ATMOS
MedizinTechnik

English

Operating Instructions

ATMOS®
C 361
Surgical Suction Unit

CE 0124

GA1DE.210101.0
2018-06 Index: 17

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Contents

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1.1 Notes on operating instructions

- These operating instructions contain important notes on how to operate the **ATMOS® C 361** safely, correctly and effectively. Therefore, they are intended not only for new operating personnel to be instructed in its use, but also for use as a reference manual. They help to avoid risks, and also to reduce repair costs and down-time. Furthermore, reliability and service-life of the equipment will be increased. For these reasons these operating instructions must always be kept available near the appliance.
  Prior to first use please peruse the chapter 2.0 “For your safety”, in order to be prepared for any possible dangerous situations.

  The basic principles are:

  Judicious and careful work provides best protection against accidents!

  Operational safety and readiness for use depend not only on your capabilities, but also on care and maintenance given to the **ATMOS® C 361**. For this reason regular cleaning and service work are a must. Major maintenance and repair work may be carried out only by expert personnel authorised by ATMOS. In case of repairs you should insist that original spare parts only are used. You will then have the warranty that operational safety, readiness for work and the value of your appliance will be preserved.

- The product **ATMOS® C 361** bears CE marking CE-0124 according to the EEC guideline of the council for medical products 93/42/EEC and meets the basic requirements of annex I of this guideline.
- The product **ATMOS® C 361** 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 standard ISO 13485.
- ATMOS will supply a service manual containing detailed circuit descriptions and schematics as well as information on adjustment and servicing organizations authorized by ATMOS.
- Reprints, also in extracts, only with written permission by ATMOS.

Abbreviations / symbols in these operating instructions:

- Indicating a list
  - Subdivision of a list/activity

The recommended sequence must be followed in each case!

☞ Indicating particularly important advice!

1.2 Intended use

Name: ATMOS® C 361

Main functions:
Suction of secretions, rinsing fluids and temporarily collection of body fluids.

Med. indications/ application:
For surgeries e.g. suction of wound cavities, abscesses etc.
For endoscopy e.g. suction of secretions and rinsing fluids.
For spontaneous suction of body fluids.

Specification of the main function:
Drainage and temporarily collection of body fluids. By means of an electrical suction pump, a negative pressure will be created. The integrated secretion canister allows a temporarily collection of the derived body fluids.

Application organ:
Natural orifices as well as openings which are created by means of a surgery (whole body; human and animal).

Application time: Short-term use on the patient (< 30 days).

Application site: The application site is the clinical, outpatient, practices as well as the veterinary medicine area. The application of the device may only be performed by medical trained and introduced staff.

Contraindications:
No application in low-vacuum range e.g. thoracic and wound drainage.
No application outside of the medical sector.
No suction of flammable, corrosive and explosive substances.
No application for the vacuum extraction.

The product is: X active □ not active

Sterility: Not necessary

Single use product / reprocessing:
The device and the accessories are partially reusable. For information on reprocessing, cleaning and disinfection see user manual.

1.3 Function

- The **ATMOS® C 361** is a mains-operated surgical suction unit, centering around a silent diaphragm-type pump which generates a vacuum inside the secretion canister, allowing secretions to be withdrawn and collected. Using a vacuum regulator and the vacuum-gauge, the target vacuum and thus the air-flow rate can be precisely adjusted.

- Several secretion canisters of different sizes are available for use with the system (section 9.0 Spare parts and accessories). A hydrophobic bacterial filter in the lid of the secretion canister is implemented to prevent that secretions enter the pump resp. bacteria the interior of the unit.

- A trolley with standard rail is available for mobile use.

1.4 Explanation of symbols


Attention, refer to operating instructions !


Follow operating instructions (blue)


Fuse


Potential equalization


Applied part Type BF

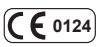
~ Alternating current


Unit of protection class II


Unit Off

Unit On


Observe operating instructions


This product complies with the relevant requirements of EU Directives


Manufacturing date


Manufacturer

SN Serial number

REF Order number

IPX 1 Protection against penetration of damaging humidity (drop water)


Professional disposal


Eurasian conformity

GOST Certificate (Russia)

