ATMOS
MedizinTechnik

Operating Instructions

ATMOS C 11 Systema

English

CE 0124

GA1GB.110300.0

2023-07 Index 23

Table of contents

1 Introduction ... 3
1.1 Notes on operating instructions ... 3
1.2 Explanation of pictures and symbols ... 4
1.3 Intended purpose ... 6
1.4 Function ... 7
1.5 Scope of delivery ... 8
1.6 Transport and storage ... 8

2 Notes for your safety ... 9
2.1 General safety instructions ... 9
2.2 Danger for users, patients, and third parties ... 9
2.3 Avoiding damage to the device ... 11

3 Setting up and starting up ... 12
3.1 Required connections (power supply) ... 12
3.2 Connection to electrical power line ... 12
3.3 Overview of complete equipment ... 13
3.4 Rear view ... 14

4 Operation ... 15
4.1 Suction system ... 15
4.2 Canister systems ... 16
4.3 Disposable canister system ... 19
4.4 Compressed-air module ... 21
4.5 ATMOS LS 21 LED – quick start ... 23
4.6 ATMOS HL 21 LED – quick start ... 25
4.7 LED cold light module ... 26
4.8 Endoscope management ... 27
4.9 Emptying the instrument disposal ... 28

5 Reprocessing ... 29
5.1 General information on cleaning and disinfection ... 29
5.2 Recommended instrument disinfectants ... 31
5.3 Recommended surface disinfectants ... 33
5.4 Recommended endoscope disinfectants ... 34

6 Maintenance and service ... 37
6.1 Sending in the device ... 37

7 Troubleshooting ... 38

8 Accessories and consumables ... 40
8.1 Using the accessories ... 40

9 Disposal ... 44

10 Technical data ... 45

11 Notes on EMC ... 47

12 Notes ... 49

1 Introduction

1.1 Notes on operating instructions

These operating instructions contain important information on how to operate your product safely, correctly, and effectively.

These operating instructions are designed for training and instructing operating personnel in the use of the system, and they are also intended for use as a reference manual. Reproduction, even partial, is only permitted with written permission from ATMOS.

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

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

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.

The unit ATMOS C 11 Systema bears CE marking CE 0124 according to the EU Council Directive 93/42/EEC concerning medical devices and meets the basic requirements of Annex I to this directive.

The unit ATMOS C 11 Systema complies with all applicable requirements of the Directive 2011/65/EU restricting the use of certain hazardous substances in electrical and electronic equipment (“RoHS”).

The declarations of conformity and our general standard terms and conditions can be obtained on our website at www.atmosmed.com.

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

Prior to start-up, please peruse chapter “2 Notes for your safety” on page 9 in order to be prepared for any possible dangerous situations.

These operating instructions are valid for the following devices:

ATMOS C 11 Systema (sitting)	REF 541.0000.0
ATMOS C 11 Systema (standing)	REF 542.0000.0
ATMOS C 11 China	REF 541.0100.0

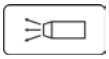
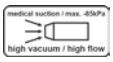
1.2 Explanation of pictures and symbols

In the operating instructions

⚠ DANGER	Warning of a danger that will result in immediate fatal or serious injury. Observe the necessary measures.
⚠ WARNING	Warning of a danger that can cause fatal or serious injury. Observe the necessary measures.
⚠ CAUTION	Warning of a danger that can cause minor injury. Observe the necessary measures.
NOTICE	Notice of a danger that can damage the product or other objects. Observe the necessary measures.
⚠	Warning of a danger that can cause injury or death.
ⓘ	Notice of potential material damage.
☞	Useful information on the handling of the device.
1.	Action. Proceed step by step.
»	Result of an action.
→	Move, plug in this direction.
click	Engage, check correct fit.

On device, type plate, and packaging

	Follow operating instructions (blue)
	Consult operating instructions
	Warning; pay special attention
	Warning; pay special attention (yellow)
	Warning; hot surface
CE 0124	This device complies with the relevant requirements of EU regulations.
EAC	This device complies with the relevant requirements of the Eurasian Economic Union.

	Manufacturer
	Date of manufacture
	Date of manufacture Country of manufacture: Germany
REF	Reference number
UDI	Unique Device Identifier of a medical device
MD	Medical device
SN	Serial number
EAN	European Article Number
LOT	Batch code
IPX0	Specification of the degree of protection against the ingress of solids and moisture
	Type BF applied part
	Professional disposal
	Do not reuse
	Compressed-air system
	Suction system
	Mirror quick heater
	Potential equalization
	Protection class I device
	Fuse
	Alternating current
	This side up

	Fragile, handle with care
	Keep dry
	Keep away from sunlight
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation

UDI application identifier

REF	541.0000.0	REF	542.0000.0
(01)	04250365175417	(01)	04250365175677
(11)	220404	(11)	220404
(21)	00000000	(21)	12345678

REF	541.0100.0
(01)	04250365193442
(11)	220411
(21)	12345678

1.3 Intended purpose

Product name: ATMOS C 11 Systema

Main functions:

- Medical suction
- Ear irrigation
- Medication spraying or spraying
- Electric power supply for visualization, illumination and illumination accessories
- Instrument storage and deposit
- Instrument heater

Intended use:	Standard ENT examination and / or therapy
Intended users / user profile:	Doctors and medical specialists
Intended patient target groups:	All patients without any restrictions
Medical conditions to be diagnosed, treated or monitored:	Diagnostic examination of anatomy of all kinds
Organ(s) applied to:	Ear, Nose, Throat
Duration of application:	< 60 min.
Use environment:	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:	Ear irrigation: Should not be applied to an infected auditory canal or a perforated eardrum
Other contra-indications:	Pharyngeal suction: Not indicated for pharyngeal suction of vomit
Warnings:	None
The product is:	active
Sterility / specific microbial state:	Not sterile
Single-use device / reprocessing:	Not a single use product. Reprocessing according to instructions for use

1.4 Function

- Suction system module
- Compressed-air module
- Ear irrigation by means of compressed air
- LED light handle ATMOS LS 21 LED
- LED headlight ATMOS HL 21 LED
- LED cold light source
- Instrument deposit
- Endoscope management
- Mirror quick heater

1.5 Scope of delivery

The ATMOS C 11 Systema was subjected to an extensive functional test and was carefully packed prior to dispatch.

Nevertheless, please compare the contents of the shipment on completeness immediately upon receipt (see delivery note).

Scope of delivery ATMOS C 11 Systema (sitting):

Basic module with two large drawers, one small drawer, service compartment for secretion canister, safe storage of three clean and three used endoscopes at a time, two connections for LED light handle ATMOS LS 21 LED and LED headlight ATMOS HL 21 LED, holder for LED light handle with automatic start-up function by means of light barriers, three holders for medication sprayers, two holders for irrigation bottles, suction module, suction hose, power cable, operating instructions.

Scope of delivery ATMOS C 11 Systema (standing):

Basic module with three large drawers, one small drawer, service compartment for secretion canister, safe storage of three clean and three used endoscopes at a time, two connections for LED light handle ATMOS LS 21 LED and LED headlight ATMOS HL 21 LED, holder for LED light handle with automatic start-up function by means of light barriers, three holders for medication sprayers, two holders for irrigation bottles, suction module, suction hose, power cable, operating instructions.

1.6 Transport and storage

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

If damage occurs during transport:

1. Document and report the transport damage.
2. Send the device to ATMOS.

Ambient conditions for transport and storage:

- Temperature: −20...+50 °C
- Humidity without condensation: 30...95 %
- Air pressure: 500...1060 hPa

2 Notes for your safety

Please read and pay attention to the safety instructions prior to using the product.

2.1 General safety instructions

Only use accessories and options that are specifically suited for combination with the product and that meet the performance and safety requirements.

If you wish to connect more than one device or applied part, you must always observe their safety instructions.

Report all serious incidents that have occurred in connection with this product to the manufacturer and your national competent authority.

Please note that the drawers may only be filled with a maximum load of 4.5 kg.

Please also note that only one drawer may be pulled out at a time.

Make sure that the rollers are always locked when using the treatment unit.

The device may not be operated in the vicinity of an MRI (magnetic resonance imaging) scanner.

2.2 Danger for users, patients, and third parties

Choking hazard for children due to accessories!

Children can strangle themselves or choke on small parts.

- Keep children away from hoses and connection cables.
- Keep children away from swallowable small parts. Examples of swallowable small parts are the fingertip and sealing ring.

Explosion and fire hazard!

Burns and injuries are possible.

- Never operate the product in potentially explosive areas or in areas that are oxygenated.
- Use only original accessories and original spare parts from ATMOS.

