ATMOS MedizinTechnik

English

Operating Instructions

ATMOS® S 41 Gyne

Gynaecological Workstation

CE 0124

GA1GB.410101.0
2020-09 Index: 14

Content

1.0 Introduction

1.1 Notes on Operating Instructions

These operating instructions contain important notes on how to operate the ATMOS® S 41 Gyne safely, correctly and effectively. Their reading helps to avoid risks, and also to avoid repair costs and down-times. This increases also the reliability and service-life of your device.

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 device.

Care and period tests in conjunction with professional execution provide for operational safety and readiness for use of your ATMOS® S 41 Gyne and are therefore a must besides regular cleaning.

Repair work and period tests may only be carried out by expert personnel authorised 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® S 41 Gyne will be preserved.

- The unit ATMOS® S 41 Gyne bears CE marking CE 0124 according to the EC Directive of the council for medical products 93/42/EEC and meets the basic requirements of Appendix I of the directive.
- The product ATMOS® S 41 Gyne complies with all applicable requirements of the Directive 2011/65/EC restricting the use of certain hazardous substances in electrical and electronic equipment (“RoHS”).
- The declaration 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 standards 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.

ATMOS

MedizinTechnik GmbH & Co. KG
Ludwig-Kegel-Straße 16
79853 Lenzkirch
Germany

Phone: + 49 7653 689-0
Fax:
+ 49 7653 689-190
+ 49 7653 689-493 (Service Center)
E-mail: atmos@atmosmed.de
Internet: www.atmosmed.de

These operating instructions are valid for the following devices:

ATMOS® S 41 Gyne

Single-tower module	REF 602.0000.0
Double-tower module	REF 601.0000.0
Three-tower module straight	REF 603.0000.0
Three-tower module angled	REF 604.0000.0
Power supply 230 V	REF 601.1800.0
Power supply 100 V-127 V	REF 601.1800.0
Power source ATMOS® LS 21 LED	REF 600.0003.0
ATMOS® C 401	REF 600.1500.0

Heated drawers

Drawer type A 2	REF 601.2300.0
Drawer type B 2	REF 601.2700.0

The operating instructions are included in the scope of delivery.

1.2 Intended use

Name:	ATMOS® S 41 Gyne
Main function:	Examinations and therapy in the gynaecological sector
Medical indications / application:	For application on humans
Specification of the main function:	• Positioning of instrumentation and accessories • Illumination and visualization • Extraction of substances and gas evacuation • Surgical therapy by means of radio frequency • Waste collection
Application organ:	Female body
Application time:	Temporary
Application site:	In clinics and practices for gynaecologists
Contraindications:	• Not for use outside of medical areas • Not for use in explosion-hazardous areas of medically-used rooms
The product is:	active
Sterility:	Not necessary
Single-use product / reprocessing:	Indications for reprocessing are listed in the operating instructions

1.3 Function

- The ATMOS® S 41 Gyne is started up by connecting the plug to the power supply (page 9).
- To determine the method of functioning of the standard equipment and the optional functions please consult pages 11 to 19, resp. consult the relevant user manual for the respective device:
  - ATMOS® RS 221 (radiofrequency surgery)
  - ATMOS® C 401 (suction system)
  - ATMOS® Cam 31 (camera)
  - ATMOS® LS 21 LED (light source)

1.4 Explanation of symbols

	ON (for direct electric supply) according to IEC 417/5007 and DIN 30600/16		Short term operation		Type BF equipment according to IEC 417/5333
	OFF (for direct electric supply) according to IEC 417/5007 and DIN 30600/16		Foot switch	~	Alternating current
	Observe operating instructions! According to ISO /7000/0434 DIN 30600/1008 IEC 348		Fuse according to IEC 417/5016, DIN 30600/0186		Potential equalisation
	Heat output in general; drawer heating		Type B equipment according to IEC 417/5333		
ATMOS® Cam 31, ATMOS® Cam 31 DV					
	Fuse according to IEC 417/5016, DIN 30600/0186		Freeze (Storage)		Signal output
	Application part type BF		Signal input		Signal input and output
IEEE 1394	DV port		Ground wire connection		Foot switch
ATMOS® RS 221					
	The device is classified as type: BF and defibrillator proof.		Neutral electrode, grounded	CE 0124	CE mark in conformity with 93/42 EEC
	Device emits non-ionising radiation HF-radiation	N	Neutral electrode (shines red at malfunction)		
ATMOS® SE 6501					
	The device is classified as type: CF and defibrillator proof.		Device On / Off	**ECB**	Used for communication to optional surgery device

Short cuts / symbols contained in these operating instructions:

- Indicating a list
  - Subdivision of a list/activity

The recommended sequence must be followed in each case!

Please read, important information

Warning, special diligent notice

2.0 For your safety

For your safety

- The ATMOS® S 41 Gyne is produced according to IEC 601 / EN 60601 and listed in the following classes:
  - Class of protection 1
  - Class IIa (EEC 93/42)
  - Class IIb (installation of ATMOS® RS 221!)
- The device may only be connected to a properly installed safety socket.
- The ATMOS® S 41 Gyne is separated from the electricity network via the rubber connector.
- Caution! Heated drawers may generate temperatures above 40°C! Check the temperature of the instruments prior to use. Contact service if necessary!
- The ATMOS® S 41 Gyne may only be used under the supervision of skilled staff who have been authorised by ATMOS and trained in its operation (IEC 601-1/EN 60601-1).
- The mains voltage indicated on the type plate must correspond to the values of the supply network.
- Make sure prior to every application of the equipment that it is technically safe and in proper condition. **Damaged leads and hoses must be replaced immediately!**
- Please pay attention to the period tests in chapter 6.0 „Maintenance and service“ on page 25.
- Correct configuration in assembly of country-specific connections:
  - green/yellow: protective conductor (PE)
  - blue: neutral conductor (N)
  - black or brown: phase (L)
- Please observe that the mobile parts could cause injury and contusion!
- If there is a failure in the temperature control then higher temperatures can occur. Check the temperature of the instruments prior to use. Contact service if necessary!
- Please note:
  A medical insulating transformer with earth leakage monitor or any similar safety system acc. to EN 60 601-1 is required, if several devices are connected over one common power supply. The transformer must correspond to the power consumption of all the devices to be connected.
- The control panel must be clearly visible and accessible for the user.
- The ambient conditions specified in the "Technical data" (chapter 9.0) must be strictly observed!
- The suction system of the ATMOS® S 41 Gyne must only be used for the suction of fluids in the medical field. Never remove explosive, inflammable or corrosive gases or fluids.
- Switch off all function modules when you finish your daily business.
- The ATMOS® S 41 Gyne may be operated only in rooms used for medical purposes, but not in areas subject to explosion hazards and in oxygen rich environments.
- The ATMOS® S 41 Gyne meets the immunity to interference requirements of IEC 601-1-2 / EN 60601-1-2 „Electromagnetic Compatibility – Medical Electrical Devices“.
- The ATMOS® S 41 Gyne may not be operated with devices not complying with the requirements of standard EN 60601-1 „Medical Electrical Equipment“ and EN 60601-1-2 „Electromagnetic Compatibility“ (Medical Electrical Equipment).
- There are no warranty claims whatsoever on defects which arise from the use of third party accessories or consumables.
- 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 authorised by ATMOS.
- Also pay also attention to the safety information in following chapters.
- The ATMOS® C 401 has been designed in accordance with IEC 601/ EN 60601. It is assigned to VDE protection class II. It may only be connected to a properly installed earthed wall socket.

2.0 For your safety

For your safety

- Check device, secretion canister, power cable, accessories, connection cables and hoses for damage before start-up.
  Defect cables and hoses must be replaced immediately.
  Check functions of the device prior to using it!
- Do not allow any liquid to get into the device. If liquids have penetrated the device, it may not be operated again until it has been checked by the customer service centre.
- Danger of tipping over! If you are transporting a straight (not angled) workstation with two or three modules (REF 601.0000.0 / REF 603.0000.0), prior to transport the drawers must be secured to prevent them from slipping out.
- After the transport of the device in temperatures below 0°C or prior to first start up it should be kept at room temperature for at least six hours. If the device is not acclimatized it may not be used as damage to the diaphragms of the pump could occur.
- The suction hose must never come into direct contact with the suction area. A suction catheter, suction attachment or medical suction instruments must always be used.
- To disconnect the device from the mains supply, first remove the plug from the wall outlet. Then disconnect the connection line from the device. Never touch plug or line with wet hands.
- This product is not re-sterilizable. Repeated reuse of components which are marked with a ⓧ is forbidden. In case of repeated reuse these components lose their function and there is a high infection risk.