2.0 For your safety

- The design of the **ATMOS® C 361** fulfills the requirements of IEC 601/EN 60601 and of protection class I. The device must only be connected to a properly installed socket with non-fused earthed wire.
- Before putting the device into operation, visually check unit, secretion canister, power cable, accessories, connection cables and hoses for signs of damage. Damaged cables and hoses must be replaced immediately. Check also function of the unit.
- The **ATMOS® C 361** may be used in supervised operation by qualified personnel only which has been authorised by ATMOS and which has been trained for operating the appliance (IEC 601-1/EN 60601-1).
- The **ATMOS® C 361** may be operated only in rooms used for medical purposes, but not in areas subject to **explosion hazards and in oxygen rich environments**. Explosion harzards may result from the use of combustible anaesthetic agents, skin cleansing agents or disinfectants.
- Liquids must not be allowed to enter the device. Should liquids have penetrated into the device, it must be inspected by an authorized service technician before being used again.
- After transport at cold temperatures (below the freezing point), the unit must acclimatize prior to first use; leave it unoperated at room temperature for a period of up to 6 hours. If the unit is not acclimatized it must not be operated as the membranes of the pump might get damaged.
- Dispose of the packaging material, observing the applicable waste-control regulations.
- Before connecting the device to the power line, check that the voltage and frequency ratings of the power line are similar to those indicated on the device.
- Never connect the unit to defective power sockets or extension cables.
- The suction hose must never come into direct contact with the application site. A suction catheter, attachment or a medical aspiration set must always be connected to the hose.
- When disconnecting the device from the power line, first remove the plug from the wall outlet. Then the power cord may be disconnected from the device. Never touch the plug or cord while your hands are wet.
- The ambient conditions specified in section 10.0 must be strictly observed.
- When using different canister systems there is a risk of contamination when operating the device without overflow protection/hydrophobic bacteria filter.
  Do not use the device respectively the canister without bacterial filter.
- There is a risk of an electric shock when liquid penetrated the overflow protection/hydrophobic bacteria filter.
- Set up the device so that the operator has a clear, unobstructed view of and easy access to the front panel. The device must be placed on a solid, level surface.
- The **ATMOS® C 361** fully complies with the electromagnetic immunity requirements of standard **IEC 601-1-2 / EN 60601-1-2** "Electromagnetic compatibility - Medical Electrical Equipment".
- Warranty period for this unit: 2 years. This period is unaffected by any repair or maintenance carried out under the terms of the warranty. Please also pay attention to our enclosed General Standard Terms and Conditions.
- The warranty will be rendered invalid in case of damages caused due to the utilization of accessories or consumables which are not approved by ATMOS for use with this unit.
- 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.
- This product is not re-sterilisable. 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.
- Please do not store DDS filters under heavy objects since this may lead to deformation and with it to loss of function.
  There is a risk of contamination for the device.
- ATMOS recommends always having another suction device ready to hand in case of any device failure. So you can suck even in the event of equipment failure.

Bild 1.

- Always set the equipment up on a secure, level surface.

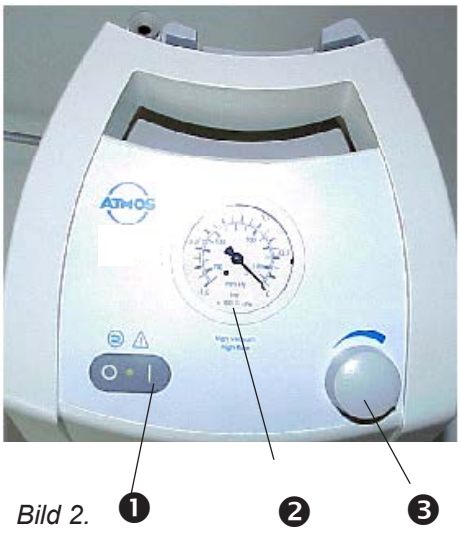


Bild 2.

3.1 Operating elements

❶ On/Off switch with pilot lamp
❷ Vaccuumgauge
❸ Vacuum controller

Bild 3.

Vacuum connection: Direct-Docking-System

☞ The vacuum connection between the pump and the secretion canister is created automatically as soon as the DDS canister is positioned correctly.

Fig. 4.

3.2 Connection area in unit base

Connect mains cable

☞ Use only mains cables with angled inlet connector for non-heating appliances.

- Check that the voltage and frequency ratings of the power line are similar to those indicated on the device.

Fig. 5.

4.1 Insert / remove DDS bacterial filter / oversuction stop

☞ Please wear gloves while changing the filter!

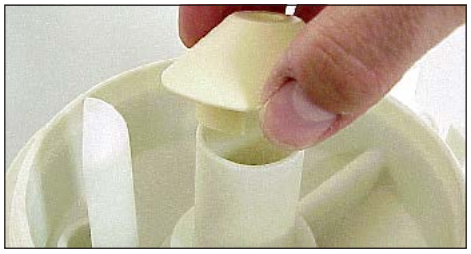


Fig. 6.