Avoid improper use or incorrect diagnosis.

Your patient can be severely injured.

- The product is only permitted for use by trained, specialist personnel under supervision.
- The product may only be applied by medically trained staff.
- A diagnosis may only be made by persons with the appropriate medical training.

Tripping hazard due to cables.

Injuries and fractures are possible.

- Lay connecting cables properly.

Electric shock due to unsuitable power connection, incorrect handling of the product, or damaged product components.

Burns, cardiac arrhythmias, and even fatal injury are possible.

- Do not operate the device if it has been dropped. In this case, clean and disinfect the device and send it to ATMOS for repair.
- Prior to each use, check for damage to the device and the power cable. Do not operate the device if you notice any damage. In this case, clean and disinfect the device and send it to ATMOS for repair.
- Disconnect the device from the power supply prior to cleaning or disinfection.
- Disconnect the device from the power supply prior to servicing, repairing, or opening it.
- You can only disconnect the device from the power supply by pulling out the power plug.
- Position the device in such a way that you can easily disconnect it from the power supply at any time.
- Only connect the device to a power supply with a protective earth conductor.
- Never touch the plug or power cable with wet hands.
- Only use the power supply unit and power cable in dry surroundings. The surroundings must be non-conductive.
- Ensure that no liquid penetrates the device. If liquid has entered the device, operation of the device must cease immediately. In this case, clean and disinfect the device and send it to ATMOS for repair.
- Only use the power supply unit and power cable according to the operating instructions.
- Only use proper power connections and extension cords.
- Never touch the device's interfaces and the patient at the same time!
- Use only original accessories and original spare parts from ATMOS.
- Observe the specifications regarding periodic tests in chapter "6 Maintenance and service" on page 37.
- Assembly, new settings, modifications, extensions, and repairs may only be carried out by authorized persons.
- Do not modify the device without the manufacturer's permission.

Keep the device fully functional at all times.

Malfunctions could cause injury to you and your patients.

- Please observe the notes on the electromagnetic compatibility (EMC) of the device in chapter "11 Notes on EMC" on page 47.
- Perform a function check prior to each use.
- Observe the specifications regarding periodic tests in chapter "6 Maintenance and service" on page 37.
- Use only original accessories and original spare parts from ATMOS.
- Assembly, new settings, modifications, extensions, and repairs may only be carried out by persons who are authorized by ATMOS.

Risk of infection due to pathogens on the product!

Deadly diseases can be transmitted.

- Always wear disposable gloves if there is a risk of you coming into contact with secretions.
- Always wear disposable gloves when using the product.

- Never use components marked with ⓧ more than once. These components are intended for single use only.
- Only use sterile packaged parts if the packaging is undamaged.
- Never operate the device without a bacterial filter.
- A suction catheter, suction attachment, or medical suction instrument must always be connected to the suction hose. The suction hose must never come into direct contact with the suction area.
- Clean and disinfect the product after every use.
- Clean and disinfect the product according to the operating instructions.
- The product must not be used following oversuction.

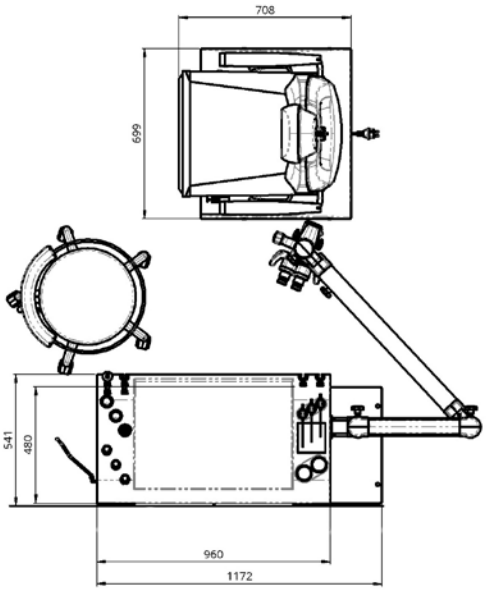
2.3 Avoiding damage to the device

Storage and operation in an unsuitable environment.

The product may become damaged.

- Please observe the ambient conditions for transport, storage, and operation.

3 Setting up and starting up



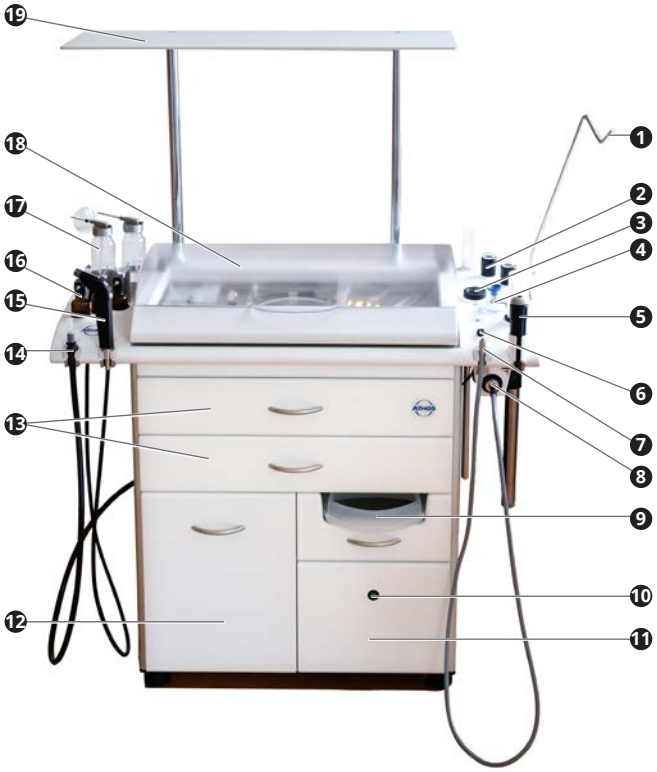
3.1 Required connections (power supply)

Unit / Device	Maximum required connections
ATMOS C 11 Systema	1x earthing contact socket outlet
Optional:	
Monitor	1x earthing contact socket outlet
Microscope ATMOS i View	1x earthing contact socket outlet
Patient chair	1x earthing contact socket outlet

3.2 Connection to electrical power line

- According to the directions of VDE 0107 and VDE 0100, medically used rooms have to be equipped with a leakage current protective circuit (FI protective circuit) with a nominal leakage current of < 0.03 A. The installation must correspond with VDE 0107.
- The power cable of the ATMOS C 11 Systema is connected to an earthing contact socket near the device (max. 5 m; see figure). This may only be carried out by authorized qualified personnel.
- The maximum power consumption is 270 W.
- Please provide for additional sockets for the connection of further electrical devices (installation of an electrically operated ATMOS patient chair, etc.).
- To switch on the unit, move the on/off switch to the “on” position.
- To switch off the unit, move the on/off switch to the “off” position. In this position, the unit is disconnected from the power supply.

3.3 Overview of complete equipment



1. Headlight holder with automatic switching (optional)
2. Endoscope management for rigid or flexible, clean endoscopes (optional)
3. Mirror quick heater (optional)
4. Endoscope quiver for used endoscopes (optional)
5. LED light handle (optional)
6. Brightness controller
7. Light guide cable
8. 1-channel cold light source (optional)
9. Instrument disposal for used instruments (optional)
10. On/off switch
11. Service compartment
12. Compartment for secretion canister
13. Drawers
14. Automatic suction equipment
15. Compressed air (optional)
16. Medication sprayer (optional)
17. Ear irrigation module compressed air (optional)
18. Instrument deposit (optional)
19. Storage shelf (optional)

3.4 Rear view

1 Power connection

4 Operation

4.1 Suction system

⚠ CAUTION

Prior to application, please check suction performance and leak tightness of the suction system.

To do this, please remove the hose from the support and close the hose end with your finger. Check whether vacuum builds up. In case of any leakage (no vacuum build-up, hissing sound), please contact the service technician (see chapter “4.2.10 DDS change-over docking station” on page 19 and “6 Maintenance and service” on page 37).

Make sure that you always insert the suction hose into the left support marked with the symbol  (see figure below).

NOTICE

Never operate the suction system without a bacterial filter. Always use the splash protection; this will prolong the service life of the bacterial filter. ATMOS does not assume any liability for malfunctions caused by operating the device without a bacterial filter.

NOTICE

Exchange the bacterial filter regularly. For more information, see chapter “4.2.2 Inserting/removing the DDS bacterial filter / oversuction stop” on page 16.

The hose attachment must be exchanged after each patient.

Please note that the hose attachments can be cleaned and disinfected mechanically up to 70 °C.

