power supply.
- The colposcope is connected to a safety connection socket with the provided power cable.
- ⚠ Attention, never point or direct the beam into the patient's eyes. Do not look directly into the light source.
- With every light source, warming of tissue due to radiation and absorption could occur. This could result in damage to biological tissue. Please 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 Starting up at a glance

Adjust colposcope to initial position on the colposcope suspension by use of the fixing wheel. Adjust colposcope horizontally and vertically.

Adjust all the clamps on the carrier and float arm to secure the movability of the arm in compliance with the requirements.

Swing in colposcope into the working space.

Adjust the interocular distance by pressing or pulling the lens tubes together or apart. The interocular distance is perfectly adjusted when you look through and a circular picture is visible!

Adjusting the eyepieces

Persons without glasses	Persons with glasses		
Eyepieces remain in initial position (eyepieces are pulled out). Diopter scale adjusted to zero	People with defective vision and glasses	People with defective vision without glasses (refraction values known)	People with defective vision without glasses (refraction values unknown)
	Keep glasses on, push eyepieces in direction of the lens tube until they engage audibly. Adjust diopter scale to zero.	Remove glasses and adjust diopter scale to matching number (eyepieces are pulled out).	Remove glasses and adjust both eyepieces to +5 dpt. Remove the lens tube from the colposcope head and focus on an object* in the distance. The object still looks blurred. Turn the diopter ring of the first eyepiece slowly in clockwise direction until the object is sharp. Keep your other eye closed while adjusting the eyepiece. Repeat this procedure a couple of times to determine an average value. Adjust the second eyepiece by the same procedure and reattach the lens tube to the colposcope head with the connective screw (eyepieces are pulled out). * Never use the sun as an object!

Set the 5-fold magnification changer unit to maximum zoom (2.0). Approach the object with the colposcope (according to the chosen focal distance) until the image is sharp. If the zoom level is changed, the grade of sharpness is retained.

Brightness can be adjusted by the rotating knob on the bottom of the device if necessary.

4.1 Colposcope suspension

By means of a corresponding suspension, the colposcope head is connected laterally to the colposcope arm. The complete range of cables run through the suspension – therefore, no disturbing cables are visible from the outside (with the exception of the connection to the HD adapter and direct connection to a monitor). Via a rotating knob, which is situated on the side of the suspension, the colposcope can be adjusted vertically to suit the individual requirements of the user.

To fix the colposcope head, turn the rotating knob away from you in a clockwise direction.

To loosen the colposcope head, turn the rotating knob towards you counterclockwise.

Attention: Check the secure connection of the colposcope to the suspension prior to every use!

Adjusting screws

4.2 Mechanical arm

The mechanical colposcope arm can be adjusted via four set screws according to the individual requirements of the user. Choose the strength of the clamping so that the free movement of the arm suits your requirements. Turn the set screw in clockwise direction to fix the arm. To loosen the arm, turn counterclockwise. To align the arm, please observe the assembly instructions for integration possibilities.

Attention: Prior to use, ensure that the brakes of the support arm are set correctly.

Automatic light switching: Once the arm is in the lower position, the LED light of the colposcope switches off automatically.

4.3 Hand grips

When purchasing the ATMOS i View COLPO, you may choose between two versions of handles.

4.3.1 T-hand grip

(see figure)

4.3.2 Lateral double hand grip

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

4.4 Adjusting the interocular distance

The interocular distance is adjustable between 50 and 75 mm.

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

The interocular distance is perfectly adjusted when you look through with both eyes and a circular field is visible.

4.5 Adjusting the eyepieces

Persons without glasses:

- Eyepieces remain in initial position. Initial position = The eye cups of the eyepieces are pulled out.
- Make sure that the zero of the diopter scale complies with the index on the eyepieces.

