ATMOS MedizinTechnik

English

Operating instructions

# ATMOS
# C 361
## Surgical suction device

CE 0124

GA1EN.210101.0
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# Contents




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# 1.0 Introduction

## 1.1 Notes on Operating Instructions

- These operating instructions contain important notes on how to operate the ATMOS 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-times. Furthermore, reliability and service-life of the equipment will be increased. For these reasons these operating instructions **must** always be kept available near the device.
  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 of the device depend not only on your capabilities, but also on the 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 only original spare parts are used. You will then have the warranty that operational safety, readiness for work and the value of your device will be preserved.
- The product ATMOS C 361 bears CE marking CE 0124 according to the EC Directive of the council for medical products 93/42/EEC and meets the basic requirements of Annex I of the directive.
- The product ATMOS C 361 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 Declaration of Conformity and our general standard terms and conditions can be viewed on our website at www.atmosmed.com.
- The quality management system applied at ATMOS has been certified according to international standards ISO 13485.
- For authorized service partners, ATMOS provides service instructions with detailed
  circuit descriptions, schematics
  and service information.

- Reprints - also in extracts - only with permission in written form by ATMOS.

**Short cuts / symbols contained in these operating instructions:**

- Indicating a list
  - Subdivision of a list/activity.

☞ The recommended sequence must be followed in each case!

☞ Indicating particularly important advice!

## 1.2 Intended use

**Name:** ATMOS C 361

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

**Med. indications / application:** For surgeries e.g. suction of wound cavities, abscesses, etc.
In endoscopy for the suction of secretion or rinsing fluids.
For spontaneous suction of body fluids.

**Specification of the main function:** Drainage and temporary collection of body fluids. An electric suction pump is used to generate negative pressure. An additional secretion canister must be attached to allow for temporary collection of drained body fluids.

**Application organ:** Natural orifices and openings resulting from a surgical intervention (entire body; human and animals).

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

**Application site:** The application site is the clinical, outpatient, medical practice and veterinary field. The device may only be used by staff who have been medically trained and instructed.

**Contraindications:**
No application in low-vacuum range e.g.thoracic and wound drainage.
No application outside of medical fields.
No suction of flammable, corrosive or explosive fluids/gases
Not suitable for use as a vacuum extraction system.

**The product is:** X active □ not active

**Sterility:** Not necessary

**Single-use product / reprocessing:**
The device and parts of the accessories are reusable. For information on reprocessing, cleaning and disinfection please see the operating instructions.

## 1.3 Function

- The **ATMOS C 361** is a mains-operated surgical suction device, the core of which is a high-performance diaphragm-type pump. The pump generates a vacuum inside the hose and secretion canister system, allowing secretions to be withdrawn and collected. Using a vacuum regulator and the vacuum gauge, the target vacuum and thus the suction capacity can be precisely adjusted.

- Several secretion canisters of different sizes are available for use with the secretion canister system (chapter 9.0 Spare parts and accessories). A hydrophobic DDS bacterial and viral filter in the secretion canister lid is implemented to prevent that secretion is sucked into the pump or bacteria and viruses enter the inside of the device.

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

## 1.4 Explanation of symbols


Attention, observe operating instructions!


Follow operating instructions (blue)


Equipment safety fuse


Potential equalisation


Applied part type BF

~ Alternating current


Device from protection class II


Device off


Device on


Observe the operating instructions

This product complies with the relevant requirements of EU Directives


Manufacturing date


Manufacturer

**SN** Serial number

**REF** Order number

**IPX 1** Degree of protection


Professional disposal


Eurasian conformity

GOST Certificate (Russia)

# 2.0 For your safety

- The design of the **ATMOS C 361** fulfils the requirements of IEC 601/ EN 60601. It is assigned to VDE protection class II. It may only be connected to a properly installed earthed power outlet.

- Before putting the device into operation, visually check the unit, secretion canister, power cable, accessories, connection cables and hoses for signs of damage. Damaged cables and hoses must be replaced immediately. Check function of the device prior to use.

- The **ATMOS C 361** may only be used in supervised operation by qualified personnel (IEC 601-1/EN 60601-1).

- The device may be operated only in rooms used for medical purposes. The **ATMOS C 361** is not designed for use in **explosion-hazardous** areas and in oxygen rich environments. Explosion-hazardous areas may be caused by the use of flammable anaesthetics, skin cleansing products and skin disinfectants.

- Do not allow any liquid to get into the device. If liquids have penetrated the device, it may not be operated again until it has been checked by the customer service centre.

- After transporting the device at temperatures below 0 °C, keep it at room temperature for at least six hours before initial start-up. If the device is not acclimatized it may not be used as damage to the diaphragms of the pump could occur.

- Dispose of wrappings accordingly.

- Before connecting the device , it must be checked whether the required mains voltage and frequency on the device matches the voltage and frequency ratings of the power line.

- Only proper and undamaged plugs and extension cables may be used.

- 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 using different secretion canister systems there is a risk of contamination when operating the device without an oversuction stop / hydrophobic DDS bacterial and viral filter.
  Do not use the device or rinsing canister without a DDS bacterial and viral filter.