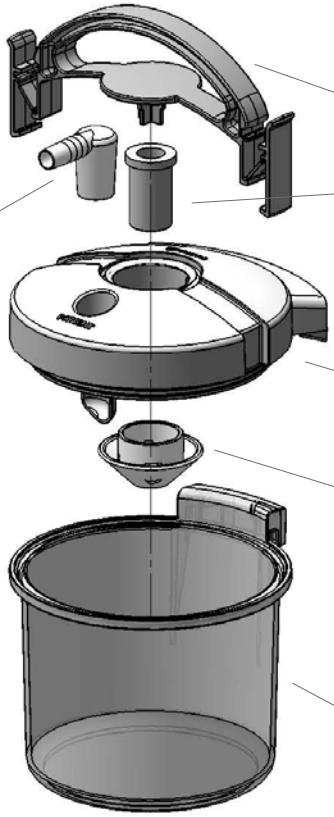
4.1.1 Activation

1. Take the handle from its holder. The suction system is automatically activated via the installed light barrier.
2. The bacterial filter / oversuction stop of the DDS reusable system and the overflow protection systems in the secretion canisters of the disposable systems safely prevent oversuction.
3. If the canisters are full, the overflow protection systems separate the canisters from the vacuum. This can be recognized by a decrease in suction capacity on the handle. In this case, please insert a new suction bag in the disposable system or remove, empty, clean, and disinfect the reusable canister system as described in chapter “5 Reprocessing” on page 29 and insert a new bacterial filter.

4.2 Canister systems

4.2.1 Reusable canister system

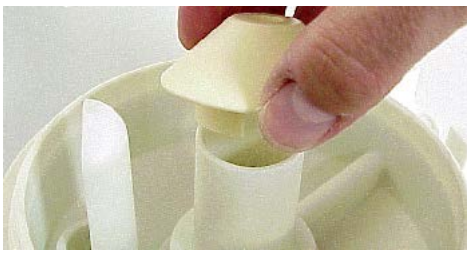
Assembly of secretion canister



4.2.2 Inserting/removing the DDS bacterial filter / oversuction stop

☞ Please wear gloves when inserting or removing the DDS bacterial filter!

4.2.3 Using the DDS splash protection



☞ Please wear gloves when inserting or removing the DDS splash protection!

4.2.4 Attaching/removing the DDS canister lid

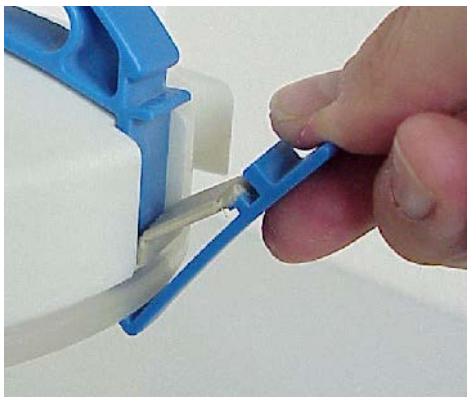
1. Place the DDS secretion canister on a firm surface and set the DDS canister lid horizontally on top (the lid cannot not be turned!).
2. Press it tightly with both hands as far as it will go onto the canister.

3. With one hand on the canister handle, lift the complete canister upwards. With the other hand on the canister bottom, guide the canister in order to prevent it from tilting when lifting it out.
4. Unhinge the snap-in hook of the canister handle on the canister. Pull out the snap-in hook with both hands and remove the canister handle upwards. Remove the bacterial filter/ oversuction stop from the canister handle.
5. Remove the canister lid from the canister with both hands. Remove the splash protection.

4.2.5 DDS canister handle

❶ Canister handle
❷ Snap-in hook
❸ Canister rim

4.2.6 Closing/opening the DDS canister handle

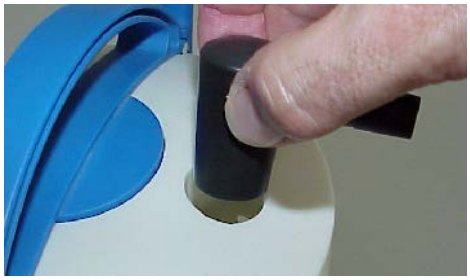


1. To close, secure the snap-in hooks under the canister rim, and then press the clips towards the middle of the canister until they lock into place.
2. To open, pull the clips outwards and unhinge the snap-in hooks under the canister rim.

4.2.7 Removing/securing the DDS secretion canister

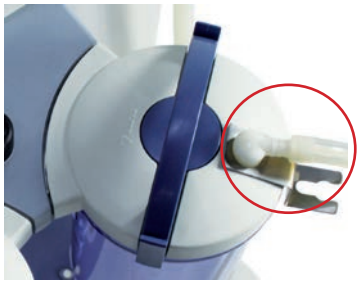
1. Open the storage compartment for the secretion canister, remove the DDS canister by lifting it vertically upwards; to reinsert it, allow it to slide vertically downwards into the securing device.

4.2.8 Inserting the DDS hose adapter



1. Press the required DDS hose adapter with 6 mm or 10 mm diameter into the opening “PATIENT“ on the DDS secretion canister lid, twisting slightly to ensure a tight fit.
2. Twist slightly in the same manner when removing the adapter.

4.2.9 Connecting the hose



1. Please put the hose on the hose adapter.

4.2.10 DDS changeover docking station

Maximum load of the station: 15 kg!

- The DDS changeover docking station for 2 canisters with changeover switch and Direct Docking System may be used with the ATMOS C 11 Systema.
- The changeover lever ❶ is used to switch the vacuum to the canister to which the lever points.
- To remove or insert a canister, switch the changeover lever towards the canister that is not being replaced.

4.2.11 Emptying the reusable canister system

NOTICE

The canister system must be cleaned and disinfected regularly. For more information, see chapter “5 Reprocessing” on page 29.

NOTICE

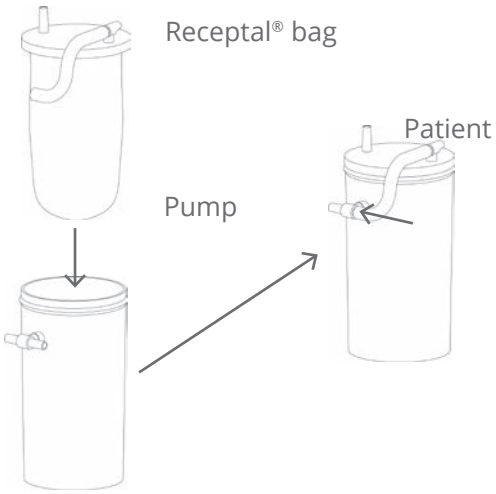
Open the side drawer regularly to **check the fill-level in the secretion canister**.

☞ Empty the secretion canister manually when it is about half full.

☞ To do this, pull the secretion canister horizontally out of the support in the service compartment and remove the suction hose.

4.3 Disposable canister system

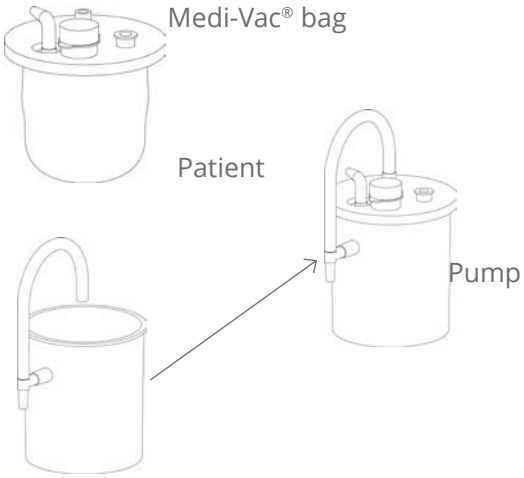
4.3.1 Assembling the Receptal® canister system



1. Insert the Receptal® suction bag into the Receptal® external canister.
2. Close the canister tightly on all sides.
3. Check again for leaks; otherwise, no vacuum can be built up.
4. Plug in the vacuum hose of the pump and attach the secretion hose to the connection marked “PATIENT”.

☞ Only suction bags with an integrated bacterial filter may be used.