Notes on EMC

The ATMOS® S 41 Gyne is an examination and treatment unit designed for use in the gynaecological sector, combining several single medical products in one system according to your individual configuration.

Each installed device has been tested for EMC.

Following the review of all individual test reports, we can declare that a significant deterioration in the stray radiation value due to the combination of the devices in the unit is not to be expected, and what is more, deterioration in the interference immunity can safely be excluded.

Please observe the instructions relating to EMC in the relevant unit-specific user manual which is enclosed with your supplied unit.

3.1 Front view

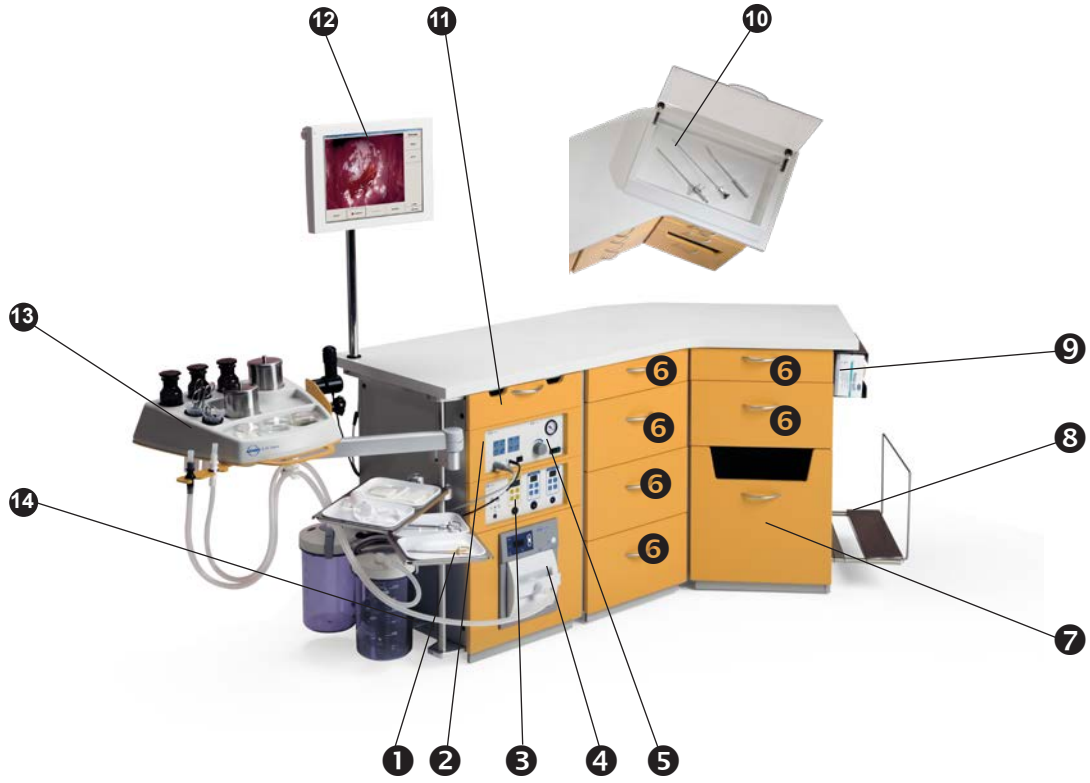


Fig. 1. ATMOS® S 41 Gyne front view

❶ Swivel-mounted instrument trays (optional)
❷ ATMOS® Cam 31 module (optional)
❸ ATMOS® RS 221, radiosurgery device (optional)
❹ ATMOS® SE 6501 smoke evacuation system (optional)
❺ ATMOS® C 401 (optional)
❻ Drawers, heated and unheated (optional)
❼ Instrument wet storage (optional)
❽ PC support (optional)
❾ Glove dispenser (optional)
❿ Instrument deposit with cover (optional)
⓫ Drawer for electrodes (optional)
⓬ TFT display (optional)
⓭ Swivel arm with deposit (optional)
⓮ Connection for foot switch
Castors for mobility (optional) (no illustration available)

3.2 Connection to electrical power line

- The power cable of the ATMOS® S 41 Gyne is connected to an earthing contact socket near the unit (max. 3 m).
- The current consumption of the ATMOS® S 41 Gyne comes to 7 A max.
- Please provide an adequate number of shock-proof plug terminals to supply the additional electrically operated units which are not defined as options, at the workstation of the gynaecologist.

Multiple sockets with moveable connection cable may not be used (please see 2.0 safety notes)!

Fig. 2.

4.1 ATMOS® S 41 Gyne - Basic module

The unique concept of the ATMOS workstation centralises and integrates all the devices required for diagnosis and treatment and therefore improves your workflow. Based on your findings all outpatient treatments can be performed directly and without any long waiting time in one room.

The instrument deposit area:

A storage area for medicine bottles and consumables (❶) is located at the head of the function column. There is also the facility for protective storage of required instruments and consumables in the drawers (❾).

The unit's surfaces are coated with a special textured lacquer that fulfils the requirements for workplace hygiene. However, as the lacquer is not resistant to all medicines and disinfectants it is imperative to wipe up splashes immediately.

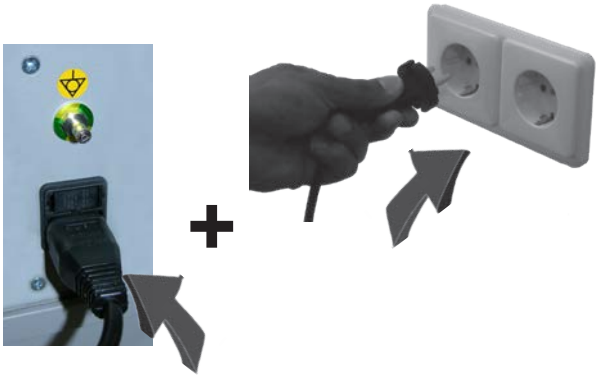


Fig. 3.

4.2 Basic functions

4.2.1 Power supply

- The ATMOS® S 41 Gyne is separated from the electricity network via the rubber connector.

4.2.2 Maximum loads

- Persons must not lean on the ATMOS® S 41 Gyne (danger of tipping over).
- Maximum load of the function carrier: 12 kg.

Fig. 4. ATMOS® RS 221

4.3 Options

4.3.1 ATMOS® RS 221 (601.1700.0)

- Please pay attention to the safety and operating notes in the attached operating manual.

ON I
OFF 0

Symbol for operating mode neutral electrode

Symbol for neutral electrode (shines red at malfunction)

Symbol for type of device according to EN 60601

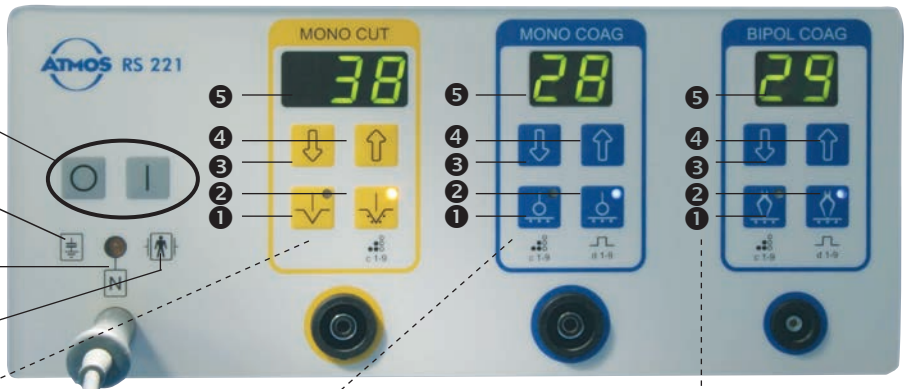


Fig. 5.

