ATMOS
MedizinTechnik

English

Operating Instructions

ATMOS S 61 Servant instruments



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 S 61 Servant instruments 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 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 periodic tests in conjunction with professional execution provide for operational safety and readiness for use of your ATMOS S 61 Servant instruments and are therefore a must besides regular cleaning.

Repair work and periodic tests may only be carried out by expert personnel authorized by ATMOS. By using only original spare parts, you will have the guarantee that the operational safety, readiness for work, and the value of your ATMOS S 61 Servant instruments will be preserved.



- The product ATMOS S 61 Servant instruments bears the CE marking CE in accordance with EC Council Directive 93/42/EEC concerning medical devices and meets the basic requirements of Annex I to this directive.
- The product ATMOS S 61 Servant instruments complies with all applicable requirements of Directive 2011/65/EU 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.

These operating instructions are valid for the following devices:

ATMOS S 61 Servant instruments	532.2100.0
ATMOS S 61 Servant instruments XL	532.0500.0
ATMOS S 61 Servant instruments XXL	532.0400.0
ATMOS S 61 CORIAN® integral	532.0800.0
ATMOS S 61 CORIAN® instruments	532.1000.0
ATMOS S 61 CORIAN® instruments XXL	532.0900.0

1.2 Intended use

Product name:	ATMOS S 61 CORIAN® integral ATMOS S 61 CORIAN® instruments ATMOS S 61 CORIAN® instruments XXL ATMOS S 61 Servant instruments ATMOS S 61 Servant instruments XL ATMOS S 61 Servant instruments XXL
Main functions:	• Instrument storage and deposit. • For expansion of the ATMOS S 61 Servant ENT workstation.
Intended purpose:	Standard ENT examination and / or therapy
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:	Ear, Nose, Throat
Application time:	< 60 min.
Application site:	Outpatient medical facilities, e.g. ENT practices, hospital outpatient departments, medical care centers
Patient selection criteria:	None
Indications:	Standard ENT examination and / or therapy
Medical contra-indications:	None
Other contra-indications:	None
Warnings:	None
The product is:	active
Sterility/specific microbial status:	Not sterile
Single use product / reprocessing:	Not a single use product. Reprocessing according to instructions for use.

1.3 Function

The device is a cabinet for the storage and management of instruments, diagnostic devices or visualisation devices for ENT specialists. The user can assemble the workplace with options and accessories according to his personal requirements. The device is used in clinics or ENT offices.

1.4 Explanation of pictures and symbols

Abbreviations and symbols contained in these operating instructions

	Follow the arrows		Check
	Please press where dot indicates		Please read, important information
	Activate the optional foot switch		Move, plug ... in this direction
	Warning; pay special attention		Turn, shift ... in this direction
■	General information		Replace
●	Numeration		Engage, check correct fit
→	Sub-numeration		Important information

Icons on the product

	Warning; pay special attention		Ground wire connection
	Fuse according to IEC 417/5016, DIN 30600/0186	~	Alternating current
|	On (feed-in, power connection)	○	Off (feed-in, power disconnection)
	Potential equalization		Type B applied part

1.0 Introduction

General symbols ATMOS S 61 Servant instruments

SN	Serial number	REF	Reference number
	Date of manufacture		Manufacturer
DE	Country of manufacture	MD	Medical device
	Consult operating instructions		Follow operating instructions (blue)
	Professional disposal	CE	This device complies with the relevant requirements of EU regulations.
EAC	This device complies with the relevant requirements of the Eurasian Economic Union.	ИМ24	GOST Certificate (Russia)
	Humidity limitation		Atmospheric pressure limitation
	Temperature limit		Fragile, handle with care
	Keep dry		This side up
CLASSIFIED C UL US E349855	UL Mark MEDICAL EQUIPMENT with respect to electrical shock, fire, and mechanical hazards only in accordance with UL60601-1/ANSI / AAMI ES60601-1 (2005)/ CAN / CSA – C22.2 No. 60601-1 (2008)		