4.2 Using the DDS splash protector

Fig. 7.

4.3 Attach / remove DDS secretion canister lid

- With the DDS secretion canister on a firm surface, position the lid horizontally on top (the lid may not be twisted!)
- Press down lightly onto the secretion canister using both hands until limit is reached.

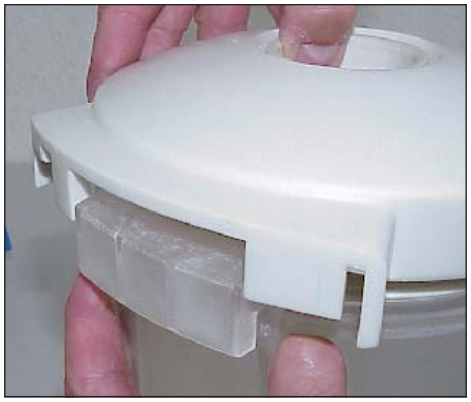


Fig. 8.

- To open the DDS secretion canister, hold the canister firmly by the reinforcing clips of the securing device and then pull the secretion canister lid up and off by gripping the filter hole.

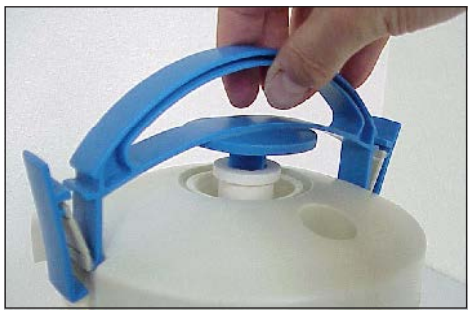


Fig. 9.

4.4 Attach DDS secretion canister handle

- Insert the DDS secretion canister handle into the grooves of the lid with the snap-in hooks open.

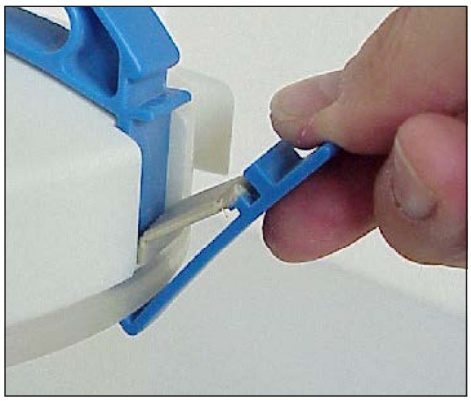


Fig. 10.

4.5 Close / open DDS secretion canister handle

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

Fig. 11.

4.6 Secure DDS secretion canister

- For removal, lift the DDS secretion canister vertically upwards; for insert it again, allow it to slide vertically downwards into the securing device.

Fig 11a.

4.7 DDS hose holder

- In the case that you would like to use the hose holder REF 340.0066.0 please mount it between the canister lid and the hose adapter as described in figure 11a.

Fig. 12.

4.8 Insert DDS hose adapter

- Press the required DDS hose adapter with 6 or 10 mm diameter into the ”patient” hole of the DDS secretion canister lid twisting slightly to ensure a tight fit.
- Twist slightly in the same manner when removing.

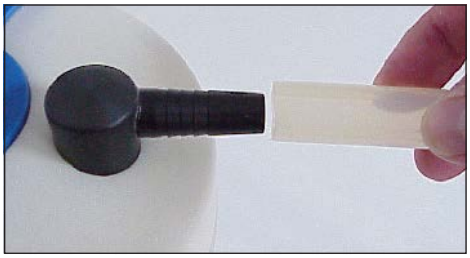


Fig. 13.

4.9 Connect hose

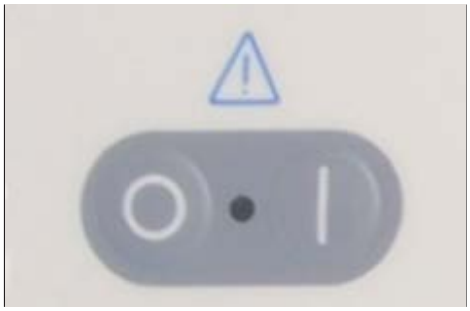


Fig. 14.

4.10 On / off switch

- Press the ”I” symbol to switch the unit on.
- Press the ”0” symbol to switch the unit off.

Fig. 15.

4.11 Set vacuum

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

☞ Do not use force to turn the knob at its limits!

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

4.12 Suction

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

☞ Prior to starting suction, containers must be checked for cracks. Damaged containers may not be used.