MONO CUT

❶ Cutting monopolar
❷ Monopolar cutting with coagulation / setting of coagulation degree
❸ Output / coagulation degree lower
❹ Output / coagulation degree higher
❺ Display output / coagulation degree

MONO COAG

❶ Permanent coagulation monopolar / setting of coagulation degree
❷ Pulse coagulation monopolar / setting of pulse duration
❸ Output / coagulation degree / pulse duration lower
❹ Output / coagulation degree / pulse duration higher
❺ Display output / coagulation degree / pulse duration

BIPOL COAG

❶ Permanent coagulation bipolar / setting of coagulation degree
❷ Pulse coagulation bipolar / setting of pulse duration
❸ Output / coagulation degree / pulse duration lower
❹ Output / coagulation degree / pulse duration higher
❺ Display output / coagulation degree / pulse duration

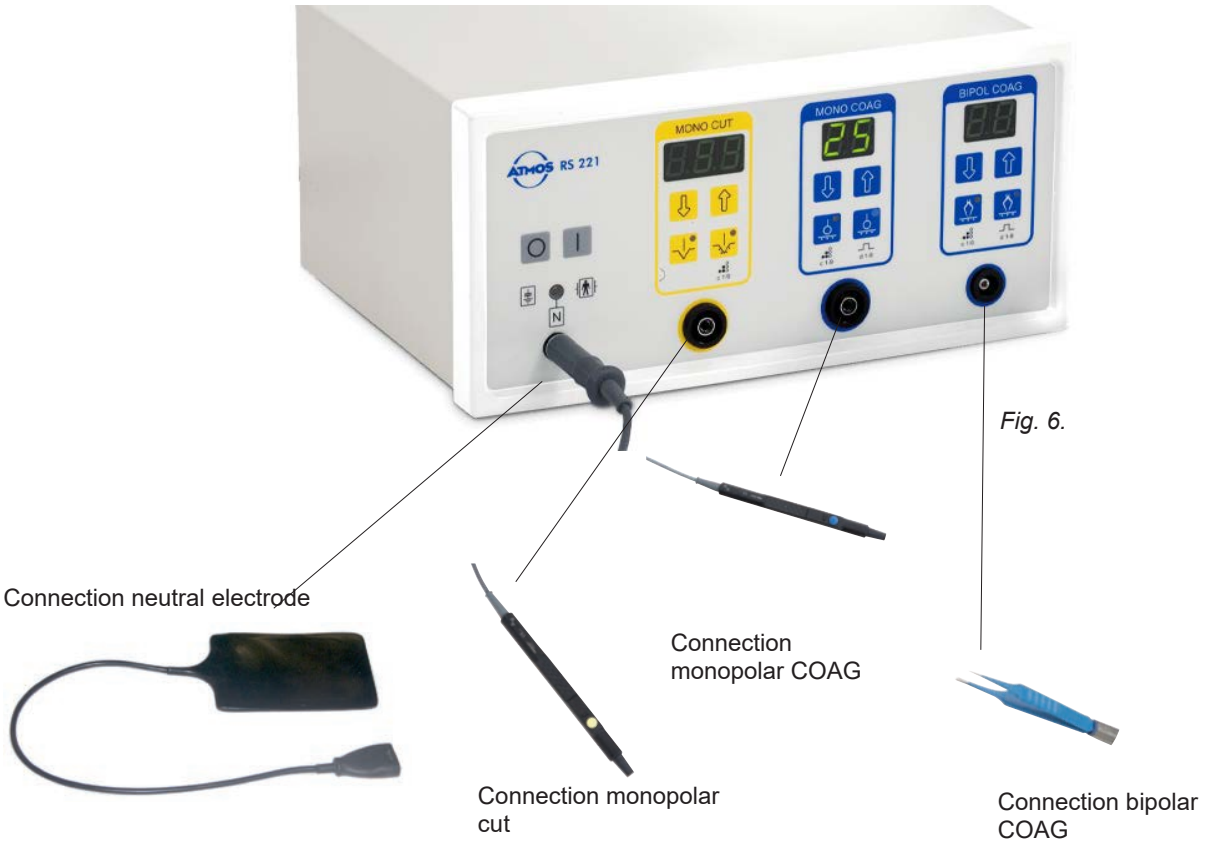


Fig. 6.

Gynaecology	Recommended adjustment	Recommended type of electrodes
Conisation on the portio uteri	approx. 65 CUT/COAG c3 approx. 40 CUT/COAG c3/c2	BIO-CONE Loop electrodes
Gynaecomasty	approx. 27 CUT	Blade electrodes Multi-Tip
Test excision (vulva)	approx. 22 CUT	Rhomb electrode
Mamma reduction (see also subcutaneous fat tissue)	approx. 28-30 CUT; CUT/COAG	Needle electrode, Multi-Tip
Mamma augmentation (see also subcutaneous fat tissue)	approx. 28-30 CUT; CUT/COAG	Needle electrode, blade electrode

Fig. 7. SE 6501

4.3.2 ATMOS® SE 6501 (601.1900.0)

- Please pay attention to the safety and operating notes in the attached operating instructions.

Whenever the electro-surgical device is used, the smoke evacuation device automatically switches to extraction operation. ATMOS® SE 6501 returns to basic suction operation after completion of the incision procedure and the tracking sequence.

Fig. 8.

4.3.2.1 Operating elements

❶ Mains on/off switch
❷ Mains filter
❸ Value higher / value lower button to adjust the value in the display
❹ Indication of suction capacity

4.3.2.2 Switching on the ATMOS® SE 6501

Switch on the power switch (❶ fig. 8). The ATMOS® SE 6501 performs a self-test. All the displays illuminate.

Suction performance and run-down time are adjustable. Select the desired function.

Using the value higher / lower buttons you can change the value of the selected function (❸ fig. 8).

You can see the value on the display. The displayed value is either a percentage or in seconds. The percentage symbol or seconds symbol illuminates. The percentage figure refers to the device's maximum output (650 l/min).

Automatic activation

With the integrated radiosurgical modules (ATMOS® RS 221) and smoke gas module (ATMOS® SE 6501) the suction is automatically activated/deactivated during application with the radiosurgical unit.

Setting operation suction

The terms manual start and manual deactivation mean the use of the <Start suction> button. Select the button <Value higher> / <Value lower> a value between 20 and 100% and confirm with the Start / Stop button. 100% corresponds to a suction capacity of approx. 650 l/min.

Setting the follow-up time

The operation suction runs on for a specified length of time after the ATMOS® SE 6501 is deactivated. This period of time is the follow-up time. Select a value between 0 and 10 seconds, using the <Higher> / <Lower> (❸ fig. 8) buttons.

You can also let the operation suction continue running for an indefinite period after deactivation of the electrosurgical unit or after manual deactivation of the ATMOS® SE 6501. Select a period longer than 10 seconds, using the <Higher> (❸ fig. 8) button. The word "On" appears on the display. The permanent operation suction mode is activated.

The permanent operation suction can be switched on and off with the <Start suction> button (❹ fig. 8).

4.3.2.3 Suction

WARNING

Position the suction device, or the instrument with suction device so that it cannot accidentally suck up swabs or the like.

Press the <Start suction> button or activate the attached laser or electro surgical device. The unit operates so long as the button is pressed or the attached laser or electro surgical device is activated. Suction then continues for the duration of the set follow-up time, after which basic suction takes place for the duration of the set basic suction time.

WARNING!

Never bring the suction hose into contact with the suction site. It could become attached to the tissue.

ATTENTION:

Do not suck up any liquids. If there is a risk that you could suck up liquids during the operation, attach an in-line filter on the main filter. Replace the in-line filter immediately if you have sucked up any liquid.

For smoke evacuation we recommend the use of the ATMOS® specula.

Fig. 9. ATMOS® C 401

Fig. 10.

4.3.3 ATMOS® C 401 (601.1500.0) suction system with DDS system (Direct Docking System)

Please pay attention to the safety and operating notes in the attached operating instructions.

4.3.3.1 Operating elements

❶ On/off switch with control display
❷ Vacuum gauge
❸ Vacuum control

4.3.3.2 On / off switch

- Push the “I” symbol to switch on the device.
- Push the “O” symbol to switch off the device.

4.3.3.3 Set vacuum

- Close the suction hose and set the desired vacuum by turning the vacuum controller according to the direction of the arrow.

⚠ Do not use force to turn the knob to its limits!

- Test the system for leaks if the desired vacuum is not achieved.

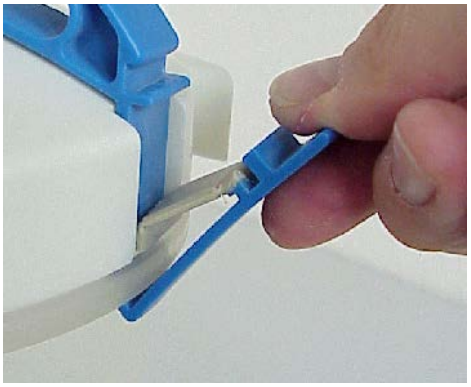


Fig. 11.

4.3.3.4 Close / open DDS secretion canister handle

- To close, secure the snap-in hooks under the edge of the secretion canister, and then press the clips downwards until they lock into place (see fig. 11).
- To open, pull the clips upwards to release the snap-in hooks and remove from under the edge of the secretion canister.

Fig. 12.

4.3.3.5 Attach DDS secretion canister handle

- Fix the secretion canister handle ❶ into the guiding of the lid with opened snap-in hook ❸.
- Fix the snap-in hook ❸ below the canister edge and press the lever towards the centre of the canister until the handle snaps in.