UDI application identifier

(01)	04250365174960
(11)	210319
(21)	11223344

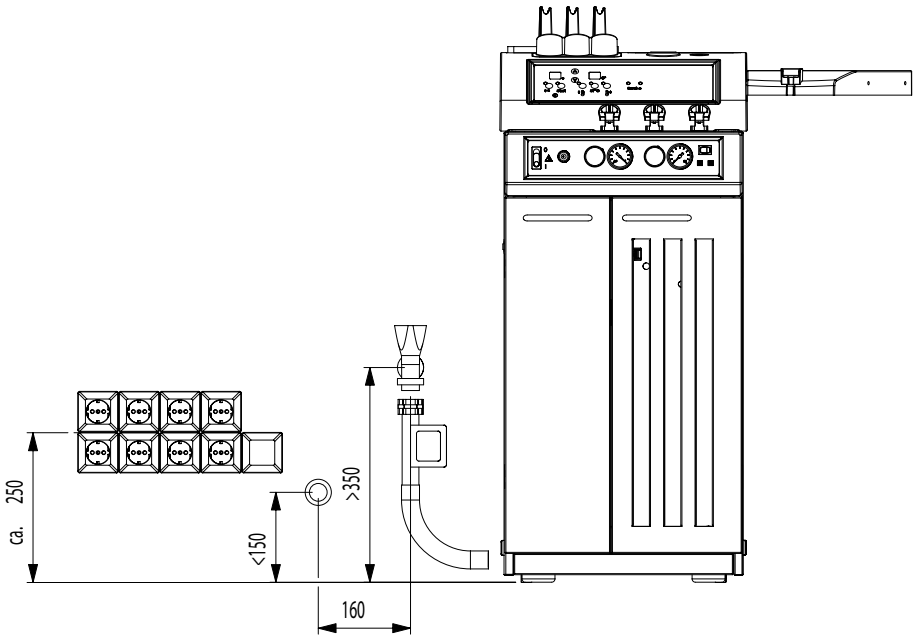
2.0 For your safety

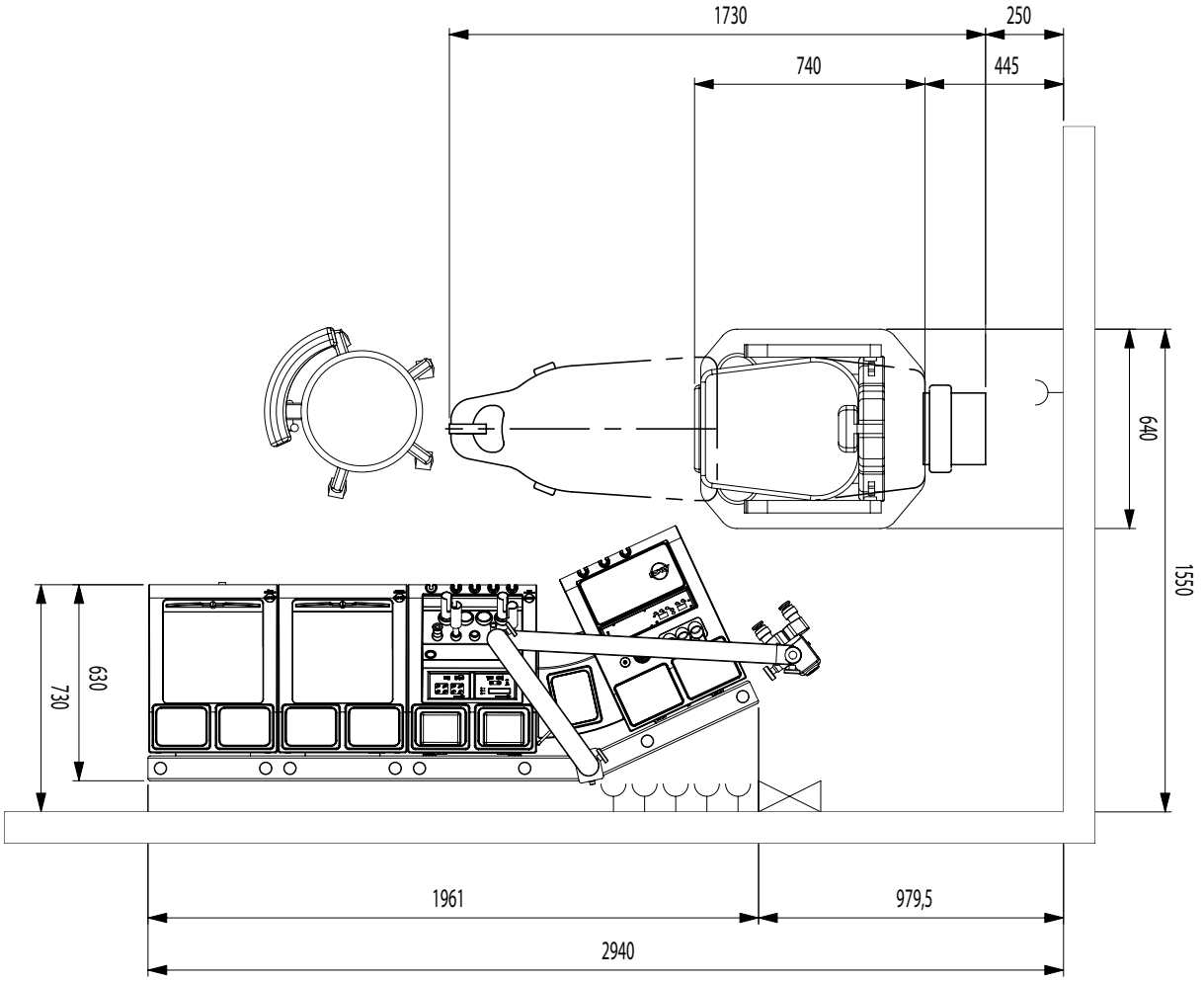


For your safety

- The ATMOS S 61 Servant instruments is produced according to IEC 601 / EN 60601 and listed in the following classes:
  - VDE Class of protection 1
  - Class IIa (EEC 93/42).
- The device may only be connected to a properly installed grounded electrical outlet.
  Correct configuration in assembly of country-specific connections:
  green/yellow: protective conductor (PE)
  blue: neutral conductor (N)
  black or brown: phase (L)
- Caution! Mirror and endoscope heaters may generate temperatures above 40 °C!
- The user must check the instruments' temperature, e.g., on the back of his/her hand.
- Clean heating modules regularly and disinfect if necessary; only heat clean instruments.
- The ATMOS S 61 Servant instruments may only be used under supervision by skilled staff who have been authorized 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!
- It is prohibited to simultaneously pull out several heavily laden instrument deposits.
- Never leave the patient unattended at the treatment unit.
- Please note:
  A medical isolation transformer with earth leakage monitor or any similar safety system acc. to EN 60601-1 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.
- Do not place used contaminated instruments on the ENT unit except on specially designated areas!
- The ambient conditions specified in the Technical Data must be strictly observed!
- Switch off main switches of the installed devices after finishing work in the practice.
- The ATMOS S 61 Servant instruments 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 61 Servant instruments meets the immunity to interference requirements of IEC 601-1-2 / EN 60601-1-2 "Electromagnetic Compatibility – Medical Electrical Devices".
- The ATMOS S 61 Servant instruments 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)".
- 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.
- In order to fully disconnect the device from the mains supply, the mains plug must be removed from the wall outlet.
