



MedizinTechnik

English

Operating Instructions

ATMOS[®] S 61 Servant instruments



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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, amongst 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 period 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 period tests may be carried out only 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 61 Servant instruments will be preserved.



- The product ATMOS® S 61 Servant instruments bears CE marking CE 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 61 Servant instruments 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.

1.2 Intended use

Name: ATMOS® S 61 Servant instruments

Main functions:

ATMOS® S 61 Servant instruments:

- Instrument management

Medical indications / application:

Standard ENT examination and/or therapy

Specification of the main function:

ATMOS® S 61 Servant instruments:

- Instrument deposit and heating
- Storage room for examination and therapy devices

User profile: Doctors and medical assistants

Patient groups: Patients of all ages with and without restrictions

Application organ:

Mouth to pharynx, auditory canal to the ear drum and the nasal cavities

Application time:

- ENT unit: Short term use (up to 30 days)
- Suction / Compressed air / ear rinsing / light source: Temporary application on the patient (less than 60 minutes)

Application site:

Application sites are clinics and practices for ENT doctors and phoniatrists. The examination and/or therapy with the ENT unit may only be executed by medically trained persons.

Contraindications:

- May not be used for irrigation of the paranasal sinuses.
- The ear irrigation should not be applied to an infected auditory canal or a perforated eardrum.

The product is: active

Sterility:

The ENT unit is no sterile product.

Single-use product / reprocessing:

The ENT unit is intended for multiple use. The device and parts of the accessories are reusable. For information on reprocessing and disinfection, please see the operating instructions.

1.3 Explanation of pictures and symbols

Short cuts / symbols contained in these operating instructions

	Follow the arrows		General information		Move, plug... in this direction
	● Please press where dot indicates		● Numeration		Turn, shift ... in this direction
	Activate the optional foot switch		→ Subnumeration		Replace
	Please read, important information		Check		Engage, check correct fit