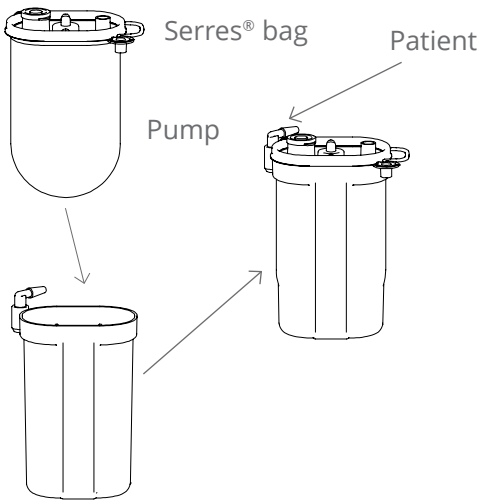
4.3.2 Assembling the Medi-Vac® canister system



1. Insert the Medi-Vac® suction bag into the Medi-Vac® external canister.
2. Close the canister tightly on all sides.
3. Check again for leaks; otherwise, no vacuum can be built up.
4. Plug in the vacuum hose of the pump and attach the secretion hose to the connection marked “PATIENT”.

☞ Only suction bags with an integrated bacterial filter may be used.

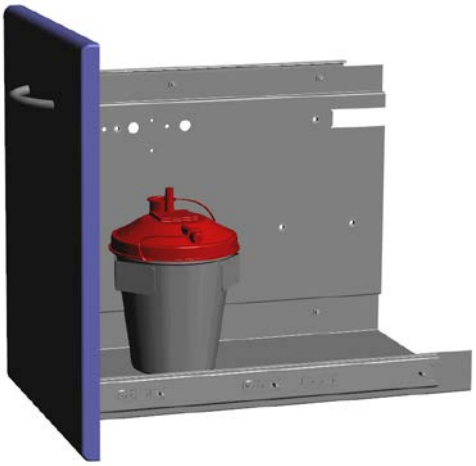
4.3.3 Assembling the Serres® canister system



1. Insert the Serres® suction bag into the Serres® external canister.
2. Close the canister tightly on all sides.
3. Check again for leaks; otherwise, no vacuum can be built up.
4. Plug in the vacuum hose of the pump and attach the secretion hose to the connection marked “PATIENT”.

☞ Only suction bags with an integrated bacterial filter may be used.

4.3.4 Bemis® canister system



1. Insert the Bemis® suction bag into the Bemis® external canister.
2. Close the canister tightly on all sides.
3. Check again for leaks; otherwise, no vacuum can be built up.
4. Plug in the vacuum hose of the pump and attach the secretion hose to the connection marked “PATIENT”.

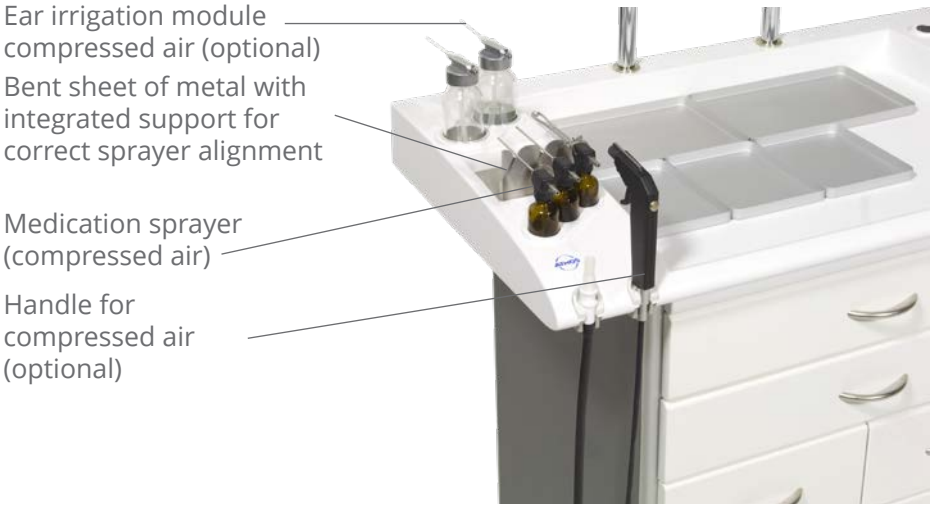
☞ Only suction bags with an integrated bacterial filter may be used.

4.4 Compressed-air module

NOTICE

☞ Prior to use, check the leak tightness of the compressed-air system.

☞ To do this, remove the handle and check for any escaping air. In case of leakage, contact the service technician (see chapter “6 Maintenance and service” on page 37).



NOTICE

For security reasons, you should avoid repeated activation of the compressed-air handle in a rapid sequence.

Make sure equipment and hoses are firmly connected in order to build up a sufficient pressure.

Make sure that you always put the compressed-air handle into the right-hand holder marked with the symbol .

NOTICE

No Politzer maneuvre may be performed with the compressed-air system!

4.4.1 Activation

Take the handle from its holder. The compressed-air module is automatically activated via the installed light barrier.

4.4.2 Adapting/depositing medication sprayers

Attaching

1. Attach the handle to the medication bottle (❶).
2. Engage and then lift the medication bottle with the handle out of the holder (❷).

☞ By pulling the trigger, compressed-air will be applied into the sprayer (❸).

Depositing

1. Insert the medication into the holder from above.
2. Press the activator (❶) and pull the handle (❷) backwards.

NOTICE

Handle the sprayers carefully to avoid injuries.

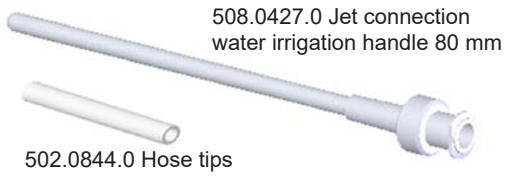
Before using the sprayer bottles, check the shelf life of the medications contained in them.

Clean all parts of the sprayers regularly! For more information, see chapter “5 Reprocessing” on page 29!

4.4.3 Ear irrigation module compressed air (REF 541.1100.0)

1. Prior to application, please check water pressure and water temperature on the back of your hand.
2. Attach the silicone hose tip to the nozzle. To start ear irrigation, close the vent valve (❷) and press the adjusting lever (❶). To stop ear irrigation, release the adjusting lever (❶) and the vent valve (❷). Ear irrigation stops.

☞ Please note that the bottles must not be filled at the treatment unit. There is a risk of spilling the rinsing liquid. This liquid could possibly penetrate the treatment unit.



- ☞ Change the jet connection after each patient. Only use reprocessed jet connections to avoid spreading germs.
- ☞ Dispose of the hose tip after each patient use and replace it with a new one.
- ☞ Check the glass bottles for intactness prior to every use (cracks, chippings on the winding, etc.). Broken glass bottles may not be used for ear irrigation.

4.4.4 Ear irrigation bowl

- Purpose: to collect the water drained during ear irrigation.
- The ear irrigation bowl is connected to the adapter of the suction system and is then held under the patient's ear.

4.5 ATMOS LS 21 LED – quick start

The ATMOS LS 21 LED has separate operating instructions.

Please note:

Read these separate operating instructions attentively and follow the safety notes listed there to guarantee ideal and safe use of all functions!

NOTICE

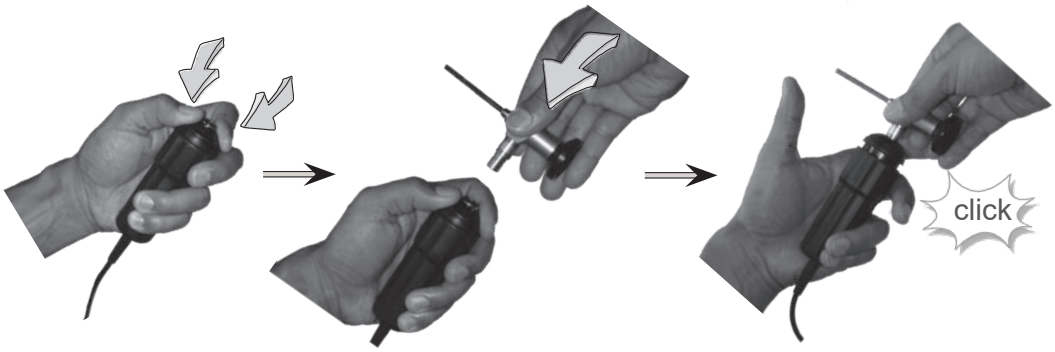
Never look directly into the light source!

Connection

*Not included in scope of delivery. Optionally available.

- ☞ If the light source is used with unsuitable adapters, the lens can be severely damaged!
- ☞ Use optics only with the supplied and/or optional adapters!
- ☞ Make sure the endoscopes with adapter engage in the light source!

4.5.1 Attaching the applied part



4.5.2 Autostart function

The light source is automatically activated when the light handle is removed from its holder.

4.5.3 Adjusting brightness

1. Switch on the light source.
2. Turn the brightness controller counterclockwise to reduce the brightness or clockwise to increase it.

☞ The last setting is retained when the device is switched off.

4.6 ATMOS HL 21 LED – quick start

The ATMOS HL 21 LED has separate operating instructions.