- This product is not re-sterilizable. Repeated reuse of components marked with a ⊗ is forbidden. In case of repeated reuse, these components lose their function and there is a high risk of infection.

3.0 Connecting conditions





3.0 Connecting conditions

3.1 Required connections for all units of ATMOS S 61 Servant

Flexible multi-port distributors may not be used as a power supply for the ATMOS S 61 Servant ENT workstation, ATMOS S 61 Servant vision, or for an optional HF or radiofrequency surgical device.

Unit / Device	Maximum required connections
ATMOS S 61 Servant ENT workstation	1 x earthing contact socket outlet
ATMOS S 61 Servant vision	1 x earthing contact socket outlet (basic version) or 1 x fixed connection for the integrated camera or stroboscope LED
ATMOS S 61 Servant instruments	3 x earthing contact socket outlet
Water separation system (WTA)	1 x earthing contact socket outlet
Monitor	1 x earthing contact socket outlet
Patient chair	1 x earthing contact socket outlet
An adequate number of socket outlets with earthing contact should be mounted for possible connection of further electrically operated devices that may be installed (e.g., installation of an electrically operated ATMOS patient chair, water separation system, camera, monitor, etc.).	

3.2 Connection to electrical power line

Prerequisites:

- Installation acc. to IEC 60346-7-710: earth leakage circuit breaker (FI circuit breaker) with rated leakage current < 0.03 A
- Connection of the power cable of the ATMOS S 61 Servant instruments to a safety socket outlet near the device, max. 3 meters, preferably left (Fig.).
- The supply circuit must be separated from other devices, e.g., PCs, etc.
- If isolation transformers are used, then isolation monitoring must be integrated in the isolation transformer.
- Maximum power consumption:
  - ATMOS S 61 Servant ENT workstation 2,300 VA
  - ATMOS S 61 Servant vision 200 VA
  - ATMOS S 61 Servant instruments 250 VA

Flexible multi-port distributors may not be used as a power supply for the ATMOS S 61 Servant ENT workstation or ATMOS S 61 Servant vision.