Use of the second container

Move the lever in the direction of the container which is not in use.

Fig. 13.

4.3.3.6 Insert / Remove DDS secretion canister handle

- For removal, lift the DDS secretion canister vertically upwards; to insert it again, allow it to slide vertically downwards into the securing device (see fig 13).

Fig. 14.

4.3.3.7 Insert / Remove bacterial filter / oversuction stop

Use gloves! The DDS bacterial filter is inserted into the DDS secretion canister handle.

To do this separate the DDS secretion canister handle and DDS secretion canister lid. Plug the DDS bacterial filter onto the cross in the middle of the DDS secretion canister handle (see fig. 14) put the DDS secretion canister handle onto the DDS secretion canister lid.

Fig. 15.

Fig. 16.

Fig. 17.

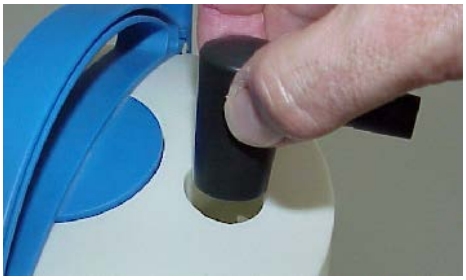


Fig. 18.

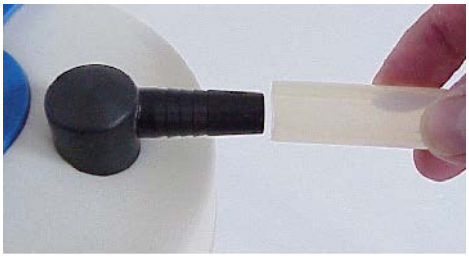


Fig. 19.

4.3.3.8 Using the DDS splash protector

Insert the DDS splash protector into the inner part of the DDS secretion canister lid (see fig. 12).

4.3.3.9 Attach DDS secretion canister lid

- With the DDS secretion canister on a firm surface, position the lid horizontally on top. The lid may not be twisted (see fig. 16)!
- Press it tightly with both hands as far as it will go onto the canister.

4.3.3.10 Remove DDS secretion canister lid

With one hand on the canister handle lift the complete canister upwards. With the other hand on the canister base guide the canister in order to prevent it from tilting when lifting it out. Press the lever apart (see fig. 18).

Unhinge the snap-in hook of the canister handle at the canister. Pull out the snap-in hook with both hands and remove the canister handle upwards. Remove bacterial filter/ oversuction stop from the canister handle.

Remove the canister lid from the canister with both hands. Remove the splash protection.

4.3.3.11 Insert / Remove DDS hose adapter

- Press the required DDS hose adapter with 6 or 10 mm diameter into the opening on the DDS secretion canister lid twisting slightly to ensure a tight fit (see fig. 18).
- Twist slightly in the same manner when removing.

4.3.3.12 Connect hose

- Fix the hose tightly to the adapter (olive) (see fig. 19).

4.3.3.13 Suction

- Use appropriate suction catheters, suction tips or suction instruments.

Make sure to disinfect the suction hose, the suction instruments and the complete secretion canisters prior to every application on a patient.

Observe the liquid level in the secretion canister during suction.

- The hydrophobic bacterial filter / oversuction stop safely prevents liquid from getting into the pump. Nevertheless, the secretion canister should be replaced when 2/3 full.

4.3.3.14 Test DDS bacterial filter / oversuction stop

- The DDS bacterial filter / oversuction stop is disposable.

Prior to each use please check whether the DDS bacterial filter / oversuction stop is dry and clean. Wet or dirty filters must be replaced with new ones.

The filter is no longer in optimum condition if the vacuum displayed is above -0.3 bar when the vacuum controller is in the ”max.” position and the suction hose is open. The filter must then be replaced.

Replace the DDS bacterial filter at least once a day. Use only original ATMOS bacterial filters!

The device may never be operated without DDS bacterial filter / oversuction stop!

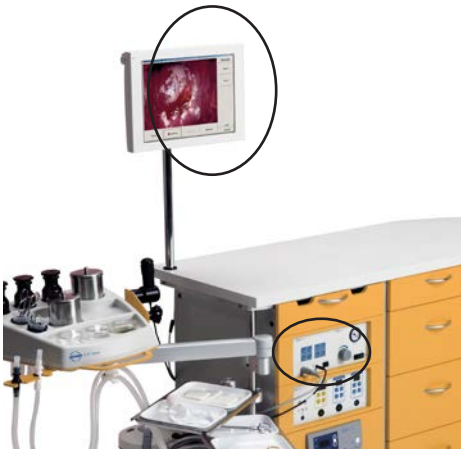


Fig. 20. TFT display and ATMOS® Cam 31 DV

4.3.4 Video system (ATMOS® Cam 31 DV, TFT display) (601.1600.0 and 534.3015.0, 534.3010.0)

- Please pay attention to the safety and operating notes in the attached operating manuals.
- To allow the patient to follow and visualise the findings of the endoscopic resp. colposcopic procedures, the ATMOS® S 41 Gyne can be supplemented optionally by a video system, consisting of a camera as well as a display on the arm carrier.
- It is possible to freeze a video image via a foot switch (camera accessory).

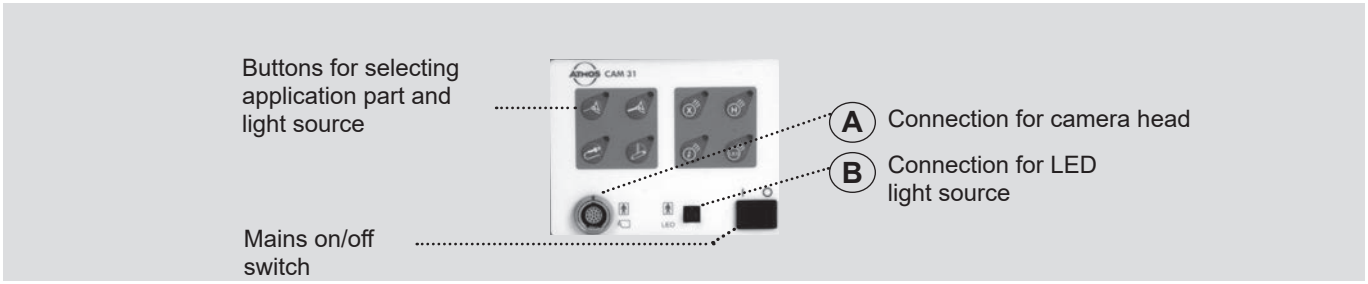
When transferring the video signal to other devices (video printer, video recorder, computer,...) attention must be paid to approval as a medical product.

4.3.4.1 ATMOS® Cam 31 DV

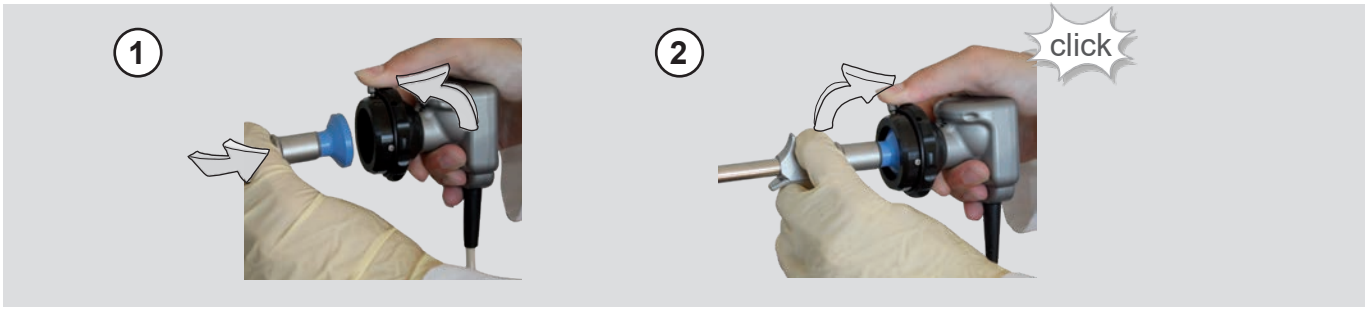
⚠ Please note:

Read the separate operating instructions attentively and follow the stated notes for your safety to guarantee ideal and safe use of all functions!

4.3.4.2 Controls and front view



4.3.4.3 Camera head



Choose light source

1.) at the treatment unit:

Take out the wanted light source. The adjustments on the unit (LED, Halogen) have been set ex works.

2.) directly at the camera:

Take out the wanted light source (see above). Choose desired optics by pressing the button at the camera (❶).

Choose the used light source (❷).