☞ Keep an eye on the level of liquid in the secretion canister during suction.

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

4.13 Test DDS bacterial filter / oversuction stop

- The DDS bacterial filter / oversuction stop is disposable.

☞ Before each use, check that the DDS bacteria filter / oversuction stop is clean and dry. Replace the DDS bacterial filter with a new filter if it is dicoloured, contaminated or oversucked.

☞ Use only original ATMOS bacterial filters!

☞ **Never operate the unit without the DDS bacterial filter / oversuction stop!**

☞ Replace the DDS bacterial filter with every cleaning respectively desinfection of the DDS canister systems.

Fig. 16.

5.1 Trolley with standard rail

- A trolley with standard rail, which can also be used with disposable systems if necessary, is available for mobile use.
- Always position the trolley on a flat, sturdy surface.

5.1.1 Securing the unit

Fig. 17.

☞ It is only possible to ensure safe operation as a mobile suction unit by using the special trolley available for use with the unit!

- The suction unit is placed on the trolley so that it's feet lock into place in the holes of the unit carrier and it can be firmly attached to the unit carrier from underneath by means of a knurled screw.

☞ It is imperative that the unit is securely attached to the trolley to ensure safe operation and safe movement!

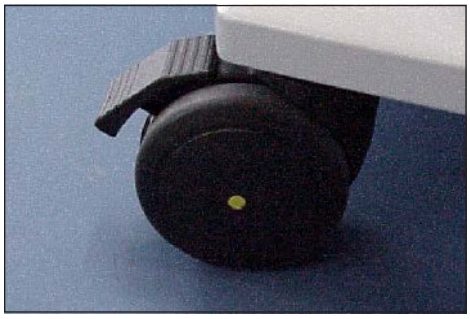


Fig. 18.

- Use the lockable castors if necessary.

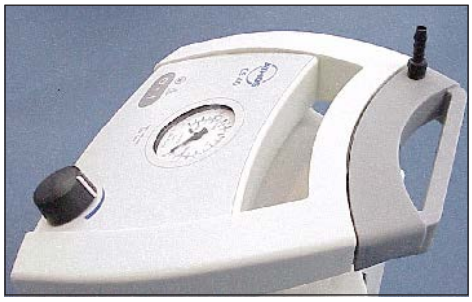


Fig. 19.

5.2 Use of suction unit with disposable systems

- Optionally the suction unit may also be used as a tabletop unit with a disposable system it can be attached to a standard rail.

- This requires the standard rail adapter with vacuum connector. Installation is performed in accordance with the attached installation instructions.

- Optionally the suction unit may also be used on the trolley with a disposable system it can be attached to a standard rail.

- When using the Receptal canisters the following supports have to be used:

2 x 1.5 l	REF 444.0027.0
1 x 2 l	REF 444.0030.0
2 x 2 l	REF 444.0028.0
1 x 3 l	REF 444.0031.0
2 x 3 l	REF 444.0029.0

6.0 Cleaning

6.1 General information on cleaning and disinfection

- For disinfection, you may use all surface and instrument disinfectants listed in chapters 6.4 / 6.5.

☞ A number of disinfection agents may cause discoloration at the secretion canister etc., however this has no effect upon the parts's function.

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

6.2 Reprocessing of hoses and secretion canister

☞ Before using the device on a new patient be sure to clean and disinfect the following parts:

– DDS secretion canister including DDS secretion canister lid, DDS hose adapter and DDS secretion canister handle
– Suction hose

- Unscrew all hose connectors, pull the DDS hose adapter out of the DDS secretion canister lid, open the lid, empty the secretion canister and dispose the suctioned material properly.
- Remove the DDS bacterial filter from the DDS secretion canister handle and dispose of it.
- All other parts, except the bacterial filter, must also be thoroughly rinsed under running water. You may add a detergent, if you wish.
  Using the cleaning agent neodisher AN or neodisher MediClean forte (manufactured by Dr. Weigert, Hamburg) cleaning in an automatic cleaner and disinfecter is also possible.
  Thermal disinfection is carried out at 93° C.
- After disinfectation, reassemble all parts (section 4.0 "Operation").
- Autoclave all the parts referred to above (134 °C, 3 bar, 5 min 3x fractionated prevacuum).

Max. number of reprocessing cycles:
DDS secretion canisters, silicone hoses: 60 cycles.

6.3 Cleaning and sterilizing the unit surface

☞ Always disconnect the device from the power line, before cleaning and disinfecting the surface.