NOTICE

Read these separate operating instructions attentively and follow the safety notes listed there to guarantee ideal and safe use of all functions!

Please be sure to use the right-hand power connection, marked with 700 mA, for the headlight ATMOS HL 21 LED.

4.6.1 Switching on

a) When the headlight is connected to the power supply of the ENT unit, the headlight switches on automatically when it is removed from the headlight holder.

b) When the headlight is connected to a battery: Move the switch on the side of the LED battery to the desired position:

- ECO mode: operation for approx. 4 hours.
- POWER mode: operation for approx. 2 hours.

4.6.2 Focusing the headlight

- The size of the light spot can be adjusted by turning the focusing ring.

4.6.3 Adjusting brightness

1. Switch on the light source.
2. Turn the brightness controller counterclockwise to reduce the brightness or clockwise to increase it.

☞ The last setting is retained when the device is switched off.

4.7 LED cold light module

The 1-channel LED cold light module is delivered with an ATMOS/Storz adapter.

Here you can connect the light guide cable to the ATMOS/Storz adapter.

When the light guide cable is removed from its holder, the light source switches on automatically due to the built-in light barrier.

In case you use a light guide cable from another manufacturer, you will then require a suitable adapter.

Changing the adapter

1. To release the adapter, turn it to the left and then pull it out.
2. Insert the new adapter and turn it to the right until it is firmly in place.

⚠ CAUTION

Take care when working with endoscopes connected to light sources. Do not look directly into the light outlets! In case of possible light failure, carefully remove the endoscope from the working area!

Prolonged use of the light source may cause the tissue to heat up due to heat radiation from the light source.

Please note that prolonged use of the light source to examine the external auditory canal may cause nystagmus stimulation due to heat radiation.

4.7.1 Adjusting brightness

1. Switch on the light source.
2. Turn the brightness controller counterclockwise to reduce the brightness or clockwise to increase it.

☞ The last setting is retained when the device is switched off.

4.8 Endoscope management

4.8.1 Overview

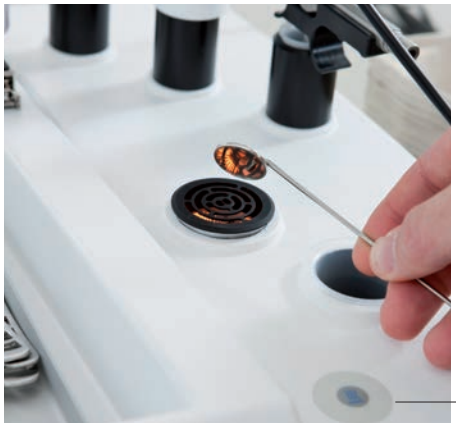
Plastic quiver for storage of clean endoscopes (removable)

Plastic quiver for storage of used endoscopes and filling with disinfectant solution (removable)

NOTICE

- Please handle the instruments carefully when inserting or removing them.
- Please note that only cleaned/disinfected endoscopes may be put into the storage quivers.
- Please put used contaminated endoscopes only into the appropriate quivers.
- Please take care to strictly separate clean from contaminated instruments.
- When reprocessing endoscopes, it is essential to observe the manufacturer's instructions for reprocessing as well as general rules and regulations.
- Reprocessing of endoscopes for reuse may not be performed at the workstation! In this context, please observe existing directives and rules.
- Clean and disinfect the storage quivers regularly! Please observe the notes in chapter "5 Reprocessing" on page 29.

4.8.2 Mirror quick heater



Power-on button

⚠ CAUTION

Never touch the cover of the mirror quick heater. The cover is hot!

Press the power-on button to activate the mirror quick heater. After 10 seconds, it switches off automatically.

⚠ CAUTION

Risk of burns!

Prior to each use on your patient, check your instruments' temperature (e.g., on the back of your hand).

NOTICE

Only lay down and heat clean instruments!

NOTICE

As soon as the mirror quick heater is activated, all other electrical devices switch off automatically until mirror heating is completed. In case that the suction system is required simultaneously, it is activated when the suction hose is removed from the holder and the mirror quick heater is switched off.

4.9 Emptying the instrument disposal

Disposal for used instruments

To be filled/emptied

1. Please put the used instruments into the provided instrument disposal.
2. To empty the instrument disposal, open the drawer and remove the entire plastic container. The lid can be removed and the instruments reprocessed.
3. Put a new or the reprocessed plastic container back into the drawer and close it.

5 Reprocessing

5.1 General information on cleaning and disinfection

NOTICE

- Switch all devices off prior to cleaning and disinfection!
- The described actions relating to cleaning and disinfection or sterilization do not replace the relevant regulations 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 given 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 plastic materials used.

5.1.1 Cleaning the treatment unit surface

- The surfaces of the ATMOS C 11 Systema are resistant to all surface disinfectants listed in chapter “5 Reprocessing” on page 29.
- Wipe the treatment unit surface with a cloth moistened with a cleaning or disinfecting solution.
- You may also use disinfectant sprays or disinfectant wipes 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.

- All applied parts that are exposed to direct contact with the patient during treatment must be exchanged or cleaned and disinfected immediately for hygienic reasons.
- Only deposit clean instruments on the shelves!
- Clean and disinfect the instrument deposits regularly!
- Do not use any organic solvents (benzine, etc.) and abrasive cleaning agents.

5.1.2 Secretion canister, bacterial filter, and suction hose

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

Reusable secretion canister with lid system and bacterial filter:

- Carefully detach all hose connections on the lid system and take the secretion canister out carefully to prevent spills and contamination of the area. Dispose of the suction material correctly.
- Grip the lid system firmly, open the lid of the filter housing by turning counterclockwise, and remove the filter. Rinse all parts thoroughly under running water. A neutral dishwashing liquid (detergent) or cleaning agent may also be used if required. For disinfection, immerse the parts into disinfectant, observing the contact time specified in the manufacturer's instructions.
- The bacterial filters are consumables and must be disposed of.
- It can also be cleaned in a washer-disinfector (with neodisher® MediClean forte) and thermally disinfected at 93 °C.
- Maximum number of reprocessing cycles:
  DDS canister system, silicone hose: 60 cycles

☞ Suction capacity is limited by the 1.5 l secretion canister. Therefore, do not use more than 1 l rinsing liquid and subsequently evacuate the canister.

☞ Insert a new filter!

5.1.3 Checking the DDS bacterial filter / oversuction stop

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

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

Never operate the device without the DDS bacterial filter / oversuction stop.

5.1.4 Medication sprayers

NOTICE

- The sprayer nozzle must be exchanged after each patient.
- Dismount the medication sprayer and thoroughly rinse all parts under running water. A dishwashing liquid (detergent) or cleaning agent may also be used if required.
- Remove residues of these agents by rinsing thoroughly with water.

☞ Make sure that the ventilation hole is not closed!

- It can also be cleaned automatically and thermally disinfected (preferred).
- The sprayer nozzles can be cleaned by rinsing them with a neutral detergent. It is advantageous to use a sprayer bottle (REF 000.0577.0) that is exclusively used for cleaning and disinfection.

☞ When placing the twin tube nozzle back on again, make sure the mark (0, X, or milling area) on the nozzle shows upwards!

☞ Sprayer nozzles are available as spare parts from ATMOS.

5.1.5 Instrument trays

- Before disinfection, thoroughly rinse the trays under running water. A dishwashing liquid (detergent) may also be used if required.
- Remove detergent residues by rinsing thoroughly with water.
- The trays can also be cleaned in a washer-disinfector (with neodisher® MediClean forte) and thermally disinfected at 93 °C.

5.1.6 Endoscope quivers

- The narrow plastic quivers of the endoscope holder must only be used to hold **previously cleaned and disinfected** endoscopes.

☞ The quivers are to be cleaned daily and subsequently disinfected.

- Plastic quivers are not autoclavable. Clean and disinfect manually. Mechanical cleaning up to max. 78 °C.

5.1.7 Ear irrigation bottle and ear irrigation bowl

- The sprayer nozzle must be exchanged after each patient.
- Dismount the ear irrigation bottle and thoroughly clean all parts under running water. A detergent or cleaning agent may also be used if required. Residues of any detergents or cleaning agents must be removed completely. Afterwards disinfection is required.
- The ear irrigation bowl is not autoclavable! Cleaning and disinfection (also mechanical cleaning) up to 93 °C.

☞ Sprayer nozzles are available as spare parts from ATMOS.