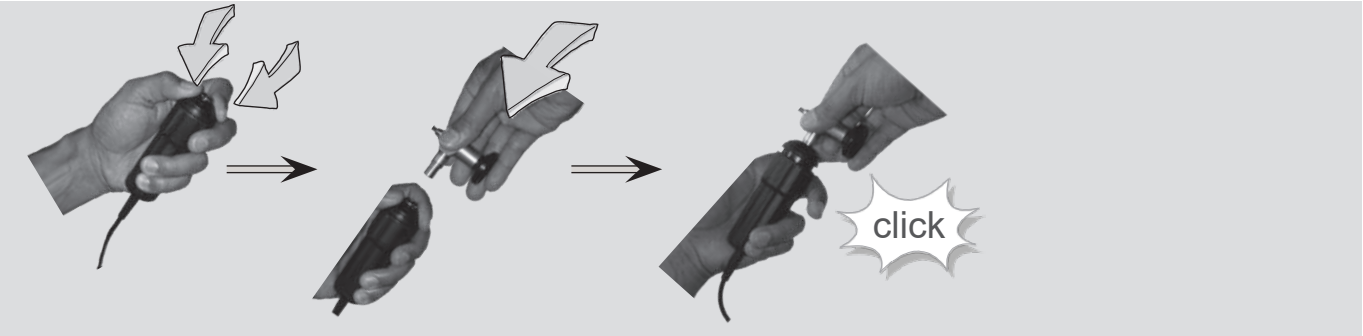
When using the camera next time, all adjustments will be taken over from prior use.

Fig. 21.

Fig. 22. ATMOS® LS 21 LED

4.3.5 ATMOS® LS 21 LED light source (600.0011.0)

Please pay attention to the safety and operating notes in the attached operating manual.



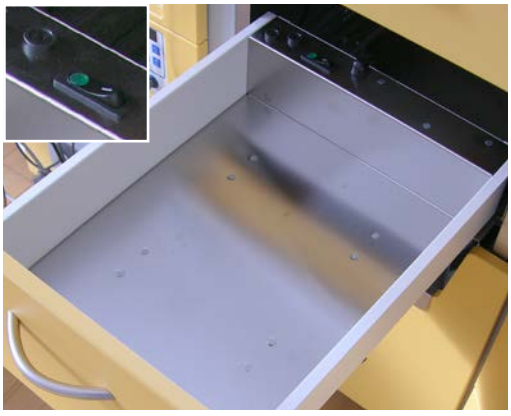


Fig. 23. Heated drawers

4.3.6 Heated drawer

⚠ Check the temperature of the instruments prior to use. If there is a failure in the temperature control then temperatures exceeding 40 °C could occur. If necessary, call the service department

Type A 2 (601.2300.0)

Type B 2 (601.2700.0)

maximum load: 10 kg

Mains switch is accessible after pulling out the drawer.

Fig. 24.

4.3.7 Instrument wet storage (optional)

- Includes a removable disinfectant-proof stainless steel holder with sieve insert and splash protection.

Dimensions: 374 mm x 289 mm x 233 mm

Capacity: 10 litres

4.3.8 Waste bin (optional)

- The door of the waste bin is fitted with a "kick box" locking device. The waste bin automatically opens a little by lightly touching the door with the hand or foot.
- The kick box locks automatically on closing.

⚠ Caution with contact or exposure to contaminated waste! Risk of infection!

5.1 General information on cleaning and disinfection

Switch all devices off prior to cleaning and disinfection!

The described action relating to cleaning and disinfection resp. sterilisation do not substitute the relevant instructions which must be adhered to prior to operation!

- For disinfection, you may use all listed surface and instrument disinfectants.

Always observe the concentration specifications and instructions by the respective manufacturer!

- Do **not** use
  - Disinfectants which contain organic or inorganic acids or bases as they could cause corrosion damage.
  - Disinfectants containing chloramides, phenol derivatives or anionic tensides, as these may cause stress cracks in the material used for the housing of the unit.

5.1.1 Cleaning the unit surface

- The surfaces of the ATMOS® S 41 Gyne are resistant against all surface disinfectants listed on page 22.
- Wipe the unit surface with a cloth moistened with a cleaning or disinfecting solution.
- You may also use disinfectant sprays or disinfectant tissues for cleaning and disinfection.
  - ↳ Please note that the alcohol contained in these agents could corrode or cloud the protective covers if employed on a long term basis.

5.1.2 Cleaning "application parts"

"Application parts" comprise:
All parts or components which come into contact with the patient and could be contaminated:

- Secretion canister,
- Secretion canister lid,
- Hose adapter,
- Secretion hose.

⚠ All application parts can be disinfected using the recommended instrument disinfecting solution (see page 21).

All application parts which are exposed to direct contact with the patient during treatment must be exchanged or cleaned and disinfected immediately for hygienic reasons.

5.1.3 Secretion canister, bacterial filter and suction hose

At the end of every working-day, **following parts must be cleaned and disinfected**:

- Secretion canister with lid system and bacterial filter:
  - Detach all hose connections carefully on the lid system and take secretion canister out carefully to prevent spills and contamination of the area. Dispose of secretions properly.
  - Grip lid system firmly, open lid of filter housing by turning in anti-clockwise direction and remove filter. Rinse all parts thoroughly under running water. A detergent or cleaning agent may also be used if required.
  - Disinfection with disinfectants recommended in chapter 5.3 for surface disinfection.
  - After cleaning the filter must be inserted (smooth side down).
  - Max. cycles of reprocessing:
    DDS secretion canister system, silicone hose: 60 cycles
- Suction system and hose attachment:
  - After every use, rinse out the suction system by drawing in a small amount of rinsing fluid (e.g. ATMOS® special cleanser for suction systems 080.0006.0, dosage: 10 ml to 1 l water).
    - ↳ Keeps the suction hoses from becoming sticky or clogged.

⚠ - Immersing the hose into disinfection solution.
- Replace the filter.
- Caution with contact or exposure to contaminated waste! Risk of infection!

5.1.4 Instrument trays

⚠
- Before disinfection, thoroughly rinse the trays under running water. A detergent or cleaning agent may also be used if required.
  - Use water to thoroughly rinse all residues of these substances.
  - Disinfection of the trays with disinfectants recommended in chapter 5.3 Surface disinfection.
- Stainless steel trays and trays made of anodized aluminium can be cleaned automatically (Neodisher MediClean forte). They can also be disinfected thermally at a temperature of 93°C.

Trays made of melamine do **not** resist temperatures of 93°C.

5.2 Recommended instrument disinfectants

Manual disinfection of instruments

Disinfectant	Ingredients	in 100 g	Manufacturer
Korsolex® med AF (Application concentrate)	N-dodecylpropane-1,3-diamine N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine Surfactants, corrosion inhibitors, ph-value regulators, foam inhibitors	15.6 g 5.1 g	Bode Chemie, Hamburg
Korsolex® basic (Application concentrate)	Glutaral (ethylenedioxy)dimethanol Surfactants, salts, corrosion inhibitors	15.2 g 19.7 g	Bode Chemie, Hamburg
Korsolex® plus (Application concentrate)	N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine Didecyldimethylammonium chloride Surfactants, corrosion inhibitors, complexing agents, ph-value regulators	9.2 g 13.0 g	Bode Chemie, Hamburg
Korsolex® extra (Application concentrate)	(ethylenedioxy)dimethanol Glutaral Benzyl-C12-18-alkyldimethyl-ammonium chlorides Didecyldimethylammonium chloride Surfactants, foam inhibitors, corrosion inhibitors	15.3 g 7.5 g 1.0 g 1.0 g	Bode Chemie, Hamburg
neodisher® Septo MED (Application concentrate)	N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine Didecyldimethylammonium chloride non-ionic surfactants, perfumes	9.2 g 13.0 g	Dr. Weigert, Hamburg
neodisher® Septo 3000 (Application concentrate)	Glutaral (ethylenedioxy)dimethanol	15.2 g 19.7 g	Dr. Weigert, Hamburg
Sekusept® aktiv (Application concentrate)	Sodiumpercarbonate, non-ionic surfactants, phosphonates		Ecolab, Düsseldorf
Gigasept® Instru AF (Application concentrate)	Cocospropylendiaminguanidindiacetate Phenoxypropanols Benzalkonium chloride non-ionic surfactants, ph-value regulators, corrosion inhibitors	14 g 35 g 2.5 g	Schülke & Mayr, Norderstedt
Gigasept® FF (new) (Application concentrate)	Succindialdehyde dimethoxytetrahydrofurane anionic and non-ionic surfactants, perfumes, methylisothiazolinone	11.9 g 3.2 g	Schülke & Mayr, Norderstedt
Gigazyme® (Application concentrate)	non-ionic surfactants enzymes, corrosion inhibitors	5- 15 g	Schülke & Mayr, Norderstedt