Persons with glasses:

- People with defective vision and glasses keep their glasses on and push the eyepieces in direction of the lens tube until they engage audibly. Adjust diopter scale to zero.
- People with defective vision (with known refraction values) should take their glasses off and adjust the diopter scale on the eyepieces to the matching number (the eye cups of the eyepieces are pulled out). The process of focusing is performed as described in chapter 4.10.
- People with defective vision without glasses adjust both eyepieces to +5 dpt. Remove the binocular tube and the eyepiece from the microscope head and focus on a distant object*. The object still looks blurred. Slowly turn the diopter ring of the first eyepiece in clockwise direction until the object is sharp. The other eye must remain closed. Repeat this procedure for a couple of times in order to determine an average value. Adjust the second eyepiece by the same procedure. Reattach the lens tube to the microscope head with the connective screw. The process of focusing is performed as described in chapter 4.10.

* Never use the sun as an object!

4.6 Exchanging the lenses

The designated thread on the colposcope head allows for easy exchange and fixation of the different lenses. Via the integrated screw mount, lenses can be loosened by turning them to the left and fixated by turning them to the right.

4.7 Exchanging the lenses with manual fine focusing

Mount lens as described above and secure it with the intermediate screwed ring.

4.8 Exchanging the VarioFocus lens

To loosen the VarioFocus lens from the colposcope head, turn it to the left. To tighten the VarioFocus lens on the colposcope head, turn it to the right onto the thread.

Position the setting dial.

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

Attention! During the process, firmly hold the Vario-Focus lens just in case it may loosen itself from the colposcope head and fall off.

Loosen the three grub screws on the lens. Continue to hold the lens and turn the setting dial in the desired position. Tighten the three grub screws.

4.9 Adjusting the 5-fold magnification changer

The 5-fold magnification changer from ATMOS enables free range zoom between 0.5x up to 2.0x.

- Select the desired zoom factor by selecting one of the lateral rotary knobs.
- Pay attention that the chosen zoom factor engages audibly with the groove.
- Freely adjustable zoom factors: 2.0 - 1.4 - 1.0 - 0.7 - 0.5.
- The magnification which points in the direction of the eyepieces is the current magnification.

4.10 Focusing

- Adjust the zoom to maximum (2.0) on the magnification unit.
- Approach the object with the colposcope until the image is sharp.
- If the zoom level is changed, the pre-adjusted degree of sharpness is still maintained.

4.10.1 Fine focusing

The optional fine focusing allows for sensitive and precise focusing in a 17 mm range. Fine focusing is necessary in order to focus accurately while zooming in.

- Replace the mounted lens with the appropriate lens for fine focusing (simple mounting via the screw mount on the colposcope head. Secure with the intermediate screwed ring).
- Conduct focusing as described above.
- Adjust focus by use of the lateral adjusting disk.

Binocular straight lens tube

Undo screw

Binocular angled lens tube 45°

Undo screw

4.11 Exchanging the binocular tube

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

Please hold the lens tube with one hand while loosening the screw. Otherwise, the lens tube could drop.

- Loosen the screw on top of the lens tube and remove the tube from the colposcope head.
- Make sure that the gudgeons and grooves of the dove tail fixation engage and the tubes lie flat.
- Tighten the screw again.
- Check for secure fit.

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 by 90° in clockwise direction to swing in the filter.
- By turning the knob by 90° in counterclockwise direction, the filter is removed from the optical beam path of the colposcope.

4.13 Shadowless illumination

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

- For shadowless illumination, no operating steps are required.

4.14 Colposcope zoom and object field size

Lens f in mm equals the approximate working distance	Factor display on the magnification unit					Eyepieces with lens tubes f = 160 mm
	0.5	0.7	1*	1.4	2.0	
	Total zoom / 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	16x
300	4.3 / 47	6 / 33	8.5 / 23	12 / 17	17 / 12	16x
400	3.2 / 62	4.5 / 44	6.4 / 32	9 / 22	12.8 / 16	16x

* Read off at factor 1 when using the colposcope zoom without the zoom unit.