First start-up

Prior to shipment, each ATMOS S 61 Servant is checked by the manufacturer for function and safety. In order to ensure the safe functioning of the device after transport and installation, the following points should be observed: The user should only operate the device when

1. a functional test has been carried out on the device at the place of operation.
2. the operating instructions have been read and acknowledged.

After transportation/storage of the device at low temperatures and prior to first start-up, it should be kept at room temperature for at least four hours. If the device has not acclimatized, the formation of condensation water is possible and a malfunction might result.

Connect the unit to a mains socket with the supplied IEC power connector. Please observe country-specific voltage!

The ATMOS S 61 Servant instruments has no mains switch for switching on the devices. Each optionally available electrical device has its own mains switch.

For separation from the power supply, please disconnect the power plug!



Roller-shutter cover with lock



Heated drawer

For switching on/off the heating, please pull out the drawer fully and operate the on/off switch in the rear of the drawer.



Mirror pre-heating

The heated mirror magazine has space for approx. 70 mirrors (size K2 to K7). In order to prevent the mirrors from fogging, the magazine is pre-heated to body temperature (38 °C).

Switch on the mirror pre-heater at the separate lateral power switch.



Deposit for used instruments

To be filled/emptied



Retractable writing surface

When pulling out the writing surface, please note that it has a stop position.



Waste bin

Tip with your foot to open.

Insert a waste bag.

Insertable shelf for keyboard

For safe storage of a wireless PC keyboard.



Drawer without cover

Height x width: 134 mm x 283 mm

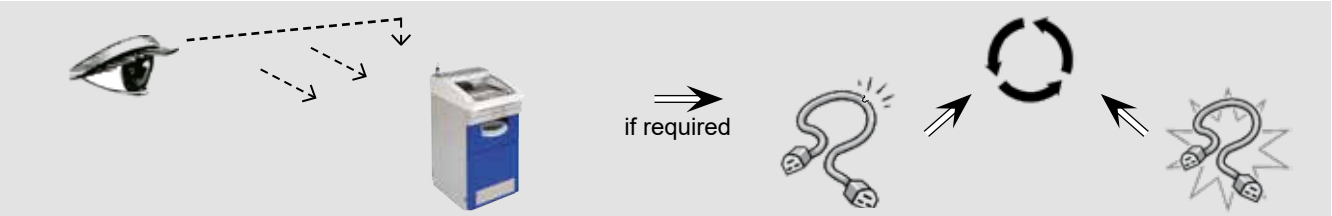
E.g., for ATMOS RS 221 radiofrequency surgery. Observe the notes in the operating instructions that are delivered separately.

5.0 Cleaning and care

5.1 General information on cleaning and disinfection

Prior to cleaning

Set the main switch of the ATMOS S 61 Servant instruments to OFF prior to cleaning and disinfection!
Prior to each 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!

- For disinfection, you may use all surface and instrument disinfectants listed on pages 12/13.
- Please ensure that no wet surfaces are left behind. Use a single-use cloth to absorb any liquid.
- If any disinfectant has spilled, make sure to wipe the surface dry immediately in order to prevent the liquid from penetrating gaps and edges.

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

- Do **not** use
  - disinfectants that contain organic or inorganic acids or bases as they could cause corrosion damage.
  - disinfectants containing chloramides or phenol derivatives, since 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 61 Servant instruments are resistant to all surface disinfectants listed on page 13.
- 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 Instrument trays

- Before disinfection, thoroughly rinse the trays under running water. A detergent or cleaning agent (surface disinfectant) may also be used if required.
  - Use water to thoroughly rinse all residues of these substances.
- Melamine and anodized aluminium trays cannot be sterilized.

- Only deposit clean instruments on the shelves!
- Clean and disinfect the instruments regularly!