- Wipe the surface clean with a cloth soaked in a cleaning solution or disinfectant. Liquids must not enter the device. All of the cleaning solutions and disinfectants listed below can be used.

☞ Should liquids have penetrated into the device, it must be inspected by an authorized service technician before being used again.

6.4 Recommended disinfectants for instruments

Disinfectant	Contents	(in 100 g)	Manufacturer
GIGASEPT FF neu (Application concentrate)	succinic acid dialdehyde	11,0 g	Schülke & Mayr, Norderstedt
	dimethoxy tetrahydrofurane	3,0 g	
	corrosion inhibitors non-ionic tensides		
Sekusept active	sodiumpercarbonate, phosphonates		Ecolab, Düsseldorf
	non-ionic tensides		

6.5 Recommended disinfectants for surfaces

Disinfectant	Contents	(in 100 g)	Manufacturer
Mikrobac forte	benzyl - C12 - C18 - alkyldimeththyl - ammoniumchloride	19,9 g	Bode Chemie, Hamburg
	N- (3-Aminopropyl) - N - dodccylpropane- 1,3 - diamine	5,0 g	
Green & Clean SK (Application concentrate)	alkyl-dimethyl-benzyl-ammoniumchloride	< 1 g	Metasys, Rum (Österreich)
	dialkyl-dimethyl-ammoniumchloride		

6.6 Recommended cleaning agents

Disinfectant	Contents	(in 100 g)	Manufacturer
neodisher MediClean forte (Application concentrate)	non-ionic tensides	< 5 g	Dr. Weigert, Hamburg
	NTA (nitrilotriacetic acid)	5-15 g	
	enzymes, preservative agent		
neodisher AN	Phosphate	> 30 g	Dr. Weigert, Hamburg
	non-ionic tensides	< 5 g	
	enzymes		

7.0 Maintenance

- Before putting the device into operation, visually check unit, secretion canister and power cable, accessories, connection cables and hoses for signs of damage. Damaged cables and hoses must be replaced immediately!
- Before each use, check that the DDS bacteria filter / oversuction stop is clean and dry. Replace the DDS bacterial filter with a new filter if it is dicoloured, contaminated or oversucked.
- The unit does not require any further maintenance.
- At least every 24 months a repeat test of the electrical safety should be performed according to IEC 62353. ATMOS recommends an inspection according to the manufacturer‘s specifications.

Repairs

The following may require repairs from the manufacturer or an authorized service partner. Prior to sending in the device, please contact your service partner by phone.

- Liquids have penetrated the device
- Sudden occurrence of unusual noises
- Operational and functional disorders which cannot be resolved by means of the hints described in the chapter “Trouble shooting”.

Measures to be taken prior to sending in the device:

If the device has to be sent in for repair after consultation with the manufacturer or an authorized service partner, we ask you to observe the following:

- Please send in the complete device (see scope of delivery).
- Please remove all disposable parts and consumables.
- Thorough cleaning and disinfection
- Airtight packing
- Please enclose a detailed error description.

Warranty

ATMOS cannot guarantee an error-free function nor can ATMOS be held liable for damages to people or goods if

- non-original ATMOS parts are used,
- the information in these operating instructions are disregarded,
- assembly, new installations, modifications, extensions and repairs are done by people who are not authorised by ATMOS.

7.1 Change fuse

- Remove mains cable.
- Press the spring clips of the fuse holder together on both sides with a small screwdriver and pull out the fuse holder.
- Replace the fuse and push the holder back in until both spring clips are locked into place.
- Then reconnect mains cable.

7.0 Maintenance

7.2 Sending in the device

1. Remove and properly dispose of consumables.
2. Clean and disinfect the products and accessories according to the operating instructions.
3. Place used accessories with the device.
4. 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.
5. The device must be well padded and packed in suitable packaging.
6. Place the 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.

8.0 Trouble-shooting

The **ATMOS® C 361** was subjected to a thorough quality control before shipment. If there is, nevertheless, some malfunction, you possibly might solve this problem yourselve if you observe the following instructions:

Problem	*Possible causes*	*Remedy*
● Unit does not start	– Loose power plug	– Check connection to supply socket
	– No power voltage	– Check inbuilding fuse
	– Defective fuse	– Replace fuse
● Insufficient performance or no suction	– Leakages within the hose system or in the secretion canister lid	– Check secretion canister lid and hose system, replace sealing ring on secretion canister lid, if necessary
	– Filter is clogged (vacuumgauge indicates a vacuum)	– Replace filter, check filling level in secretion canister; evacuate canister, if necessary
	– Secretion or blood has been sucked in and valve plates of the pump are contaminated sealed?	– Unit has to be returned for repair