Icons on the product

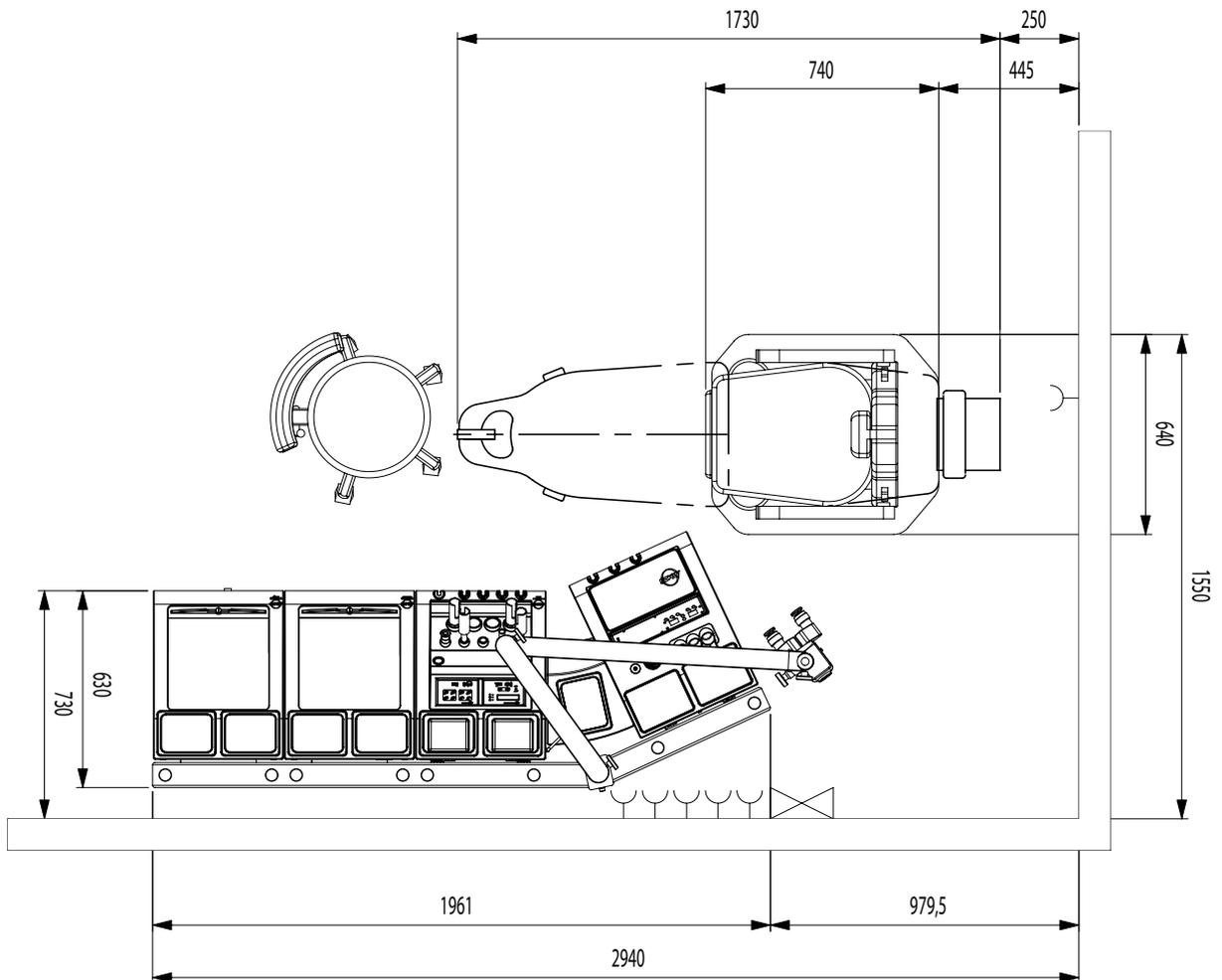
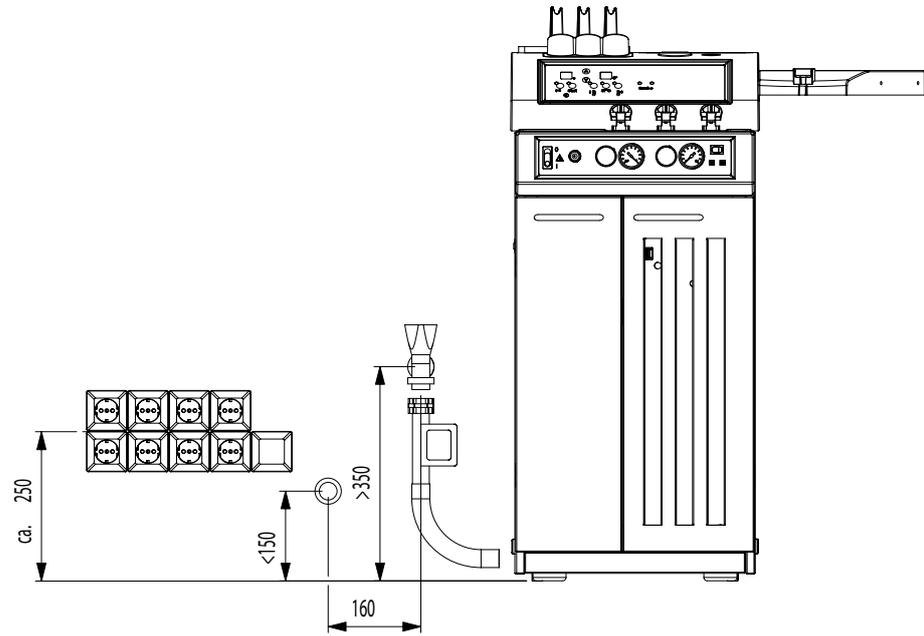
	Warning, special diligent notice		Ground wire connection
	Fuse according to IEC 417/5016, DIN 30600/0186		Alternating current
	Potential equalisation		On (feed-in, power connection)
			Off (feed-in, power connection)



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: non-fused earth conductor (PE)
blue: neutral conductor (N)
black resp. brown: phase (L)
- Caution! Mirror and endoscope heaters may generate temperatures above 40°C!
- The ATMOS® S 61 Servant instruments 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!
- 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 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.
- Do not place used contaminated instruments on the ENT unit except on destined places!
- 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 authorised 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 which are marked with a ⓧ is forbidden. In case of repeated reuse these components lose their function and there is a high infection risk.