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 inhibitors	9.2 g 13.0 g	Bode Chemie, Hamburg
Korsolex® extra (Application concentrate)	(ethylenedioxy)dimethanol glutaral benzyl-C12-18-alkyldimethyl ammonium chloride 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 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® 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

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

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	80.0 g	Bode Chemie, Hamburg
Dismozon® plus (Granulate)	magnesium monoperoxyphthalate hexahydrate	95.8 g	Bode Chemie, Hamburg
Kohrsolin® FF (Application concentrate)	glutaral benzyl-C12-C18-alkyldimethylammonium chloride 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 aminoalkylglycines 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	80.0 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 chloride didecyldimethylammonium chloride	5 g 3 g 3 g	Bode Chemie, Hamburg
Bacillocid® rasant End of product	glutaral benzyl-C12-18-alkyldimethyl ammonium chloride didecyldimethylammonium chloride	10 g 6 g 6 g	Bode Chemie, Hamburg
Mikrobac® forte (Application concentrate)	benzyl-C12-18-alkyldimethyl ammonium chloride 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 aminoalkylglycines non-ionic surfactants, perfumes	22 g 17 g 0.9 g	Schülke & Mayr, Norderstedt
Surface disinfection FD 312	alkyl-benzyl-dimethyl ammonium chloride non-ionic surfactants, complexing agents, hexyl cinnamal, butylphenyl methylpropional, linalool	13 g	Dürr Dental, Bietigheim-Bissingen

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 (ethylenedioxy)dimethanol surfactants, corrosion inhibitors, salts, perfumes	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 (ethylenedioxy)dimethanol surfactants, corrosion inhibitors, salts, perfumes	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) (Granulate)	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

Hygiene plan

Cleaning and disinfection plan
ATMOS C 11 Systema

	What	How			Recommendations	When				Who
	Parts to be reprocessed	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									
	Hose connection (nozzle)	X	X[2,4,5]		Cleaning and disinfection (mechanical or manual)		X			
	Canister lid	X	X[2,4,5]		Cleaning and disinfection (mechanical or manual)		X			
	Canister holder	X	X[2,4,5]		Cleaning and disinfection (mechanical or manual)		X			
	Bacterial filter				Exchange daily or when blocked		X			
	Splash protection	X	X[2,4,5]		Manual cleaning and disinfection		X			
	Secretion collection canister	X	X[2,4,5]		Empty when the canister is full		X			
	Disposable canister system				Exchange and disposal of full canister					
	Ear irrigation / medication sprayer									
	Ear irrigation bowl	X	X[2,4,5]		Cleaning and disinfection (mechanical or manual)	X				
	Nozzle	X	X[2,4,5,6]		Cleaning and disinfection (mechanical or manual)	X				
	Splash protection	X	X[2,4,5]		Wipe cleaning and wipe disinfection		X			
	Hose tip (disposable)				Exchange after each procedure	X				
	Rinsing lid with rinsing hose	X	X[2,4,5]		Cleaning and disinfection (mechanical or manual)		X			
	Rinsing bottle	X	X[2,4,5,6]		Cleaning and disinfection (mechanical or manual); cleaning in the dishwasher with the glass care programme		X			
	Compressed-air handle	X	X		Manual wipe cleaning and wipe disinfection		X			
	Sprayer nozzle	X			Cleaning after each use	X				
			X[2,4,5,6]		Cleaning and disinfection (mechanical or manual)		X			
	Sprayer head	X	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		
	Endoscope management									
	Plastic quiver	X	X[2,4,5]		Cleaning with a brush; subsequent disinfection		X			
	Endoscope quiver	X	X[2,4,5,6]		Cleaning with a brush; subsequent disinfection		X			
	Endoscope quiver adapter (Teflon element for endoscope quiver)	X	X[2,4,5]		Cleaning and disinfection (mechanical or manual)		X			

	What	How			Recommendations	When				Who
	Parts to be reprocessed	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)
	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 consult the additional operating instructions for the ATMOS ENT instruments.	X				
	Instrument disposal tray with cover	X	X[2,4,5]		Cleaning with a brush; subsequent disinfection (mechnical or manual)		X			
	Visualization									
	Flexible endoscope	X	X[1]	X[1]	Immediate pre-cleaning after the procedure See the manufacturer's operating instructions!	X				
	Rigid endoscope	X	X[1]		See the manufacturer's operating instructions!	X				
	Laryngoscope	X	X[1]	X[1]	Immediate pre-cleaning after the procedure See the manufacturer's operating instructions!	X				
	Light guide cable	X	X[3]		Wipe cleaning and wipe disinfection		X			
	Light handle	X	X[3]		Wipe cleaning and wipe disinfection		X			
	Microscope	X	X[3]		Wipe cleaning and wipe disinfection		X			
	Headlight	X	X[3]		Wipe cleaning and wipe disinfection		X			
	Surfaces									
	Housing	X	X[3]		Wipe cleaning and wipe disinfection		X			
	Cover lid	X	X[3]		Wipe cleaning and wipe disinfection		X			
	Drawers	X	X[3]		Wipe cleaning and wipe disinfection		X			
	Instrument disposal	X	X[3]		Wipe cleaning and wipe disinfectionWipe cleaning and disinfection		X			
	Quick mirror heater	X	X[3]		Wipe cleaning and wipe disinfection		X			
	Instrument tray	X	X[3]		Wipe cleaning and wipe disinfection daily or when replacing 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 disinfectant FD 312 (Dürr Dental)
- Green & Clean SK (ATMOS)
- Incidin® Plus (Application concentrate)

[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 GmbH)

[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)

[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 new (Schülke & Mayr)
- Endozime® AW Plus()
- ADAPTACLEAN™ (ASP)

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

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] Preferred: mechanical cleaning and disinfection in the washer disinfector
[6] Material dimensionally stable at 134 °C

Wrong concentration of disinfectants may lead to material damage!

This hygiene plan was created on the basis of the MDR, the Medical Devices Operator Ordinance, §18 IfSG, the recommendations of the Robert Koch Institute and the currently valid standards and recommendations of the professional associations. The required reprocessing steps were defined on the basis of DIN EN ISO 17664: 2018-04 and the recommendations "Requirements for the reprocessing of medical devices", from Robert Koch Institute. The medical products were categorised in the risk groups uncritical, semi-critical and critical.
The disinfectants recommended in this hygiene plan are listed disinfectants (VAH/RKI list) and have been tested for their material compatibility for this device.
ATMOS MedizinTechnik cannot be held liable for any damage caused by wrong concentration of the disinfectants or by the application of any other disinfectants.
For further information, please read the operating instructions, which provide additional information about this device and its accessories.

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

GA3GB.110300.0 2022-06 Index: 05

6 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 (see chapter 23 "Test instructions" in the service instructions ATMOS C 11 Systema).

☞ Circuit and wiring diagrams, etc. can be requested from and provided by ATMOS.

In case of any malfunction, please contact your ATMOS partner or our service hotline +49 7653 689 222.

6.1 Sending in the device

1. Remove and properly dispose of consumables.
2. Clean and disinfect the product and accessories according to the operating instructions.
3. Place used accessories with the product.
4. 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.

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

7 Troubleshooting

Description	Cause	Measure
Electric power supply		
No function, main switch is active, control light does not light up	No voltage on power plug	Check house fuses; they possibly burnt through
	Cable/plug defective	Exchange cable/plug
Suction		
Weak or no suction capacity at all, but vacuum is available at the support for the canister system	Suction hose is clogged	Clean suction hose
	Oversuction protection is activated	Check oversuction protection; replace if necessary
	Filter moistened/blocked	Replace filter
	Suction hose snapped off	Remove breaks; pass hose a different way
	System leaky	Check all joints; reassemble the system
	Hose adapter is not securely connected to the canister lid	Insert the hose adapter correctly
	Seal of the canister lid is defective	Replace the seal
	Missing lid clip	Close upper edge of the secretion canister
Weak or no suction capacity suction at all No vacuum at the support for the canister system	Secretion penetrated the suction pump	Inform the service department
Suction pump does not switch on or off	Soiled/defective light barrier in suction hose holder	Clean both light barrier openings in the suction hose holder; if necessary, inform the service department
No suction, but pressure pump is operating	Positions of handles have been mixed up	Insert handles in the correct holders
Vacuum pump does not start	Compressed-air handle and the suction hose were removed from their holders at the same time	Put the compressed-air handle back into its holder