4.15 Measuring scale

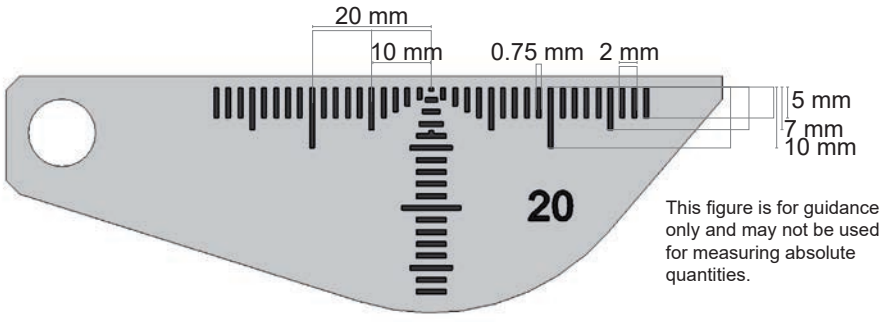


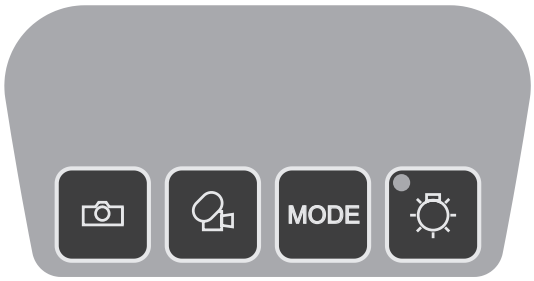
Figure not true to scale

Via a small turning knob beneath the lens, a true-to-scale dimension scale can be faded into the field of the illumination light path. This documentation display enables the measurement of objects regardless of the selected magnification. The scale will be displayed in both the 3D picture and on all camera pictures, and if required, it can be faded out at any time.

- To fade in the scale, turn the knob by 45° in clockwise direction.
- Via a 45° rotation in counterclockwise direction, the scale can be faded out from the path of illumination.

The following measures have to be observed: - Distance 2 mm, - Line width 0.75 mm.

Please note that these specifications are only correct for the following combination: Measuring scale for 300 mm lenses, 300 mm lenses with fine focusing, or wide-angle eyepieces 16x.



4.16 Image and video recording

Integrated camera: If desired, an HD camera can be integrated in the ATMOS i View 31 COLPO.

External video recorder: External video recorders can be controlled via the panel buttons if they are connected to the jack plugs “Freeze” and “Record”.

Control panel buttons:

Save image.

Start/stop the recording of a video frequency.

Adjust the light mode of the integrated HD camera.

The data are transmitted to a connected PC (USB interface).

Only with an integrated HD camera

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

Also observe this within the automatic light switching.

4.16.1 Adjusting the light mode of the integrated HD camera

By pressing the MODE button once, the current light mode of the integrated HD camera is displayed on the monitor. By pressing the MODE button again, the light mode can be changed.

Light mode	Display on the monitor
Standard	LED light remains unchanged. When the power is switched on, the default setting is automatically selected.
Center	LED light will be displayed with fewer reflections. Suitable for recordings through a speculum.
Warm	LED light appears warmer.

4.17 Endoscope adapter

The standardized endoscope adapter allows for easy connection to an external ATMOS Cam or other external endoscope or digital camera (third-party products). The ATMOS Cam can be easily and swiftly attached to the endoscope adapter by means of a special clip seal. Other endoscopic cameras that provide a standardized connection interface can also be adapted without any trouble. To attach an external digital camera, a special adapter (which is suitable for the respective digital camera) is required.

4.18 HD adapter

Via the specially developed HD adapter, it is possible to connect a SONY digital camera with e-mount bayonet to the ATMOS i View COLPO. This camera enables you to take and archive HD resolution pictures.

At dispatch, the HD adapter is covered with a cover cap. This cap is to protect against contamination and has to be reattached at any time, e.g. if the camera is removed or when the adapter is unused.

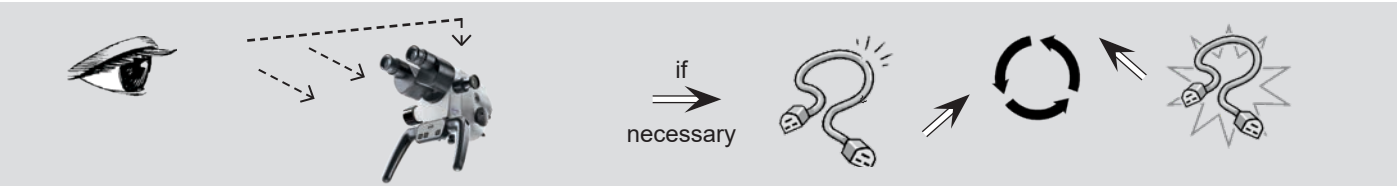
Please make sure that externally connected cameras do not exceed a weight of 300 g.