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 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 separating 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 units which may be installed (e.g. installation of an electrically operated ATMOS® patient chair, water separating 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 supply 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 isolating transformers are used then isolation monitoring must be integrated in the isolating transformer.
- Maximum power consumption:
 - ATMOS® S 61 Servant 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 vision or ATMOS® S 61 Servant workstation.

i First start-up

Prior to shipment each ATMOS® S 61 Servant instruments is being inspected by the manufacturer for function and safety. In order to make sure that the appliance is working safely after transport and installation, the following points should be observed: The user should put the appliance into operation only if

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

Following transportation at low temperatures the appliance must be held for up to four hours at ambient temperature before first start-up. When the appliance has not been acclimatised the formation of condensation water is possible and a malfunction might be the result.

i 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 optional 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

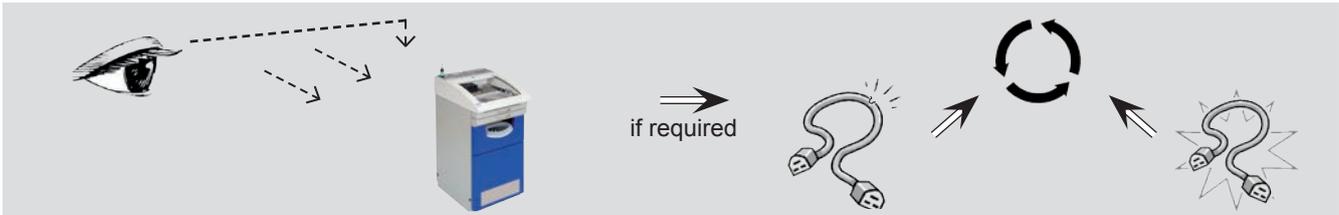
E.g. for ATMOS® RS 221 Radiofrequency surgery. Observe the notes in the operating instructions which are delivered separately.

5.1 General information on cleaning and disinfection

Prior to cleaning

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

Prior to each use:



- ☞ 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 surface and instrument disinfectants listed on page 10.
- Please take care that all surfaces are dry wiped. Use a single-use cloth to absorb any liquid.
- In case that any disinfectant is spilled, please take care to dry wipe the surface immediately in order that no liquid may penetrate gaps and edges.

☞ 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 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 against all surface disinfectants listed in on page 11.
- 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 sterilised.

-  Only deposit clean instruments on the board!
- 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)	(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® PLUS (Application concentrate)	glucoprotamin	25 g	Ecolab, Düsseldorf
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 dimethoxytetrahydrofuran 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, poly carboxylates 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, 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® 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, 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

When using disinfectants containing aldehyde and amine at the same object colour 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)	sodiumpercarbonate, 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 dimethoxytetrahydrofuran 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 Parts to be reprocessed	How			Notices	When				Who Qualified and trained staff who are familiar with reprocessing. (Please fill in the responsible person -> use a water-based overhead marker)
		C Cleaning	D Disinfection	S Sterilization		After each application	Daily	Weekly	Monthly	
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 Qualified and trained staff who are familiar with reprocessing. (Please fill in the responsible person, use a water-based overhead marker)
	Parts to be reprocessed	C Cleaning	D Disinfection	S Sterilization		After each application	Daily	Weekly	Monthly	
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® Strobe 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;	X				
	Bipolar electrode	X	X ^{1,2,4,5}	X ¹	Cleaning and disinfection (manual or automatic); Use of enzymatic detergents	X				
	Bipolar electrode cable	X	X ^{1,2,4,5}	X ¹	Immediate pre-cleaning after application;	X				
	Neutral electrode	X	X ^{1,2,4,5}	X ¹	Cleaning and disinfection (manual or automatic); Use of enzymatic detergents	X				
	Neutral electrode cable	X	X ^{1,2,4,5}	X ¹	Immediate pre-cleaning after application;	X				
	ENT electrodes	X	X ^{1,2,4,5}	X ¹	Cleaning and disinfection (manual or automatic); Use of enzymatic detergents	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 disinfecter