Automatic disinfection of instruments

Disinfectant	Ingredients	in 100 g	Manufacturer
Dismoclean® 24 Vario (Application concentrate)	surfactants, micro-encapsulated enzymes, corrosion inhibitors, complexing agents		Bode Chemie, Hamburg
Dismoclean® 28 alka med (Application concentrate)	alkali dispenser, complexing agents, corrosion inhibitors, surface active materials		Bode Chemie, Hamburg
Dismoclean® twin basic Dismoclean® twin zyme	alkali dispenser, complexing agents, corrosion inhibitors surface active materials, enzymes, stabilisers, corrosion inhibitors		Bode Chemie, Hamburg
neodisher® FA	Phosphates	15 - 30 g	Dr. Weigert, Hamburg
neodisher® MediClean forte (Application concentrate)	non-ionic and anionic surfactants enzymes	< 5 g	Dr. Weigert, Hamburg
Thermosept® RKN-zym	non-ionic surfactants enzymes, corrosion inhibitors, glycols	5 - 15 g	Schülke & Mayr, Norderstedt
Thermosept® alka clean forte (Application concentrate)	non-ionic surfactants anionic surfactants NTA (nitrilotriacetic acid) and its salts enzymes, poly carboxylates corrosion inhibitors	< 5 g < 5 g < 5 g < 5 g	Schülke & Mayr, Norderstedt

5.3 Recommended surface disinfectants

Coated surfaces

Disinfectant	Ingredients	in 100 g	Manufacturer
Green & Clean SK	Di alkyl dimethyl ammonium chloride Alkyl dimethyl ethyl benzyl ammonium chloride Alkyl dimethyl benzyl ammonium chloride	< 1 g < 1 g < 1 g	Metasys, Rum (Austria)
Dismozon® plus (Granulate)	magnesium monoperoxyphthalate hexahydrate	95.8 g	Bode Chemie, Hamburg
Kohrsolin® FF (Application concentrate)	glutaral benzyl-C12-C18-alkyldimethyl-ammonium chlorides Didecyldimethylammonium chloride	5 g 3 g 3 g	Bode Chemie, Hamburg
Perform®	Pentapotassium-bis(peroxymonosulphate)-bis(sulphate)	45 g	Schülke & Mayr, Norderstedt
Terralin® Protect (Application concentrate)	Benzyl-C12-16 alkyldimethyl-, chloride 2-phenoxyethanol aminoalkylglycine non-ionic surfactants, perfumes	22 g 17 g 0.9 g	Schülke & Mayr, Norderstedt

Other surfaces

Disinfectant	Ingredients	in 100 g	Manufacturer
Dismozon® plus (Granulate)	magnesium monoperoxyphthalate hexahydrate	95.8 g	Bode Chemie, Hamburg
Kohrsolin® FF (Application concentrate)	glutaral benzyl-C12-18-alkyldimethyl-ammonium chlorides Didecyldimethylammonium chloride	5 g 3 g 3 g	Bode Chemie, Hamburg
Mikrobac® forte (Application concentrate)	benzyl-C12-18-alkyldimethyl-ammonium chlorides N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine	19.9 g 5 g	Bode Chemie, Hamburg
Perform®	Pentapotassium-bis(peroxymonosulphate)-bis(sulphate)	45 g	Schülke & Mayr, Norderstedt
Terralin® Protect (Application concentrate)	Benzyl-C12-16 alkyldimethyl-, chloride 2-phenoxyethanol aminoalkylglycine non-ionic surfactants, perfumes	22 g 17 g 0.9 g	Schülke & Mayr, Norderstedt
Surface disinfection F 312	alkyl-benzyl-dimethyl-ammonium chloride non-ionic surfactants, complexing agents, hexyl cinnamal, butyl phenyl methyl proionale, linalool	13 g	Dürr Dental, Bietigheim-Bissingen

5.4 Cleaning and disinfection plan

	What	How			Recommendations	When				Who
	Reusable parts	C Cleaning	D Disinfection	S Sterilisation		After each procedure	Daily	Weekly	Monthly	Qualified and trained staff who are familiar with reprocessing. (Please fill in the responsible person -> use a water-based overhead marker)
	Secretion canister									
	Secretion suction hose				Monthly exchange.				X	
		X	X[2), 4), 5)]		Cleaning and disinfection (manually or automatically)		X			
	Hose connection (nozzle)	X	X[2), 4), 5)]		Cleaning and disinfection (manually or automatically)		X			
	Suction lid	X	X[2), 4), 5)]		Cleaning and disinfection (manually or automatically)		X			
	Hand grip	X	X[2), 4), 5)]		Cleaning and disinfection (manually or automatically)		X			
	Gasket	X	X[2), 4), 5)]		Cleaning and disinfection (manually or automatically)		X			
	Bacterial filter				Daily exchange or when filter is blocked		X			
	Secretion collection canister	X	X[2), 4), 5)]		Empty when canister is full.		X			
					Cleaning and disinfection (manually or automatically)					
	**Instrument management**									
	Gynaecology instruments	X	X	X	Immerse instruments into solution immediately after use, complete wetting is required, air must be removed from any cavities, after the contact time instruments must be cleaned with a brush and rinsed with water, have to be dried and sterilised after-wards. Please also observe the ATMOS operating instructions for GYNE instruments.	X				
	Wet storage									
	Canister	X	X[4)]		Manual cleaning and disinfection.		X			
	Sieve	X	X[2), 4), 5)]		Cleaning and disinfection (manually or automatically)		X			
	Splash protection	X	X[4)]		Manual cleaning and disinfection.		X			
	**Visualisation**									
	ATMOS® Cam 21 / 31	X	X[3)]		Wipe cleaning and wipe disinfection.	X				
	Rigid scope	X	X[1)]	X[1)]	Immediate pre-cleaning after each procedure (wipe disinfection) Reprocessing acc. to instructions stated in the operating instructions.	X				
	Light conductor	X	X[3)]		Wipe cleaning and wipe disinfection.		X			
	Light source	X	X[3)]		Wipe cleaning and wipe disinfection.		X			
	Microscope / Colposcope	X	X[3)]		Wipe cleaning and wipe disinfection.		X			
	**Radiofrequency surgery**									
	ATMOS® RS 221 (surface)	X	X		Wipe cleaning and wipe disinfection.		X			
	Ergonomic plastic handles	X	X[2), 4), 5)]	X[1)]	Wipe cleaning and wipe disinfection.	X				
	Bipolar-tweezers	X	X[2), 4), 5)]	X[1)]	Immediate pre-cleaning after the procedure or dispose of in wet disposal tray; use of enzymatic detergents	X				
	Bipolar electrode	X	X[2), 4), 5)]	X[1)]		X				
	Bipolar electrode cable	X	X	X[1)]	Immediate pre-cleaning after the procedure or dispose of in wet disposal tray; use of enzymatic detergents	X				
	Neutral electrode	X	X[2), 4), 5)]	X[1)]		X				
	Neutral electrode cable	X	X	X[1)]	Immediate pre-cleaning after the procedure or dispose of in wet disposal tray; use of enzymatic detergents	X				
	GYNE electrodes	X	X	X[1,6)]	Immediate pre-cleaning after the procedure or dispose of in wet disposal tray; use of enzymatic detergents	X				
	**Smoke evacuation**									
	Suction hose	X	X[2), 4), 5)]		Cleaning and wipe disinfection (manually or automatically)		X			
					monthly exchange				X	
	Surface filter housing	X	X		Wipe cleaning and wipe disinfection		X			

5.0 Cleaning and care

	What	How			Recommendations	When				Who
	Reusable parts	C Cleaning	D Disinfection	S Sterilisation		After each procedure	Daily	Weekly	Monthly	Qualified and trained staff who are familiar with reprocessing. (Please fill in the responsible person -> use a water-based overhead marker)
	Surfaces									
	Housing	X	X[3]		Wipe cleaning and wipe disinfection.		X			
	Shutter	X	X[3]		Wipe cleaning and wipe disinfection.		X			
	Rotary arm	X	X[3]		Wipe cleaning and wipe disinfection.		X			
	Drawers	X	X[3]		Wipe cleaning and wipe disinfection.		X			
	Deposit	X	X[3]		Wipe cleaning and wipe disinfection.		X			
	Support glove dispenser	X	X[3]		Wipe cleaning and wipe disinfection.		X			
	PC support	X	X[3]		Wipe cleaning and wipe disinfection.		X			
	Castors	X	X[3]		Wipe cleaning and wipe disinfection.		X			
	Waste disposal	X	X[3]		Wipe cleaning and wipe disinfection., every day or when emptying the container.		X			
	Instrument tray Melamin	X	X[3]		Wischreinigung und -desinfektion, every day or when replacing with new instruments		X			