9.0 Spare parts and accessories

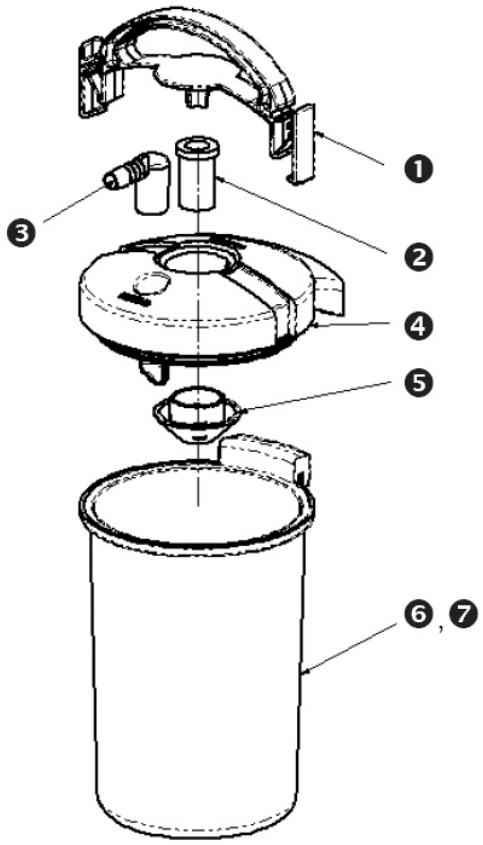


Fig. 20.

9.1 Spare parts

Description	*Article-No.*
❶ DDS-canister handle, grey	340.0055.0
DDS-canister handle, blue	340.0326.0
❷ DDS-bacterial filter / oversuction stop, hydrophobic, disposable part, price for 10 pcs.	340.0054.0
❸ DDS-hose adapter set, Ø 6 + 10 mm	340.0057.0
❹ DDS-canister lid with gaskets	340.0053.0
❺ DDS-splash protection	340.0056.0
❻ DDS-secretion canister, polysulphone, 1.5 l	340.0050.0
❼ DDS-secretion canister, polysulphone, 3.0 l	340.0051.0
Expansion bellows, silicone rubber	000.0739.0
Fuse 230 V T 0.63 A/H	008.0634.0
Fuse 115 V T 1.25 A/H	008.0720.0
Mains cable angle-angle, 5 m	008.0818.0
Push-in foot for housing	505.0337.0
Clamping ring for fixing screw	000.0727.0
Operating instructions	340.0001.i

9.2 Accessories

9.2.1 Canisters

Description	Article-No.
DDS-secretion canister, polysulphone, 1.5 l	340.0050.0
DDS-secretion canister, polysulphone, 3 l	340.0051.0
DDS-canister lid with gaskets	340.0053.0
DDS-canister handle, grey	340.0055.0
DDS-canister handle, blue	340.0326.0
DDS-splash protection	340.0056.0
DDS-hose adapter set, Ø 6 + 10 mm	340.0057.0

9.2.2 For ATMOS® C 361 with trolley

Trolley with standard rail	320.0070.1
DDS-standard rail adapter with vacuum connection for the use of disposable systems at the unit	340.0059.0
Grad. secretion canister 3 l, glass	444.0033.0
Grad. secretion canister 5 l, glass	444.0034.0
Secretion canister lid complete, for 3 l + 5 l glass canister	441.0208.1
Holder for 3 l glass canister	000.0040.0
Holder for 5 l glass canister	000.0041.0
Receptal container set II, support with 2 x collection containers,	
Receptal® canister 1.5 l	310.0221.0
Receptal® canister 2 l	443.0256.0
Receptal® canister 3 l	444.0157.0
Receptal® suction bag 1.5 l, not autoclavable, 50 pcs.	310.0222.2
Receptal® disposable bag 2 l, without integrated overflow protection	443.0257.0
Receptal® suction bag 2 l, with integrated overflow protection	443.0257.2
Receptal® suction bag 3 l, without integrated overflow protection	444.0153.0
Receptal® suction bag 3 l, with integrated overflow protection	444.0154.0

9.2.3 Facilities to simplify the handling

Hose holder on canister	340.0066.0
Catheter quiver for flex. catheters, attached to trolley	444.0140.0
Catheter quiver with holder for rail system (for catheter storing)	443.0780.0
Quiver holder, small, incl. standard rail holder	444.0145.0
Hose holder, for attaching to standard rail (white plastic)	444.0450.0