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 listed herein are listed disinfectants (VAHRKI) and have been tested on their suitability of use on the ATMOS® S 61 Servant. ATMOS MedizinTechnik cannot be held 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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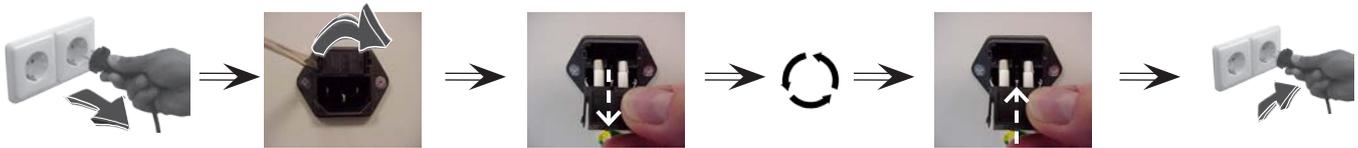
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Maintenance, repairs and period tests may only be carried out by persons who have the appropriate technical knowledge and are familiar with the product. To carry out these measures the person must have the necessary test devices and original spare parts.

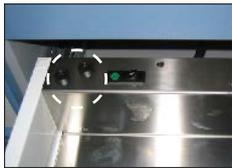
ATMOS recommends: Work should be carried out by an authorized ATMOS service partner. This ensures that repairs and testing are carried out professionally, original spare parts are used and warranty claims remain unaffected.

- 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.

7.1 Replacing the fuse ATMOS® S 61 Servant instruments



7.2 Replacing the fuse 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 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.

Voltage	230 V~ ± 10 %; 50/60 Hz Special voltage: 100-127 V~ ± 10 %; 50/60 Hz Relevant for single 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 (250 V)
Other safety equipment	Heating elements by design max. 60°C

8.0 Technical data



Mirror preheater	
• Temperature of Instruments	Approx. 37 °C
• Heating performance	Max. 50 VA
Heated drawer	
• Temperature of Instruments	Approx. 37 °C
• Heating performance	Max. 230 VA
Operating time	Continuous operation
Protective earth conductor resistance	Max. 0,1 Ω
Earth leakage current	Max. 0.5 mA
Housing leakage current	Max. 0.1 mA
Patient leakage current	Max. 0.1 mA
Ambient conditions for transport/storage	
• Temperature	-10...+50°C
• Air humidity	30...95 % without condensation
• Air pressure	500...1060 hPa
Ambient conditions operation	
• Temperature	+10...+35°C
• Air humidity	30...95 % without condensation
• Air pressure	700...1060 hPa
Maximum operational altitude	≤ 3000 m
Contamination level	Class 2
Overvoltage category	II
Dimensions HxWxD	88.5 x 41.2 x 54.0 cm
Weight	15-32 kg
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	No application parts
Type of protection	IP X0
Classification in accordance with Appendix IX EC Directive 93/42/EEC	Class 1
CE marking	CE
GMDN code	11585
UMDNS code	10-585 ENT treatment unit
ID No. (REF)	532.0000.0 Basic module 532.0110.0 power supply module 230 V 532.0111.0 power supply module 100 - 127 V

9.0 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.



10.0 Notes on EMC



- Medical electrical equipment is subject to special precautions with regard to EMC and must be installed acc. to following EMC notes.
- Portable and mobile HF communication facilities can influence medical electrical equipment.
- The use of other accessories, other converters and cables than stated may lead to an increased emission or a reduced interference immunity of the equipment or system.

10.1 Guidelines and Manufacturer's Declaration - Emissions

The ATMOS® S 61 Servant instruments is intended for use in the electromagnetic environment specified below. The customer or user of the ATMOS® S 61 Servant instruments should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions acc.to CISPR 11	Group 1	The ATMOS® S 61 Servant instruments uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions according to CISPR 11	Class B	The ATMOS® S 61 Servant instruments 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.
Harmonic emissions according to IEC 61000-3-2	Inapplicable	
Voltage fluctuations/flicker according to IEC 61000-3-3	Inapplicable	



The device may not be used directly next to other devices or piled up with other devices. If operation next to or piled with other devices is necessary, please watch the device to check its intended operation in this arrangement.