Description	Cause	Measure
Compressed air		
Compressed-air pump does not switch on or off	Soiled/defective light barrier in compressed-air holder	Clean both light barrier openings in the compressed-air holder; if necessary, inform the service department
No compressed air, but suction pump is operating	Positions of handles have been mixed up	Insert handles in the correct holders
No adequate pressure build-up	Leaky connections	Check joints; if necessary, inform the service department
Sprayer does not work	Sprayer is clogged	Clean sprayer; clean ventilation borehole in sprayer head
		Twin sprayer nozzle is not attached correctly
Mirror quick heater		
Heater does not switch on	Switch or control unit defective	Inform the service department to exchange the switch or control unit
Insufficient or no heater power	Heater coil defective; no glow	Exchange heater coils
Heater does not switch on	Vacuum pump active	Put the vacuum handle back into its holder
Insufficient heating performance	Interruption of heating due to required vacuum	If vacuum is no longer needed, please put the handle back into its holder
Light sources		
Light does not switch on	Light source plug is loose	Insert the plug
Light does not switch off	Light source does not fit properly in the holder	Adjust the position of the light handle
	Other light source disturbs the sensor on the holder	Reposition secondary light source
Headlight		
Headlight does not switch on	The headlight holder is weighed down by another weight	Remove the weight
	Automatic headlight holder does not move freely	Restore free mobility

8 Accessories and consumables

Product name	REF
Sprayer, straight (fluids)	506.5225.0
Sprayer, flexible nozzle (fluids & oils)	506.5120.0
Sprayer, straight (powder)	505.0253.0
Politzer olive (universal size)	000.0241.0
Politzer olive (children)	000.0241.1
Sparehose sprayer bottle (10 pcs.)	506.5229.0
Ear irrigation bowl, separate suction channel	530.2070.0
Jet connection water irrigation handle 40 mm	502.0984.0
Jet connection water irrigation handle 80 mm	508.0427.0
Jet connection water irrigation handle 110 mm	508.0429.0
Hose tips	502.0844.0
Splash protection to be slipped on jet connection	501.0331.0
Ear irrigation bowl	505.0353.0
Monitor holder (C 21 / C 31 / C 11)	541.2500.0
Monitor holder (C11)	541.2200.0
Instrument tray, small (stainless)	508.0058.2
Instrument disposal bowl	506.7751.0
Cover for instrument disposal bowl	506.7752.0
Stainless steel sieve (instrument disposal)	506.7759.0
Instrument tray, large (stainless steel)	505.0516.2
Tray, narrow	532.0146.0
Tray, narrow (instrument deposit)	534.0146.0
Holder ear specula / Politzer olives	508.0545.0
Shelf (glass)	534.3050.0
Shelf (metal)	534.3060.0
Shelf (glass), high	534.3055.0
Shelf (metal), high	534.3065.0
Instrument tray set (stainless steel)	506.7033.0
Serrated instrument holder, small	508.0567.0
Serrated instrument holder, large	508.0566.0

Light module economy	REF
Lithium-ionic battery for mobile use	507.4510.0

8.1 Using the accessories

8.1.1 Compressed-air handle

The compressed-air handle is used to adapt applied parts for the compressed-air system. These are connected to the compressed-air system of the ATMOS C 11 Systema via a self-locking quick connector (10). For safety reasons, the hose and the

quick connector are firmly connected to the compressed-air handle. Therefore, it is only available as a complete spare part.

Two compressed-air handles are available that match the selected configuration of the ATMOS C 11 Systema.

- REF 541.1010.0 Compressed air handle, standard, for use with medication sprayers,
- REF 541.1110.0 Compressed air handle incl. additional air valve for use with medication sprayers and ear irrigation.

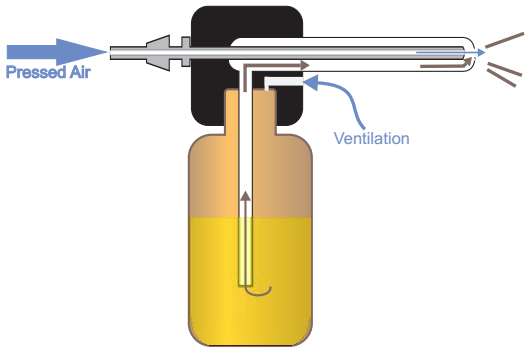
The additional air valve on the handle (REF 541.1110.0) is necessary so that the jet of water can be immediately stopped during ear irrigation.

8.1.2 Medication sprayers

The compressed-air module is required to use the medication sprayers. Different sprayers are available depending on the consistency of the medication:

- Sprayer, straight, for liquid medicines (REF 506.5225.0)
- Sprayer, double-barreled, with flexible nozzle for oily and liquid medicines (REF 506.5120.0)
- Sprayer, straight, for powdery medicines (REF 505.0253.0)

Sprayer, straight, REF 506.5225.0



Sprayer, straight

The sprayer head (1) of this sprayer has an inner tube that is connected to the compressed-air connection. The compressed air is greatly accelerated within this tube. The outer tube (2), which has a slightly larger diameter, is pulled over the inner tube. The medication channel runs through this outer tube and is immersed in the medicine via a hose piece (3). The inner tube is slightly shorter at the outlet opening. When the compressed air exits the inner tube through this small space and flows at high speed through the outlet opening of the outer tube, a slight vacuum is created within this space. This vacuum is sufficient to draw in some medicine through the outer tube. Here, the aspirated medication mixes with the compressed air and is then blown out in a finely atomized form.

Individual parts

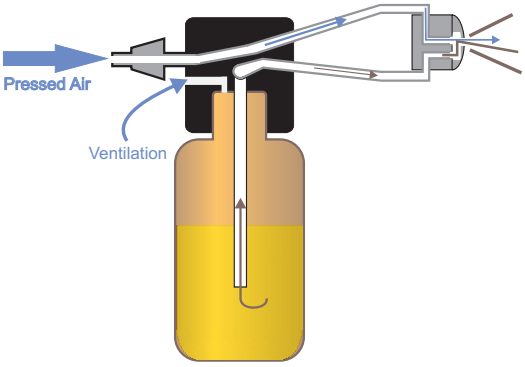
REF 506.5227.0 Sprayer head, straight, complete (1)+(2)+(3)

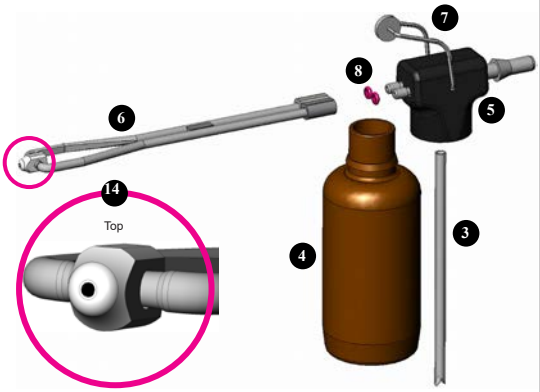
REF 000.0577.0 Sprayer bottle (4)

REF 505.0280.0 Outer tube, straight (2)

REF 506.5228.0 Hose piece for medication sprayer (3)

Sprayer, double-barreled for oily medicines, REF 506.5120.0





Sprayer, double-barreled for oily medicines

The straight sprayer would not be able to transport oily medication very well or atomize it that finely, but the double-barreled sprayer can.

The principle of operation is the same as that for the straight sprayer. However, the medication is drawn to the nozzle in a parallel tube. The rotatable nozzle is mounted on the end of the tubes so that the medication can be applied to even hard-to-reach areas. There is a small chamber behind the outlet opening on the nozzle head, into which the compressed air flowing through it draws in the medication and mixes it with the air. The high pressure and the small outlet opening enable fine atomization of the oily medication.

Individual parts

REF 506.5121.0 Sprayer head twin sprayer (7)

REF 000.0219.0 Twin tube nozzle (6)

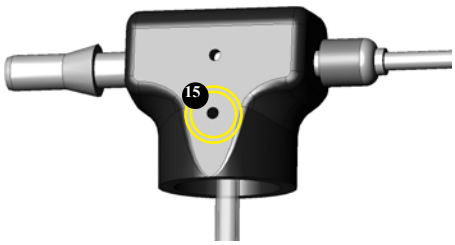
REF 000.0237.0 Spring clip with roll (7)

REF 055.0029.0 O-ring (8)

REF 000.0577.0 Sprayer bottle (4)

REF 506.5228.0 Hose piece for medicine sprayer (3)

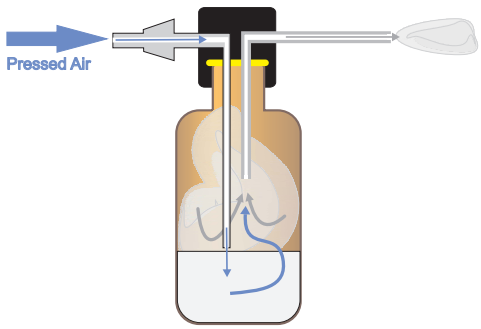
☞ This sprayer only works when the flat side of the nozzle points upwards (14).