5.0 Cleaning and care

5.1 General information on cleaning and disinfection

Prior to cleaning

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



☞ The described actions relating to cleaning and disinfection or sterilization do not substitute the relevant instructions that must be adhered to prior to 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 wiped and disinfected after each application. Do not use aggressive or abrasive cleansing agents.

Residues can be removed with a mixture made from equal parts of ethyl alcohol and distilled water to which a drop of standard washing-up liquid is added.

⚠ If fluids have penetrated the ATMOS i View COLPO, it needs to be sent in and may only be used after being checked by a person authorized by ATMOS.

⚠ Disconnect the power plug prior to cleaning and disinfecting the colposcope surface.

For sterile covering of the device, single-use sterilization drapes may be used. The sterilization drapes may only be used once. Affix the cover loosely so that there is enough room left for the colposcope support and the unit. The drapes must be especially loose around the hand grips, as the physician must be able to use the operating elements though the cover.

5.3 Cleaning of lenses/eyepieces

5.3.1 Cleaning optical surfaces

The multilayer T* coating of optical components (e.g., eyepieces, lenses) results in optimum image quality.

Image quality could be reduced even by the slightest contamination of the optics or by fingerprints. In order to protect the internal optics from dust, the instrument should never be left without a safety cover, HD adapter, lens, binocular tube, or eyepiece installed when it is not in use.

After use, the colposcope should be covered in order to protect it from dust. Always store lenses, eyepieces, and accessories that are not being used in clean, dust-free cases.

The external surfaces of optical components should only be cleaned when required.

- Dust that has accumulated on the optical surfaces can be blown off or removed with a soft, clean brush.

5.3.2 Optical surface of the endoscope connection

The endoscope connection is protected against contamination and humidity by an end glass cover. For cleaning and care of this glass plate, proceed in the same way as with the other optical surfaces of the ATMOS i View COLPO. This can be done by following the instructions for cleaning optical surfaces.

On delivery, the endoscope connection is protected with a cover against contamination and humidity.

5.3.3 Fogging of optical surfaces

To prevent the eyepiece optics from fogging, we recommend using an anti-fogging agent.

Note:

Anti-fogging agents provided by eyecare professionals for use with eyeglass lenses are also suitable for the ATMOS i View COLPO's optics.

- Please observe the instructions supplied with each anti-fogging agent.

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

5.4 Recommended surface disinfectants

When using disinfectants containing aldehyde and amine at the same, object color changes may occur.

- *Do **not** use*
  - Disinfectants that contain organic or inorganic acids or bases, as they could cause corrosion damage.
  - Disinfectants that contain chloramines or phenol derivatives, as they could cause stress cracks in the material used for the housing.

Disinfectant	Suitable for				
	Microscope	Handle	Control unit	Other mechanical surface treatment	Optical surfaces
Green & Clean SK				x	x
Bacillol® 30 Foam				x	
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				Details
	R	D	S	after each application	daily	weekly	monthly	
Housing	X	X		X				Manual wiping and disinfection
Lens / optics	X	X			X			Manual wiping and disinfection
Operation parts*	X	X		X				Manual wiping and disinfection
Protective covers (disposables)				X				Single-use product -> not for reprocessing, change after use
Hand grips	X	X		X				Manual wiping and disinfection

C = Cleaning, D = Disinfection, S = Sterilization

* Operation parts

Knobs to adjust (color filter, 5-fold magnification changer, control panel, adjusting screws on the arm)