10.2 Guidelines and Manufacturer's Declaration - Immunity

The ATMOS® S 61 Servant instruments is intended for use in the electromagnetic environment specified below. The customer or user of the ATMOS® S 61 Servant instruments 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 wood, concrete, or ceramic tile. If floors are 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 Inapplicable	Mains power quality should be that of a typical commercial or hospital environment.
Surges IEC 61000-4-5	± 1 kV differential mode ± 1 kV common-mode	± 2 kV differential mode ± 1 kV common-mode	Mains power quality should be that of a typical commercial or hospital environment.
Magnetic field at power frequency 50/60 Hz acc. to IEC 61000-4-8	3 A/m	Inapplicable	Power frequency magnetic fields should be that of a typical commercial or hospital environment.

10.0 Notes on EMC

Immunity Test	IEC 60601- Test Level	Compliance Level	Electromagnetic Environment - Guidance
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 s	$< 5\% U_T$ (> 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 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the ATMOS® S 61 Servant instruments demands continued function even in case of interruptions of the energy supply, it is recommended to supply the ATMOS® S 61 Servant instruments from an uninterruptible current supply or a battery.
NOTE U_T is the mains alternating current prior to application of the test levels.			

10.3 Guidelines and Manufacturer's Declaration - Immunity

The ATMOS® S 61 Servant instruments is intended for use in the electromagnetic environment specified below. The customer or user of the ATMOS® S 61 Servant instruments should ensure that it is used in such an environment.

Immunity Test	IEC 60601- Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	$3 V_{eff}$ 150 kHz to 80 MHz	$3 V_{eff}$	Portable and mobile communications equipment should be separated from the ATMOS® S 61 Servant instruments incl. the cables by no less than the distances calculated/listed below. Recommended distances: $d = (3.5 / \sqrt{P}) * \sqrt{P}$ $d = (3.5 / E1) * \sqrt{P}$ 80-800 MHz $d = (7 / E1) * \sqrt{P}$ 0.8-2.5 GHz where „P“ is the max. power in watts (W) and d is the recommended separation distance in meters (m). Field strengths from fixed transmitters, as determined by an electromagnetic site (a) survey, should be less than the compliance level (b). Interference may occur in the vicinity of equipment containing following symbol: 
Radiated RF IEC 61000-4-3	$3 V/m$ 80 MHz to 2.5 GHz	$3 V/m$	

10.0 Notes on EMC

NOTE 1 By 80 MHz and 800 MHz the higher frequency range applies.

NOTE 2

These guidelines may not be applicable in all cases. The emanation of electromagnetic waves is affected by absorption and reflection 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 determine the electromagnetic environment in regard to stationary transmitters, a study of the location is to be considered. If the measured field strength at the location where the ATMOS® S 61 Servant instruments is used exceeds the above compliance level, the ATMOS® S 61 Servant instruments is to be observed to verify the intended use. If abnormal performance characteristics are noted, additional measures might be necessary, e. g. a changed arrangement or another location for the device.

b

Within the frequency range of 150 kHz to 80 MHz the field strength should be below 3 V/m.

10.4 Recommended safety distance between portable and mobile RF Communications equipment and the ATMOS® S 61 Servant instruments

The ATMOS® S 61 Servant instruments is intended for use in electromagnetic environment in which radiated disturbances are controlled. The customer or user of the ATMOS® S 61 Servant instruments can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications equipment and the ATMOS® S 61 Servant instruments as recommended below, according to the maximum output power of the communications equipment.

Nominal output of the transmitter W	Safety distance, depending on transmit-frequency m		
	150 kHz to 80 MHz $d = [3.5 / 3] \sqrt{P}$	80 MHz to 800 MHz $d = [3.5 / 3] \sqrt{P}$	800 MHz to 2.5 GHz $d = [7.0 / 3] \sqrt{P}$
0.01	0.12	0.12	0.24
0.1	0.37	0.37	0.74
1	1.2	1.2	2.4
10	3.69	3.69	7.38
100	11.66	11.66	23.32

For transmitters for which the maximum nominal output is not indicated in the above table, the recommended safety distance d in meters (m) can be determined using the equation belonging to the respective column whereas P is the maximum nominal output of the transmitter in watts (W) acc. to manufacturer's specification.

NOTE 1 By 80 MHz and 800 MHz the higher frequency range applies.

NOTE 2

These guidelines may not be applicable in all cases. The emanation of electromagnetic waves is affected by absorption and reflection of buildings, objects and people.



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