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)	(ethylendioxy)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® PLUS (Application concentrate)	glucoprotamin	25 g	Ecolab, Düsseldorf
Sekusept® aktiv (Application concentrate)	sodium percarbonate, 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 / twin zyme			Bode Chemie, Hamburg
Dismoclean® twin basic	alkali dispenser, complexing agents, corrosion inhibitors		
Dismoclean® twin zyme	surface active materials, enzymes, stabilisers, corrosion inhibitors		
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® alka clean forte (Application concentrate)	non-ionic surfactants anionic surfactants NTA (nitrilotriacetic acid) and its salts enzymes, polycarboxylates corrosion inhibitors	< 5 g < 5 g < 5 g < 5 g	Schülke & Mayr, Norderstedt
thermosept® RKN-zym	non-ionic surfactants, enzymes, corrosion inhibitors, glycols	5 - 15 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® pur (Granulate) End of product 12/2014	magnesium monoperoxyphthalate hexahydrate	80 g	Bode Chemie, Hamburg
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
perform®	pentapotassium-bis(peroxymonosulphate)-bis(sulphate)	45 g	Schülke & Mayr, Norderstedt
terralin® protect (Application concentrate)	benzyl-C12-16-alkyldimethyl, chlorides 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® pur (Granulate) End of product 12/2014	magnesium monoperoxyphthalate hexahydrate	80 g	Bode Chemie, Hamburg
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, chlorides 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 methylpropional, linalool	13 g	Dürr Dental, Bietigheim-Bissingen

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

5.4 Recommended endoscope disinfectants

Manual disinfection of endoscopes

Disinfectant	Ingredients	in 100 g	Manufacturer
Helipur® H plus N	glutaral 2-propanol ethyl hexanol surfactants, complexing agents, corrosion inhibitors, colorants, perfumes	12 g 7.5 g 0.5 g	BBraun, Melsungen
Helix® Ultra	peracetic acid		BBraun, Melsungen
Korsolex® basic	glutaral (ethylendioxy) dimethanol surfactants, salts, corrosion inhibitors	15.2 g 19.7 g	Bode Chemie, Hamburg
neodisher® MediClean forte (Application concentrate)	non-ionic and anionic surfactants enzymes	< 5 g	Dr. Weigert, Hamburg
Sekusept® aktiv (Application concentrate)	sodium percarbonate, non-ionic surfactants, phosphonates		Ecolab, Düsseldorf

Automatic disinfection of endoscopes

Disinfectant	Ingredients	in 100 g	Manufacturer
Korsolex® basic	glutaral (ethylendioxy) dimethanol surfactants, salts, corrosion inhibitors	15.2 g 19.7 g	Bode Chemie, Hamburg
neodisher® MediClean forte (Application concentrate)	non-ionic and anionic surfactants enzymes	< 5 g	Dr. Weigert, Hamburg
gigasept® FF (new) (Application concentrate)	succindialdehyde dimethoxytetrahydrofurane anionic and non-ionic surfactants, perfumes, methylisothiazolinone	11.9 g 3.2 g	Schülke & Mayr, Norderstedt
Endozime® AW Plus	2-propanol		Ruhof, Mineola (USA)
Adaptaclean™	Potassium hydroxide, surfactants		ASP, Norderstedt