10.0 Technical specifications

Air flow rate of pump	36 ± 4 l/min
Max. vacuum at sea level	-91kPa (-910 mbar or 682,5 mmHg)*@ NN
Vacuum readout	-1...0 bar ± 16 mbar(class 1.6)
Additional air regulation	Mechanical regulating valve, ball vacuum regulator
Secretion canister	1.5 l or 3 l canisters made of polysulphone
Suction hose	ø 6 mm or ø 10 mm
Rated voltage	230 V~ 50/60 Hz, 340.0001.0
Rated current	Approx. 0.45 A for 230 V~
Power consumption	Approx. 100 W
Operating time	> 8 h of continuous operation without interruption, within 24 h
Fuses	T 630 mA/H for 230 V~
Protective earth conductor resistance	–
Earth leakage current	–
Enclosure leakage current	< 0,1 mA NC
Patient leakage current	–
Heat emission	Max. 100 J/s
Noise level	< 50 dB (A) @ 1 m (ISO 7779)
Ambient conditions Transport/Storage Operation	 -30...+50°C 5...90 % humidity, non-condensing air pressure 700...1060 hPa +5...+35°C 20...80 % humidity, non-condensing air pressure 700...1060 hPa
Dimensions H x W x D	H 330 mm x W 240 mm x D 360 mm (with secretion canister) H 900 mm x W 410 mm x D 450 mm (with trolley)
Weight	6.3 kg (with secretion canister)
Protection class (IEC 601)	II
Applied Part	Type BF 
Degree of protection	IPX 1
Period tests	Repeat test of the electrical safety every 24 months. Recommended: inspection according to the manufacturer‘s specifications.
Classification acc. to Annex IX EEC directing 93/42/EEC	IIa
CE marking	CE 0124
Rules applied	See enclosed list
UMDNS-Code	10 - 217
Reference-No.	340.0001.0
Soundlevel	< 50dB (A) @ 1 m (ISO 7779)
GMDN-Code	36777
CE marking	CE 0124
UMDNS-Code	10-217
Canadian Classification Device Group PNC Risk Class Description	 General & Plastic Surgery 79QBU 2 ASPIRATOR, SURGICAL

*1 bar @ 750,06 mm Hg @ 1000 hPa / depends on daily atmospheric pressure

Rules applied: DIN EN 1041, DIN EN 1441, DIN EN 60601-1, DIN EN 60601-1-2, DIN EN ISO 10079-1,DIN EN 980,DIN EN ISO 10993-1

Technical Specification 12.01.2017

10.0 Technical specifications

11.0 Checking / Reprocessing / Disposal

11.1 Checking ATMOS suction devices

The ATMOS suction devices are maintenance-free when they are used according to the operating instructions. At least every 24 months a repeat test of the electrical safety should be performed according to IEC 62353. ATMOS recommends an inspection according to the manufacturer‘s specifications.

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

A regular check of the condensate-controller on the rear side is necessary. Pull out the plastic plug and check the colour at the end of the hose. In case of discolouration/deposits a maintenance measure must be performed by a certified ATMOS service partner!

11.2 Reprocessing

In case secretion was sucked into the device it may not be operated until it is repaired by the ATMOS service.

Handling of the suction device determines to a large extent its reliability and safety. The hygiene measures described in the previous chapters are necessary measures for the protection of patients and users, and to maintain functional reliability.

11.3 Disposal

- The ATMOS® C 361 is not comprised of any hazardous materials.
- The materials of the housing can be recycled completely.
- Prior to disposal, device and accessories must be decontaminated.
- The materials are to be separated carefully.
- Pay attention to country-specific regulations for disposal (e.g. waste incineration).

Disposal within the EU

The suction device described above is a high-quality medical product with a long service life. After its life cycle it must be disposed professional. According to the EU directives (WEEE and RoHS) the device may not be disposed in domestic waste. Please observe existing national laws and rules for disposal of old devices.

Disposal within the Federal Republic of Germany

In the Federal Republic of Germany the law for electrical devices (ElektroG) rules the disposal of electrical devices. Since this type of product is mainly used at home for secretion suction in the respiratory tract (after laryngectomy), it must be assumed that those suction devices could be contaminated. Therefore, this type of device is excluded from the law for electrical devices. In order to guarantee a proper disposal of your old device, please either pass on your old device to your specialised dealer or send it directly to ATMOS MedizinTechnik GmbH & Co. KG for a professional disposal.

Prior to disposal respectively before transport all secretion containers and hoses must be thoroughly cleaned and disinfected. The device surface must be disinfected.

12.0 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.