6.0 Maintenance and service

6.1 General advice

- Prior to every use, a visual inspection of the colposcope and colposcope connection line must be performed. **Damaged cables must be replaced immediately!**
- Maintenance, repairs, and periodic tests may **not** be carried out while the product is being used on the patient.
- Maintenance, repairs, and periodic tests may only be carried out 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 recommends: Work should be carried out by an authorized ATMOS service partner. This ensures that repairs and testing are carried out professionally, original spare parts are used, and warranty claims remain unaffected.
- At least every 24 months, a repeat test of the electrical safety should be performed according to IEC 62353.
  ATMOS recommends an inspection according to the manufacturer's specifications.
- ATMOS neither guarantees for fault-free operation nor is liable for personal injuries and damage to property if
  - no original ATMOS parts are being used,
  - the advice for use in these operating instructions is not being observed,
  - assembly, new settings, alterations, extensions, and repairs have not been executed by personnel authorized by ATMOS.
- There are no warranty claims whatsoever on defects or malfunctions that arise from the use of third-party accessories or consumables.
- The instructions and regulations for the respective field of application should be observed.

6.2 Sending in the device

- Remove and properly dispose of all consumables.
- Clean and disinfect the product and accessories according to the operating instructions.
- Place any used accessories with the product.
- Fill in form QD 434 "Delivery complaint / return shipment" and the respective **decontamination certificate**.

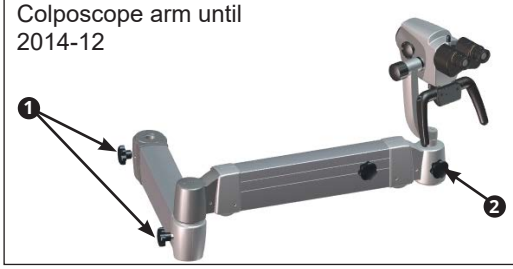
☞ This form is enclosed with each delivery and can be found at www.atmosmed.com.

- The device must be well padded and packed in suitable packaging.
- Place form QD 434 "Delivery complaint / return shipment" and the respective **decontamination certificate** in an envelope.
- Affix the envelope to the outside of the package.
- Send the product to ATMOS or your dealer.

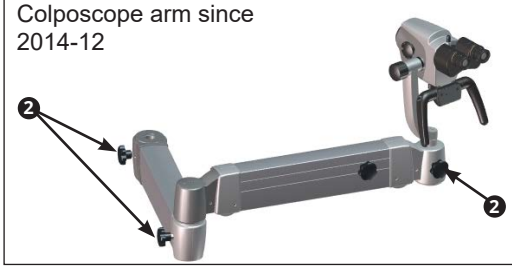
6.3 Exchange of spare parts

❶ Brake star grip with copper REF 538.2013.0
❷ Brake star grip with POM REF 538.2015.0

Colposcope arm until 2014-12



Colposcope arm since 2014-12



Fuse T 3.15 A/H 250 V REF 008.0751.0

Prior to exchanging the main fuse, the system must be disconnected from the power supply. For this, it is necessary to unplug the power cord from the power outlet.

Fuse exchange

7.0 Troubleshooting

Description	Possible causes	Remedy
ATMOS i View COLPO cannot be switched on	Power cable not connected Defective fuse	Connect power cable Exchange fuse
ATMOS i View COLPO is hot		Please ensure sufficient air ventilation
		Switch off and let cool down for 2-3 hours
ATMOS i View COLPO is over-heated		Please contact ATMOS Service
No function whatsoever	ATMOS i View is switched off	Switch on AMTOS i View COLPO at the connec-tion box
5-fold magnification changer is defective		Contact ATMOS Service
Arm follows	Tie bar is not vertically adjusted	Adjust tie bar
Too little or no light at all	The ATMOS i View COLPO was moved into “parking position” and thereby the light was switched off	Pull ATMOS i View COLPO into working position
	Malfunction of the LED light source	Contact ATMOS Service
	Extreme decline in the LED light source	
	Light source is dimmed down too low	Increase brightness of the light source

8.0 Options and accessories

Lens

	REF
Objective: 200 mm	538.1000.0
Objective: 250 mm	538.1100.0
Objective: 300 mm	538.1200.0
Objective: 400 mm	538.1300.0
Objective 200 mm (manual fine focusing 17 mm)	539.1700.0
Objective 250 mm (manual fine focusing 17 mm)	539.1800.0
Objective 300 mm (manual fine focusing 17 mm)	539.1900.0
Objective 400 mm (manual fine focusing 17 mm)	539.2000.0
VarioFocus lens (200 - 500 mm)	538.4500.0