6.0 Hygiene plan

	What	How			Notices	When				Who
	Parts to be reprocessed	C Cleaning	D Disinfection	S Sterilization		After each application	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**									
	Hose connection (grommet)	X	X[2,4,5]		Cleaning and disinfection (manual or automatic)		X			
	Secretion canister lid	X	X[2,4,5]		Cleaning and disinfection (manual or automatic)		X			
	Seal	X	X[2,4,5]		Cleaning and disinfection (manual or automatic)		X			
	Bacterial filter				Exchange daily or when blocked		X			
	Splash guard	X	X[2,4,5]		Cleaning and disinfection (manual or automatic)		X			
	Float ball	X	X		Cleaning and disinfection (manual or automatic)		X			
	Suction hose in the canister	X	X[2,4,5]		Cleaning and disinfection (manual or automatic)		X			
	Secretion canister	X	X		Empty when the canister is full; at least daily; Cleaning and disinfection (manual or automatic)		X			
	Disposable canister system				Exchange and disposal of full canister		X			
	**Hose rinsing system**									
	Suction nozzle for hose rinsing	X	X[3]		Wipe cleaning and disinfection		X			
	Silicone attachment piece	X	X[2,4,5,6]		Cleaning and disinfection (manual or automatic)		X			
					Exchange of the silicone attachment				X	
	Suction nipple	X			Manual cleaning after each application	X				
			X[2,4,5,6]		Cleaning and disinfection (manual or automatic)		X			
	Secretion suction hose	X			Rinse the secretion hose with the hose rinsing system after each application;	X				
			X[2,4,5,6]		Exchange or disinfection of the hose				X	
	Storage canister hose rinsing	X	X[2,4,5,6]		Cleaning with a brush; cleaning and disinfection (automatic or manual)		X			
	**Ear irrigation / Thermal nystagmus stimulation**									
	Ear irrigation bowl	X	X[2,4,5]		Cleaning and disinfection (manual or automatic)	X				
	Handle	X	X[3]		Wipe cleaning and disinfection		X			
	Jet connection	X	X[2,4,5,6]		Cleaning and disinfection (manual or automatic)		X			
	Splash guard	X	X[2,4,5]		Cleaning and disinfection (manual or automatic)		X			
	Hose tip (disposable)				Exchange after each application	X				
	Rinsing attachment	X	X[2,4,5]		Cleaning and disinfection (manual or automatic)	X				
	Hygiene filter				See operating instructions for hygiene filter				X	
	Rinsing lid with rinsing hose	X	X[2,4,5]		Cleaning and disinfection (manual or automatic)		X			
	Rinsing bottle	X	X[2,4,5,6]		Cleaning and disinfection (manual or automatic); cleaning in the dishwasher with the glass care programme		X			
	**Medication nebulisation / Politzer**									
	Handle compressed air	X	X[3]		Manual cleaning and disinfection		X			
	Sprayer jet	X			Cleaning after each application	X				
			X[2,4,5,6]		Cleaning and disinfection (manual or automatic)		X			
	Sprayer head		X[2,4,5]		Multiple rinsing of the sprayer head with water			X		
	Hose at sprayer head	X	X		Weekly exchange of the hose or when changing the medication			X		
	Sprayer bottle	X	X[2,4,5,6]		Cleaning in a cleaning and disinfection device; weekly or when changing the medication			X		
	Politzer olive	X	X[2,4,5,6]		Exchange after each application, cleaning and disinfection	X				
	Politzer connection	X	X[2,4,5,6]		Exchange after each application, cleaning and disinfection	X				
	**Endoscope management**									
	Plastic quiver	X	X[2,4,5]		Cleaning with a brush; disinfection		X			
	Metal quiver	X	X[2,4,5,6]		Cleaning with a brush; disinfection (automatic or manual)		X			
	Fixation adapter for plastic quiver	X	X[2,4,5]		Cleaning and disinfection (manual or automatic)		X			
	Protective sleeve (teflon element for metal quiver)	X	X[2,4,5]		Cleaning and disinfection (manual or automatic)		X			

6.0 Hygiene plan

	What	How			Notices	When				Who
	Parts to be reprocessed	C Cleaning	D Disinfection	S Sterilization		After each application	Daily	Weekly	Monthly	Qualified and trained staff who are familiar with reprocessing. (Please fill in the responsible person, use a water-based overhead marker)
	**Instrument management**									
	ENT instruments	X	X[2,4,5]	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 rinsed with water, have to be dried and sterilised afterwards. Please also observe the ATMOS operating instructions for ENT instruments.	X				
	Instrument bowl	X	X[4]		Cleaning and disinfection (manual)		X			
	Instrument bowl with cover	X	X[4]		Cleaning with a brush; disinfection (manual)		X			
	**Visualization**									
	ATMOS® Cam 21 / 31	X	X[3]		Wipe cleaning and disinfection		X			
	ATMOS® Strobo 21 LED	X	X[3]		Wipe cleaning and disinfection		X			
	ATMOS® LS 31 LED	X	X[3]		Wipe cleaning and disinfection		X			
	Flexible Endoscope	X	X[1,7,8]	X[1]	Immediate pre-cleaning after application	X				
	Rigid endoscope	X	X[1,7,8]	X[1]	Immediate pre-cleaning after application	X				
	Laryngoscope	X	X[1,7,8]	X[1]	Immediate pre-cleaning after application	X				
	Light cable	X	X[3]		Wipe cleaning and disinfection		X			
	Light grip	X	X[3]		Wipe cleaning and disinfection		X			
	Microscope	X	X[3]		Wipe cleaning and disinfection		X			
	Headlight	X	X[3]		Wipe cleaning and disinfection		X			
	**Radiofrequency surgery**									
	ATMOS® RS 221 (surface)	X	X[3]		Wipe cleaning and disinfection		X			
	Ergonomic handles	X	X[1,2,4,5]	X[1]	Wipe cleaning and disinfection	X				
	Bipolar tweezers	X	X[1,2,4,5]	X[1]	Immediate pre-cleaning after application; Cleaning and disinfection (manual or automatic); Use of enzymatic detergents	X				
	Bipolar electrode	X	X[1,2,4,5]	X[1]		X				
	Bipolar electrode cable	X	X[1,2,4,5]	X[1]	Immediate pre-cleaning after application; Cleaning and disinfection (manual or automatic); Use of enzymatic detergents	X				
	Neutral electrode	X	X[1,2,4,5]	X[1]		X				
	Neutral electrode cable	X	X[1,2,4,5]	X[1]	Immediate pre-cleaning after application; Cleaning and disinfection (manual or automatic); Use of enzymatic detergents	X				
	ENT electrodes	X	X[1,2,4,5]	X[1]		X				
	**Surfaces**									
	Housing	X	X[3]		Wipe cleaning and disinfection			X		
	Roller shutter	X	X[3]		Wipe cleaning and disinfection			X		
	System frame	X	X[3]		Wipe cleaning and disinfection			X		
	Drawers	X	X[3]		Wipe cleaning and disinfection			X		
	Writing surface	X	X[3]		Wipe cleaning and disinfection	X				
	Instrument deposit	X	X[3]		Wipe cleaning and disinfection	X				
	Mirror preheater	X	X[3]		Wipe cleaning and disinfection			X		
	Tongue patches and swab dispenser	X	X[3]		Wipe cleaning and disinfection; Daily or when refilling		X			
	Waste disposal	X	X[3]		Wipe cleaning and disinfection; Daily or when refilling		X			
	Instrument tray	X	X[3]		Wipe cleaning and disinfection; Daily or when refilling		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 disinfectant FD 312 (Dürr Dental)