12.1 Guidelines and Manufacturer´s Declaration - Emissions

The ATMOS® C 401 and ATMOS® C 361 are intended for use in the electromagnetic environment specified below. The customer or user of the ATMOS® C 401 and ATMOS® C 361 should ensure that they are used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
Harmonics IEC 61000-3-2	Class 1	The ATMOS® C 401 und ATMOS® C 361 are 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.
Flicker IEC 61000-3-3	Match	

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.

12.2 Guidelines and Manufaturer´s Declaration - Immunity

The ATMOS® C 401 and ATMOS® C 361 are intended for use in the electromagnetic environment specified below. The customer or user of the ATMOS® C 401 and ATMOS® C 361 should ensure that they are used in such an environment.

Immunity Test	IEC 60601- Test Level	Compliance Level	Electromagnetic Environment - Guidance
ESD IEC 61000-4-2	± 6 kV Contact ± 8 kV Air	± 6 kV Contact ± 8 kV Air	Floors should be wood, concrete, or ceramis tile. If floors are synthetic, the relative humidity should be at least 30%.
EFT IEC 61000-4-4	± 2 kV Mains ± 1 kV I/Os	± 2 kV Mains	Mains power quality should be that of a typical commercial or hospital environment.
Surges IEC 61000-4-5	± 1 kV Differential ± 2 kV Common	± 1 kV Differential ± 2 kV Common	Mains power quality should be that of a typical commercial or hospital environment.
Power Frequency 50/60 Hz Magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.

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 sec	< 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 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the ATMOS® C 401 und ATMOS® C 361 demands continued function even in case of interruptions of the energy supply, it is recommended to supply the ATMOS® C 401 und ATMOS® C 361 from an uninterruptible current supply or a battery.
NOTE U_T is the mains alternating current prior to application of the test levels.			

12.3 Guidelines and Manufacturer´s Declaration - Immunity

The ATMOS® C 401 and ATMOS® C 361 are intended for use in the electromagnetic environment specified below. The customer or user of the ATMOS® C 401 und ATMOS® C 361 should ensure that they are used in such an environment.

Immunity Test	IEC 60601- Test Level	Compliance Level	Electromagnetic Environment - Guidance
			Portable and mobile communications equipment should be separated from the ATMOS® C 401 and ATMOS® C 361 incl. the cables by no less than the distances calculated/listed below. **Recommended distances:** d = [3,5 / V_1] $\sqrt{P}$ d = [3,5 / E_1] $\sqrt{P}$ d = [7,0 / E_1] $\sqrt{P}$ 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. 
Conducted RF IEC 61000-4-6	3 V_{eff} 150 kHz to 80 MHz	[V_1] V	
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	[E_1] V/m	

NOTE 1 With 80 MHz and 800 MHz the higher frequency range applies. NOTE 2 These guidelines are not like to be applicable in any case. The propagation of electromangetic sizes is influenced by absorptions and reflections of buildings, objects and people.
a The field strength of stationary transmitters, such as base stations of cellular phones and mobile terrain radio equipment, amateur radio transmitters, cbm broadcast and TV stations cannot be predestined exactly. To 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® C 401 und ATMOS® C 361 is used exceeds the above compliance level, the ATMOS® C 401 und ATMOS® C 361 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 is to be below 3 V/m.

12.4 Recommended separations between portable and mobile RF communications equipment and the ATMOS® C 401 und ATMOS® C 361

The ATMOS® C 401 and ATMOS® C 361 are intended for use in electromagnetic environment in which ratiated disturbances are controlled. The customer or user of the ATMOS® C 401 and ATMOS® C 361 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment and the ATMOS® C 401 and ATMOS® C 361 as recommended below, according to the maximum output power of the communications equipment.

	Separation distance, depending on transmit-frequency m		
Nominal output of the transmitter **W**	**150 kHz to 80 MHz** **d =** [3,5 / V_1]$\sqrt{P}$	**80 MHz to 800 MHz** **d =** [3,5 / E_1] $\sqrt{P}$	**800 MHz to 2.5 GHz** **d =** [7,0 / E_1] $\sqrt{P}$
0.01	0.1	0.1	0.2
0.1	0.4	0.4	0.7
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	11.7	11.7	23.3

For transmitters for which the maximum nominal output is not indicated in the above table, the recommended separation 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 With 80 MHz and 800 MHz the higher frequency range applies.

NOTE 2 These guidelines are not like to be applicable in any case. The propagation of electromagnetic sizes is influenced by absorptions and reflections of buildings, objects and people.

For your notes

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