Lens tube

	REF
Binocular straight tube 10-times, f = 160 mm	538.3900.0
Binocular straight tube 16-times, f = 160 mm	605.2000.0
45° adaption (binocular tubes)	606.1106.0

Cable (only for the ATMOS i View 31)

	REF
Cable HDMI type A/C, L = 5 m (only with an integrated HD camera)	538.1902.0
Cable HDMI extension, L = 5 m (only with an integrated HD camera)	008.0909.0

9.0 Technical data

Mains voltage	100-240 V~ ± 10 %; 50/60 Hz
Power consumption:	max. 45 VA
Fuses	2 x T 3,15 A / H 250 V
Power cycle	Continuous operation
Light intensity	
F 200	min. 120 klux
F 250	min. 80 klux
F 300	min. 55 klux
F 400	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
Enclosure leakage current	max. 0,1 mA
Patient leakage current	max. 0,1 mA
Environmental conditions: Transport/Storage	
- Temperature range	-10...+50°C
- Air humidity without condensation	30...95 %
- Air pressure	500...1060 hPa
Environmental conditions: Operation:	
- Temperature range	+10...+35°C
- Air humidity without condensation	30...95 %
- Air pressure	700...1060 hPa
Maximum operating altitude	≤ 3000 m
Contamination level	2
Overvoltage category	II
Weight:	3,65 – 5,6 kg
Periodical tests:	Repeat test of the electrical safety every 24 months. Recommended: inspection according to the manufacturer's specifications.
Protection class against electric shock (acc. to EN 60601-1)	I
Degree of protection against electric shock	No applied parts
Degree of protection against ingress	IP X0
CE mark	CE
Ident-Nr. (REF)	538.0000.0 ATMOS i View 21
	539.0000.0 ATMOS i View 31
	538.9000.0 ATMOS i View 21 PRO
	539.9000.0 ATMOS i View 31 PRO
	605.0000.0 ATMOS i View 21 COLPO
	606.0000.0 ATMOS i View 31 COLPO

Status of the Technical Data: 11.11.2020

10.0 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.
- Please observe national disposal regulations (e.g., waste incineration).

Disposal within the EU

The colposcope described above is a high-quality medical device with a long service life. After its life cycle, it must be disposed of professionally. According to EU directives (WEEE and RoHS), the colposcope may not be disposed of in domestic waste. Please observe existing national laws and rules for 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 foundation (Used Electrical Appliances Register), this type of device is excluded from ElektroG regulations. In order 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.

Before disposal or before transport, the colposcope surface must be disinfected.

11.0 Notes on EMC

☞ Medical electrical equipment is subject to special precautions with regard to EMC and must be installed according to the following EMC notes.

Guidance and manufacturer's declaration – ambient conditions

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

- In fields of home health care in any buildings, outdoor areas, and means of transport.
- In professional healthcare facilities such as medical practices, hospitals/clinics, first-aid facilities, and operating theatres/rooms.

The following environments are not suitable:

- Special environments such as factory or military facilities and medical areas near HF surgical devices, short-wave therapy equipment, or within an HF-shielded room of a magnetic resonance imaging system.

The customer or user of the ATMOS i View COLPO must ensure that the device is used in a prescribed environment.

Guidance and manufacturer's declaration – key features

☞ Please note the Technical Data in these instructions. The essential features are fully usable even in the presence of electromagnetic disturbances.

Guidance and manufacturer's declaration – removable components that can be replaced by the operator

The ATMOS i View 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

Guidance and manufacturer's declaration – warnings

⚠ WARNING

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

⚠ WARNING

Portable RF communications equipment (e.g. radios, antenna cables) should be used no closer than 30 cm* to any part of the ATMOS i View COLPO, including cables, specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

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

⚠ WARNING

Avoid placing the device on top of or next to another device. This could result in faulty operation. If such placement cannot be avoided, the proper functioning of the device must be monitored regularly. If possible, please switch off any nearby devices that are not in use.

12.0 Notes

12.0 Notes

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