Important information

Wipe cleaning and 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.

[4] Manual disinfection of instruments:
- 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® PLUS (Ecolab)
- Sekusept® aktiv (Ecolab)
- Gigasept® Instru AF (Schülke & Mayr)
- Gigazyme® (Schülke & Mayr)
- Gigasept FF neu (Schülke & Mayr)

[5] Automatic disinfection of instruments:
- 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)

[1] Please observe the manufacturer's operating instructions.
[2] Preferred: machine cleaning and disinfection in the washer disinfector
[6] Material dimensionally stable at 134°C

[7] Endoscopes - manual disinfection:
- Helipur® H plus N (BBraun)
- Helix® Ultra (BBraun)
- Korsolex® Basic (Bode Chemie)
- neodisher® MediClean forte (Dr. Weigert)
- Sekusept® aktiv (Ecolab)

[8] Endoscopes - automatic disinfection:
- Korsolex® Basic (Bode Chemie)
- neodisher® MediClean forte (Dr. Weigert)
- Gigasept® FF neu (Schülke & Mayr)
- Endozime® AW Plus (Ruhof)
- ADAPTACLEAN™ (ASP)

For concentrations, contact time, temperature, material compatibility, please see the relevant information from the manufacturer.

Wrong concentration of disinfectants may lead to material 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", from Robert Koch Institute. The medical products were categorised in the risk groups uncritical, semi-critical and critical. The reprocessing measures mentioned in this cleaning and disinfection plan are a recommendation of ATMOS MedizinTechnik. 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 61 Servant. 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.
The Medical Devices Act, IfSG, the RKI directives, BGR 250 and TRBA 250 always have to be considered.

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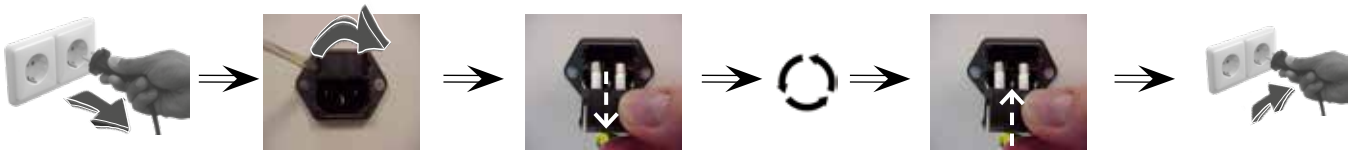
7.0 Maintenance and service

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.

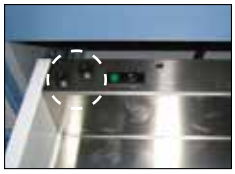
ATMOS recommends: Work should be carried out by an authorized ATMOS service partner. This ensures that repairs and testing are carried out professionally, original spare parts are used, and warranty claims remain unaffected.

- At least every 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.

7.1 Replacing the fuses ATMOS S 61 Servant instruments



7.2 Replacing the fuse of the heated drawer



Remove the fuse carrier beside the on/off switch and exchange the fuse.

7.3 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 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 to your dealer.