Recommended disinfectants

[3] Surface disinfection for coated surfaces:
- Green & Clean SK (ATMOS)
- Dismozon® plus (Bode Chemie)
- Kohrsolin® FF (Bode Chemie)
- Perform® (Schülke & Mayr)
- Terralin® Protect (Schülke & Mayr)

Other surfaces:
- Dismozon® plus (Bode Chemie)
- Kohrsolin® FF (Bode Chemie)
- Mikrobac® forte (Bode Chemie)
- Perform® (Schülke & Mayr)
- Terralin® Protect (Schülke & Mayr)
- Surface disinfection FD 312 (Dürr Dental)

[4] Instruments - manual disinfection:
- Korsolex® med AF (Bode Chemie)
- Korsolex® basic (Bode Chemie)
- Korsolex® plus (Bode Chemie)
- Korsolex® extra (Bode Chemie)
- neodisher® Septo MED (Dr. Weigert)
- neodisher® Septo 3000 (Dr. Weigert)
- Sekusept® aktiv (Ecolab)
- Gigasept® Instru AF (Schülke & Mayr)
- Gigazyme® (Schülke & Mayr)
- Gigasept FF neu (Schülke & Mayr)

[5] Instruments - automatic disinfection:
- Dismoclean® 24 Vario (Bode Chemie)
- Dismoclean® 28 alka med (Bode Chemie)
- Dismoclean® twin basic/twin zyme (Bode Chemie)
- neodisher® FA (Dr. Weigert)
- neodisher® MediClean forte (Dr. Weigert)
- Thermosept® alka clean forte (Schülke & Mayr)
- Thermosept® RKN-zym (Schülke & Mayr)

Please see the manufacturer's instructions for concentration, contact time, temperature and the compatibility of materials.

Important information

Wipe cleaning and wipe disinfection: All surfaces have to be wiped with a clean (disposable) wipe which is damped with disinfectant solution; the entire surface has to be wiped thoroughly and may not be dried afterwards.

[1] Please observe the manufacturer's operating instructions.

[2] Alternative to automatic cleaning and disinfection: cleaning and disinfection device 78°C

Wrong concentration of disinfectants may lead to damage!

The above stated hygiene requirements are based on the regulations according to the Medical Devices Act, the Medical Devices Operator Ordinance, §18 IfSG and the recommendations of the Robert Koch Institute.
Definition of the required reprocessing steps result from the recommendations of the Robert Koch Institute: „Requirements for the reprocessing of medical products". The medical products were categorised in the risk groups uncritical, semicritical and critical. The reprocessing steps stated in this diagram have to be performed. Any additional reprocessing measures are at the operator's discretion.
All the recommended disinfectants which are stated herein are listed disinfectants (VAH/RKI) and have been tested on their suitability of use on the ATMOS® S 41 Gyne. ATMOS MedizinTechnik cannot be hold liable for any damage caused by wrong concentration of the disinfectants or by the application of any other disinfectants.
Patients with suspicion of a clinical disease or who developed a transmissible spongiform encephalopathy (CJK, vCJK, etc.) have to be treated at facilities which are able to provide for the necessary preventive measures against infection. The reprocessing of the reusable instruments and material may only be performed at facilities which have an externally certified QM Management acc. to DIN EN ISO 13485/13488.
The Medical Devices Act, IfSG, the RKI directives, BGR 250 and TRBA 250 always have to be considered.

ATMOS MedizinTechnik GmbH & Co. KG
Ludwig-Kegel-Str. 16 ■ 79853 Lenzkirch/Germany
Phone +49 7653 689-0 ■ Fax +49 7653 689-190
atmos@atmosmed.de ■ www.atmosmed.de

6.0 Maintenance and Service

Maintenance, repairs and period 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 12 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.
- The electrical options, especially the electrical surgical units, are subject to the relevant operating manuals and the specified testing and maintenance instructions stated therein.
- The ATMOS® S 41 Gyne is equipped with maintenance-free pumps for suction. Nevertheless, to ensure correct functioning of the unit over a long period of time simple maintenance work which can either be done by the user himself, or, if desired, by service technicians, is necessary from time to time.

6.1 Sending in the device

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

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

- The device must be well padded and packed in suitable packaging.
- Place the 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 to your dealer.

Fig. 25.

7.1 Electrical protection

- The supply line voltage reaches the individual components an inlet connection for non-heating apparatus. The power supply is guaranteed by means of fusible cut outs in the inlet connection on the rear side of the unit.

Note: Please also refer to the causes and measures for troubleshooting in the operating instructions of the respective optional devices.

Please check your system according to the following diagrams before you get in touch with the ATMOS customer service:

7.2 Power supply

Error indication	Possible cause	Remedy
No voltage at the unit, no function, pilot lamps do not light up	• No voltage to power plug • Blown fuse	• Check the fuses of the individual devices • Replace fuse on the rear of the unit • Check fuse in building, connect other units (lamp) to the socket, if necessary • Contact the ATMOS service
	• power plug or cable is defective	• check power plug or cable and replace, if necessary

7.3 Heated drawer

Error indication	Possible cause	Remedy
No heating, control lamp activated	• Control electronics or heater is defective	• Contact the ATMOS service
	• Power plug / cable is defective	• check power plug or cable and replace, if necessary
No heating, control lamp not activated	• Blown fuse	• Check the fuses
	• Power plug / cable is defective	• Remove the drawer completely and check the cable resp. plug connection

7.4 Suction system

Error indication	Possible cause	Remedy
Weak suction or no suction at all	• Suction hose is clogged	• Rinse the suction hose with water (hose can also be removed)
	• Auxiliary air control open	• Check the auxiliary air control
	• Float of overflow safety closes the suction opening	• Check filling level in the secretion canister
	• Lid of secretion canister is not closed tightly	• check that lid of the secretion canister is closed properly
	• Bacterial filter is clogged	• Replace the bacterial filter
	• Hose connections are leaking	• Seal up or replace connections
	• Connection hose is kinked	• Check hose connections, remove kinks
	• Secretion penetrated the suction pump	• Have suction pump cleaned by a service technician
No suction, but vacuum gauge indicates -0.7 bar	• Suction hose is clogged	• Rinse the suction hose with water (hose can also be removed)
	• Float of overflow safety closes the suction opening	• Check filling level in the secretion canister
	• Bacterial filter is clogged	• Replace the bacterial filter
	• Connection hose is kinked	• Check hose connections, remove kinks
No suction and suction motor does not start, control lamp is activated	• Pump / motor defective	• Please contact your service technician authorised by ATMOS

If, nevertheless, the errors cannot be removed inform the ATMOS service staff. Do not start any attempts to repair the unit yourself!

Also pay attention to corresponding chapters in respective operating instructions!

8.0 Accessories and consumables

Accessories radiosurgery	REF
Monopolar accessories set gynaecology	600.0159.0
Bipolar set	506.5860.0
Handpiece for Bio-Cone	600.0161.0
Foot switch ATMOS® RS 221	506.5861.0
Bio-Cone 9 x 30 mm	600.0162.0
Bio-Cone 15 x 18 mm	600.0163.0
Bio-Cone 15 x 24 mm	600.0164.0
Bio-Cone 18 x 24 mm	600.0165.0
Bio-Cone 15 x 30 mm	600.0166.0
Handle for loop electrode	600.0171.0
Loop electrode, D = 10 mm	600.0167.0
Loop electrode, D = 15 mm	600.0168.0
Loop electrode, D = 20 mm	600.0169.0
Loop electrode, D = 25 mm	600.0170.0
Ball-shaped electrode, D = 2.3 mm	600.0472.0
Magnetic support for handles	On request

8.0 Accessories and consumables

Consumables ATMOS® C 401	REF
DDS bacterial filter	340.0054.0
Tissue collector	340.0061.0
Collecting sieve for tissue samples	401.0555.0
DDS adapter for tissue collector	340.0062.0
Adapter tissue collector for Receptal	444.0148.0
Suction hose, D = 6 mm, L = 2 m	000.0361.0
Suction hose, D = 6 mm, L = 2.1 m, not autoclavable, 50 pcs.	006.0059.0

Consumables ATMOS® SE 6501	REF
Main filter unit, ULPA, change after 150 patients	445.0040.0
Pre-filter (HEPA), increases filter lifetime, use is mandatory in combination with laser applications, 50 pcs., sterile, single-use	445.0044.0
Air hose, internal diam. 10 mm, L = 1.8 m	005.0204.0
Connection hose, straight, D = 22 mm (M) to D = 10 mm (M)	006.0689.0
Connection hose, straight, D = 22 mm (W) to D = 10 mm (M)	006.0688.0