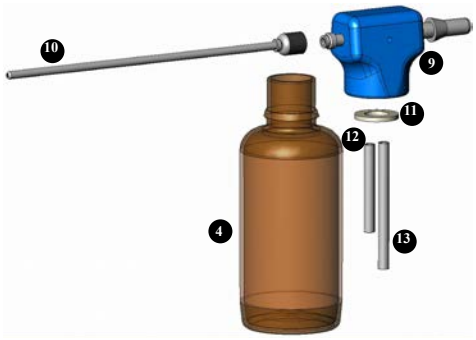


The falling fill-level in the sprayer bottle creates a vacuum that counteracts the suction vacuum at the outlet opening. When the vacuum in the sprayer bottle reaches the same level as that of the suction vacuum at the end of the inner tube, medication can no longer be drawn in and blown out. There is a small ventilation hole (15) in the pump head of both liquid sprayers that prevents counter-pressure from developing when the fill-level in the sprayer bottle drops. The decreasing liquid volume is compensated by ambient air through this hole.

☞ This hole must always remain open. The sprayer will not work if the hole is blocked, for example, by dried medication.

Powder blower, REF 505.0253.0





Powder blower

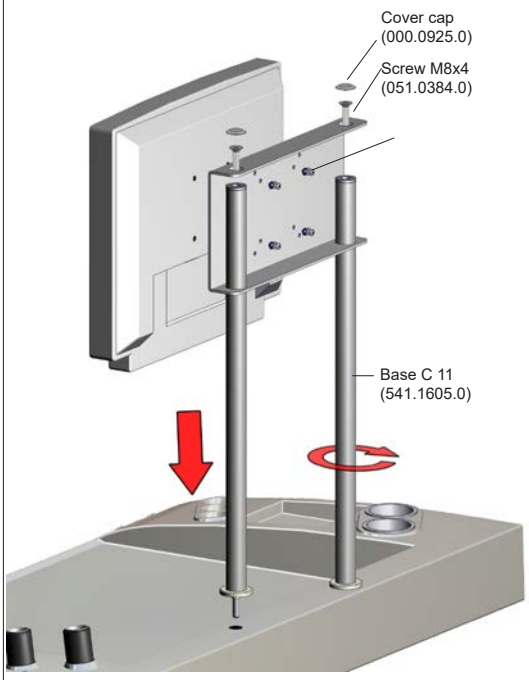
The principle of liquid sprayers does not work with powdered medicines.

With the powder blower, the compressed air is fed directly into the sprayer bottle (4). The airflow stirs up the dry medication. Due to overpressure in the bottle, the air flowing towards the outlet carries the medication along with it. The bottle (4) and sprayer head (9) are sealed with a sealing (11), thereby ensuring that the overpressure can only escape via the delivery tube.

This sprayer head (9) is blue to better distinguish it from the straight sprayer for liquids. Since the powder blower (REF 505.0253.0) operates using overpressure, it has no ventilation hole (15). Instead, it is closed by means of a seal, since overpressure is required within the bottle for the system to work.

☞ Ensure all parts are clean and dry before filling the bottle.

8.1.3 Monitor holder C11, REF 541.2200.0



To assemble the monitor support, please observe the notes in the service instructions.

9 Disposal

- Die ATMOS C 11 Systema does not contain any hazardous materials.
- 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).

Before disposal and before transport, all parts that have come into contact with the patient must be thoroughly cleaned and disinfected. The device surface must be disinfected.

Disposal within the EC

The device described above is a high-quality medical device with a long service life. After its life cycle it must be disposed of professionally. According to EU directives (WEEE and RoHS), the 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.

10 Technical data

Input voltage	100–240 V~ ± 10 %; 50/60 Hz
Current consumption	Max. 1.5 A (@230 V~) Max. 2 A (@127 V~)
Power consumption	max. 270 W
Fuses	2 x T 2.0 A (high cut-off current 1.500 A), 250 V
Suction system	High vacuum / high flow
• Power density (free flow)	≥ 20 l/min at the end of the suction hose
• Vacuum (absolute)	200 mbar
• Vacuum (relative)	−80% (−800 mbar)
• Suction hose	Inner diameter = 8,0 mm Max. length = 1,6 m
• Volume of the secretion canister	1,5 l (optional 3,0 l)
Compressed-air system	
• Free flow	≥ 8 l/min. (on the handle)
• Pressure	200 kPa ± 20%
Ear irrigation	
• Water temperature	37 °C +/- 2 °C
LED power connections	1 x 1000 mA (adjustable from 10 %–100 %) 1 x 700 mA (adjustable from 10 %–100 %)
• LED cold light module	min. 80 kLux (@1000 mA)
• ATMOS LS 21 LED	200 kLux (@700 mA)
• ATMOS HL 21 LED	100 kLux (@700 mA)
Operating time	Continuous operation Pump max. 15 min. Mirror heater approx. 15 sec.
Protective earth conductor resistance	max. 0.1 Ω
• Earth leakage current	max. 5 mA
• Touch current	max. 0.1 mA
• Patient leakage current	max. 0.1 mA
Environmental conditions: Transport/ storage	
• Temperature range	−20...+50 °C
• Air humidity without condensation	30...95 %
• Air pressure	500...1060 hPa
Environmental conditions: Operation	
• Temperature range	+10...+35 °C
• Air humidity without condensation	30...95 %
• Air pressure	700...1060 hPa
Maximum operating altitude	≤ 3000m (NN)
Contamination level	2
Overvoltage category	II
Dimensions (H x W x D)	Sitting 840 x 960 x 535 mm Standing 960 x 960 x 535 mm
Weight	105 kg

Periodical tests	Repeat test of the electrical safety every 12 months. Recommended: inspection according to the manufacturer's specifications.
Protection class against electric shock (acc. to EN 60601-1)	I
Classification of applied parts	Type BF applied parts 
Degree of protection	IPX0
CE marking	CE 0124
Reference number (REF)	541.0000.0 542.0000.0 541.0100.0

Status: 02 June 2023

11 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 C 11 Systema is suitable for use in the following environments:

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

The following environments are not suitable:

Vicinity of HF surgical devices and in settings outside of an HF-shielded room of a magnetic resonance imaging system.

The customer or user of the ATMOS C 11 Systema must ensure that the device is used in a prescribed environment.

Guidance and manufacturer's declaration – key features

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

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

The ATMOS C 11 Systema has the following removable components that can be replaced by the operator:

Type	REF	Max. cable length
ATMOS LS 21 LED	541.4300.0	2.0 m
ATMOS LS 21 LED, warm white	541.4400.0	2.0 m
ATMOS HL 21 LED	530.4020.0	2.0 m
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 C 11 Systema, 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.

Immunity

Immunity	Test	Test level
☒	EN 61000-4-2:2009 Electrostatic discharge (ESD)	± 8 kV contact discharge ± 15 kV air discharge
☒	EN 61000-4-3:2006 +A1:2008+A2:2010 High-frequency electromagnetic fields	10 V/m (80 MHz–2.7 GHz) 27 V/m (380–390 MHz) 28 V/m (430–470 MHz) 9 V/m (704–787 MHz) 28 V/m (800–960 MHz) 28 V/m (1.7–1.99 GHz) 28 V/m (2.4–2.57 GHz) 9 V/m (5.1–5.8 GHz)
☒	EN 61000-4-4:2012 Fast electrical transient (burst)	±2 kV
☒	EN 61000-4-5:2006 Surges	±1 kV symmetrical ±2 kV unsymmetrical
☒	EN 61000-4-6:2014 Conducted disturbances	6 V/m (150 kHz – 100 MHz)
❑	EN 61000-4-8:2010 Magnetic fields	30 A/m
☒	DIN EN 61000-4-11:2004 Voltage dips	40 % U (45°, 90°, 135°, 180°, 225°, 270°, 315°) 70 % U (45°, 90°, 135°, 180°, 225°, 270°, 315°) 80 % U (45°, 90°, 135°, 180°, 225°, 270°, 315°) 0 % U (180°, 360°)
☒	DIN EN 61000-4-11:2004 Voltage dips	0 % U (250 periods)
☒	EN 55011:2009+A1:2010 Conducted emission	Class A (150 kHz – 30 MHz)
☒	EN 55011:2009+A1:2010 Radiated emission	Class B (30 MHz – 1 GHz)
☒	EN 61000-3-2:2006 +A1:2009+A2:2009 Harmonic distortion	Class A (Ed. 4.0 2014)
☒	EN 61000-3-3:2013 Flicker	Compliance

12 Notes

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

www.atmosmed.com