8.0 Technical data

Mains voltage	230 V~ ± 10 %; 50/60 Hz special voltage: 100-127 V~ ± 10 %; 50/60 Hz relevant for the individual modules
Current consumption:	max. 1,1 A (230 V~) max. 2,2 A (100 V~)
Power consumption:	max. 250 W
Fuses	2 x T 3,15 A (f. 230 V~, 50/60 Hz) 2 x T 6,3 AH (f. 100 V~, 50/60 Hz)
Other security parts:	Heating elements depending on design max. 60 °C
Mirror preheater - Temperature of instruments - Heating performance	 approx. 37°C max. 50 VA
Heated drawer - Temperature of instruments - Heating performance	 approx. 37°C max. 230 VA
Power cycle	Continuous …. operation
Protective earth conductor resistance Earth leakage current Touch current Patient leakage current	max. 0,1 Ω max. 5 mA max. 0,1 mA max. 0,1 mA
Environmental conditions: Transport/Storage - Temperature range - Air humidity without condensation - Air pressure	 -10...+50°C 30...95 % air humidity without condensation 500...1060 hPa
Environmental conditions: Operation: - Temperature range - Air humidity without condensation - Air pressure	 +10...+35°C 30...95 % air humidity without condensation 700...1060 hPa
Maximum operating altitude	≤ 3000 m
Contamination level	class 2
Overvoltage category	II
Dimensions (H x W x D):	ATMOS S 61 Servant instruments 532.2100.0: 885 x 412 x 540 mm ATMOS S 61 Servant instruments XL 532.0500.0: 890 x 646 x 530 mm ATMOS S 61 Servant instruments XXL 532.0400.0: 990 x 897 x 555 mm
Weight:	ATMOS S 61 Servant instruments 532.2100.0: 30 kg ATMOS S 61 Servant instruments XL 532.0500.0: 41.7 kg ATMOS S 61 Servant instruments XXL 532.0400.0: 97 kg
Periodical tests:	Repeat test of electrical safety every 12 months. Recommended: Inspection according to 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-No. (REF)	532.2100.0 Basic module 532.0110.0 Power supply module 230 V 532.0111.0 Power supply module 100 - 127 V

* Important: Note on MPBetreibV only for devices that are listed there accordingly!

9.0 Accessories

General accessories	REF
Stand (S 61 Servant)	534.0119.0
Slanted microscope column	534.0170.0
Monitor arm ATMOS S 61 ENT professional	534.3020.0
Monitor holder (Shelf adapter/S61 system)	534.3095.0
Shelf for storage device	538.2120.0
Shelf, small (metal)	541.1600.0
Shelf, broad (metal)	541.2700.0
Instrument tray, small (melamine)	000.0746.0
Instrument tray, small (aluminium)	508.0058.0
Fixation adapter plastic quiver	508.0782.0
Cover for instrument disposal bowl	506.7752.0
Stainless steel sieve (instrument disposal)	506.7759.0
Roller cover (Second instrument level)	506.7730.0
Instrument tray, large (aluminium)	505.0516.0
Tray, narrow	532.0146.0
Tray, narrow (instrument deposit)	534.0146.0
Holder ear specula / Politzer olives	508.0545.0
Instrument tray, large (melamine)	000.0747.0
Tray for melamine trays, narrow	532.0145.0
Tray for melamine trays, narrow (instrument deposit)	534.0145.0
Instrument deposit module	534.3040.0
Instrument deposit module, high	534.3045.0
Shelf (glass)	534.3050.0
Shelf (metal)	534.3060.0
Shelf (metal)	534.3060.0
Shelf (glass), high	534.3055.0
Shelf (metal), high	534.3065.0
Shelf adapter	534.3090.0
Quiver, flexible endoscopes	508.0790.0
Push-on sleeve, flex optic sleeve	506.0715.0
Quiver, used flexible endoscopes	508.0795.0
Holder flexible optic incl. Quiver	506.7017.0
Instrument tray set (aluminium)	506.7032.0
Instrument tray set (stainless steel)	506.7033.0

10.0 Disposal

- The materials of the housing can be recycled completely.
- The ATMOS S 61 Servant instruments does not contain any hazardous goods.
- The component parts of the ATMOS S 61 Servant instruments must be disposed of correctly and the materials are to be separated carefully.



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 S 61 Servant instruments 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 S 61 Servant instruments must ensure that it 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 S 61 Servant instruments 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 S 61 Servant instruments, 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 otherwise 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



MedizinTechnik

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