9.0 Technical data

Voltage	230 V~ ±10 %, 50/60 Hz Special voltage: 115 V~ ±10 %, 50/60 Hz 127 V~ ±10 %, 50/60 Hz
Current consumption	At 230 V~
• CAM 31 / 31 DV	0.15 A (35 VA)
• Monitor	1.0 A (220 VA)
• LS 21 LED power supply	0.04 A (10 VA)
• C 451 secretion suction device	0.45 A (100 VA)
• RS 221 electrosurgery device	0.95 A (220 VA)
• SE 6501 smoke evacuation device	1.4 A (330 VA)
• Heated drawer	max. 1.0 A (220 VA)
With full equipment	7.0 A (1600 VA)
Power consumption	Max. 1600 VA
Fuses	2 x T 10.0 A / 250 V
Suction system	
• output per litre	40 l/min ± 10 %
• Vacuum	90% from ambient pressure
• Volume of the secretion canister	1 x 3.0 l and 1 x 1.5 l
Power source LS 21 LED	
• Output current for LED	700 mA
Drawer heating	
• Temperature	40° C regulated
Operating time	Continuous operation
Protective earth conductor resistance	Max. 0.1 Ω
Earth leakage current	Max. 0.5 mA
Enclosure leakage current	Max. 0.1 mA
Patient leakage current	Max. 0.1 mA
Ambient conditions for transport/storage	
• Temperature	-20...+50° C
• Humidity without condensation	5...95 %
• Air pressure	500...1060 hPa
Ambient conditions operation	
• Temperature	+5...+35° C
• Humidity without condensation	30...95 %
• Air pressure	700...1060 hPa
Maximum operational altitude	≤ 3000 m
Contamination level	Class 2
Overvoltage category	II
Dimensions	
Cabinet (H x W x D)	97.2 x 72.0 x 49.0 cm
Cabinet, mobile (H x W x D)	97.2 x 87.0 x 49.0 cm
Instrument deposit height	13.0 cm
Function support, circumradius	28.5 - 42.0 cm
Weight	Max. 150 kg (full equipment)

9.0 Technical data

Period tests	Repeat test of the electrical safety every 12 months. Recommended: inspection according to the manufacturer‘s specifications.
Safety class (EN 60601-1)	I
Degree of protection	Application parts type BF
Protection category	IP X0
Classification in accordance with Appendix IX EC Directive 93/42/EEC	Class II b (with electrosurgical device) Class II a (with suction system) Class I (without electricosurgical device and suction system)
CE marking	CE 0124
GMDN code	40599
UMDNS code	10-534
ID No. (REF)	600.0000.0

Issue of technical data: 09.01.2018

10.0 Checking / Disposal

10.1 Checking ATMOS® devices

At least every 12 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.

Regular, thoroughly cleaning and disinfection of the devices and the application parts respectively the operation in line with the operating instructions are assumed.

10.2 Disposal

- The ATMOS® S 41 Gyne does not contain any hazardous goods.
- The housing is recyclable.
- Device and accessories must be decontaminated prior to disposal.
- Pay attention to a careful separation of the different materials.
- Please observe national disposal regulations (e.g. waste incineration).

Disposal within the EC

The device described above is a high-quality medical product with a long service life. After its life cycle it must be disposed of professionally. According to the EC directives (WEEE and RoHS) the device 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 order to guarantee a proper disposal of your old device, please either pass on your old device to your specialised dealer or send it to ATMOS MedizinTechnik for disposal.

Before disposal respectively before transport all parts, which came into contact with the patient must be thoroughly cleaned, disinfected. The device surface must be disinfected.

11.0 Notes on EMC

Where EMC is concerned, medical electrical equipment is subject to special safety measures and must be installed and commissioned according to the EMC instructions stated herein.

ATTENTION:

The use of internal cables other than those specified in the Service Manual may result in increased emissions or decreased immunity of the equipment.

ATTENTION:

The equipment should not be used adjacent to or stacked with equipment, other than with that which is intended for this purpose. If adjacent or stacked use is necessary, the entire system should be observed to verify normal operation in the configuration in which it will be used.

Guidance and manufacturer's declaration - electromagnetic immunity		
The device is intended for use in the electromagnetic environment specified below. The customer or user of the device should ensure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic Environment - Guidance**
RF Emission acc.to CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and it is unlikely that nearby electronic devices will be affected.
RF Emission acc.to CISPR 11	Class B	The device is suitable for use in all establishments, including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonics acc. to IEC 61000-3-2	Class A	
Voltage fluctuations/flicker according to IEC 61000-3-3	complies	

Guidance and manufacturer's declaration - electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or user of the device should ensure that it is used in such an environment.			
Immunity test	**IEC 60601- Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic discharge (ESD) according to IEC 61000-4-2	± 6 kV Contact ± 8 kV Air	± 6 kV Contact ± 8 kV Air	Floors should be made of wood or concrete or tiled with ceramic tiles. If floors are non-conductive synthetic, the relative humidity should be at least 30 %.
Fast electrical transient/burst IEC 61000-4-4	± 2 kV Mains ± 1 kV I/Os	± 2 kV Mains ± 1 kV I/Os	Mains power quality should be that of a typical commercial or hospital environment.

Guidance and manufacturer's declaration - electromagnetic immunity			
Surges IEC 61000-4-5	1 kV Common 2 kV Differential	1 kV Common 2 kV Differential	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips / Dropout IEC 61000-4-11	<5% U_T (>95% Dip of the U_T) for 0.5 Cycles 40% U_T (60% Dip of the U_T) for 5 Cycles 70% U_T (30% Dip of the U_T) for 25 Cycles <5% U_T (>95% Dip of the U_T) for 5 seconds	<5% U_T (>95% Dip of the U_T) for 0.5 Cycles 40% U_T (60% Dip of the U_T) for 5 Cycles 70% U_T (30% Dip of the U_T) for 25 Cycles <5% U_T (>95% Dip of the U_T) for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued function during interruptions of the energy supply, it is recommended to supply the device from an uninterruptible power supply or a battery.
Magnetic field at power frequency 50/60 Hz acc. to IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.
Note: U_T is the AC mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration - electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or user of the device should ensure that it is used in such an environment.			
Immunity test	**IEC 60601- Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
			Portable and mobile HF communications equipment should be used no closer to any part of the equipment, including cables, than the recommended separation distance. The separation distance is calculated from various equations depending on the frequency of the portable and mobile HF communications equipment:
			Recommended distances
conducted interference according to IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Equation 1) d=1.2 P1/2
Radiated RF disturbances according to IEC 61000-4-3	3 V/m 80 MHz to 800 MHz	3 V/m	Equation 2) d=1.2 P1/2
	3 V/m 800 MHz to 2.5 GHz	3 V/m	Equation 3) d=2.3 P1/2

Guidance and manufacturer's declaration - electromagnetic immunity	
	P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.d is the recommended separation distance in metres (m). Field strengths from fixed transmitters, as determined by an electromagnetic site survey a) should be less than the compliance level in each frequency range b). Interference may occur in the vicinity of equipment marked with the following symbol:
NOTE 1: At 80 MHz equation 2) applies. At 800 MHz equation 3) applies. NOTE 2: These guidelines may not be applicable in all situations. The propagation of electromagnetic sizes is influenced by absorptions and reflections of buildings, objects and people.	
a) The field strength of stationary transmitters, such as base stations of cellular phones and mobile terrain radio equipment, amateur radio transmitters, cbm broadcast and TV stations cannot be predestined exactly. To assess the electromagnetic environment due to fixed HF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the equipment is used exceeds the applicable compliance level above, the equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the equipment. b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.	

Recommended safety distance between portable and mobile RF Communications equipment			
The device is intended for use in electromagnetic environment in which radiated disturbances are controlled. The customer or the user of the equipment can help prevent electromagnetic interference. This can be achieved by maintaining the minimum distance recommended below between the communications equipment (transmitters) and the equipment. The minimum distance depends on the maximum output power and the frequency of the communications equipment.			
Power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz d=1.2 P1/2	80 kHz to 800 MHz d=1.2 P1/2	800 MHz to 2.5 GHz d=2.3 P1/2
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance can be determined using the equation applicable to the frequency of the transmitter. P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.NOTE 1: An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the frequency bands between 80 MHz and 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. NOTE 2: These guidelines may not be applicable in all situations. The propagation of electromagnetic sizes is influenced by absorptions and reflections of buildings, objects and people.			

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