- There is a risk of an electric shock in the event of oversuction of the oversuction stop / hydrophobic DDS bacterial and viral filter.

- To disconnect the device from the mains supply, first remove the plug from the wall outlet. Then disconnect the power cable from the device. Never touch plug or cables with wet hands.

- Please observe the ambient conditions stated in the technical data (chapter 10.0).

- Always set up the device in such a way that the operating elements are in clear view and within easy reach of the operator. The device must be placed on a stable, 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 Devices“.

- The warranty period for this device is 2 years. This period is unaffected by any repair or maintenance carried out. Please also pay attention to the enclosed General Terms and Conditions.

- There are no warranty claims whatsoever on defects or malfunctions which arise from the use of third-party accessories or consumables.

- ATMOS is not liable for personal injury and damage to property if
  - no original ATMOS parts are being used,
  - the advice for use in these operating instructions is not being observed,
  - assembly, new settings, alterations, extensions and repairs have been carried out by personnel not author ised 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 bacterial and viral 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. That way you can perform suctioning even in the event of device failure.

*Fig. 1.*

- Always place the device on a firm and level surface.

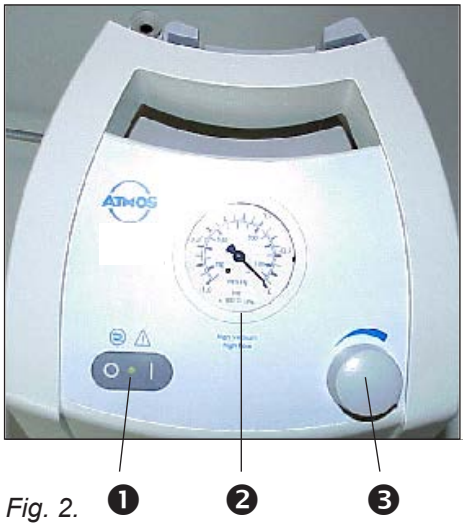


*Fig. 2.*

## 3.1 Operating elements

❶ On/off switch with pilot lamp
❷ Vacuum gauge
❸ Vacuum regulator

*Fig. 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 the unit base

**Connect the power cable.**

☞ Use only power cable with angled inlet connector for non-heating appliances!

- Check that the mains voltage and mains frequency specified on the device correspond to the values of the mains power supply.

*Fig. 5.*

## 4.1 Insert / remove the DDS bacterial and viral filter / oversuction stop

☞ Please wear gloves while changing the DDS bacterial and viral filter!

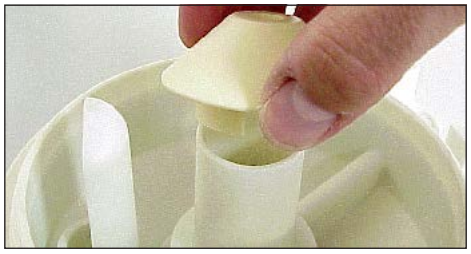

*Fig. 6.*

## 4.2 Using the DDS splash protection

*Fig. 7.*

## 4.3 Attach / remove DDS secretion canister lid

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

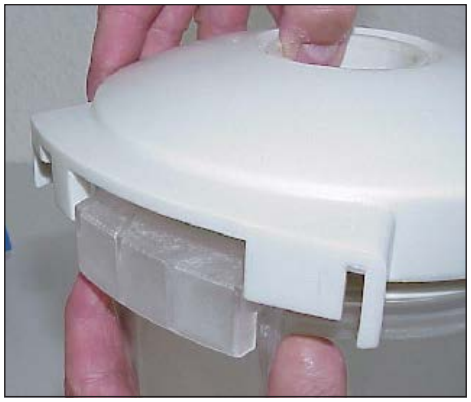

*Fig. 8.*

- 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 upwards by gripping the filter hole.

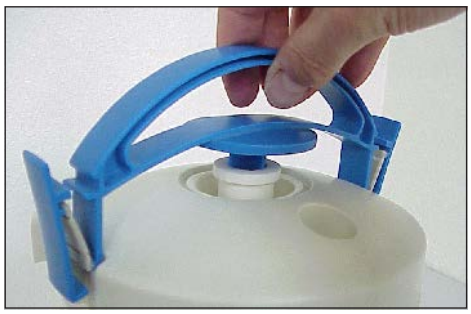

*Fig. 9.*

## 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.

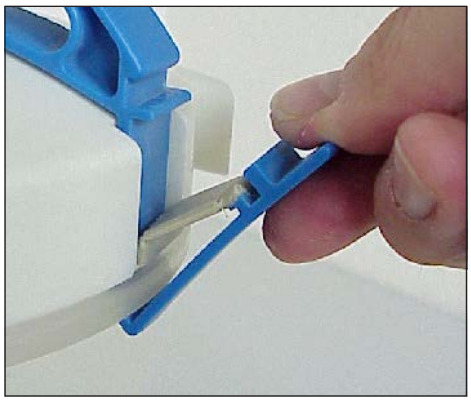

*Fig. 10.*

## 4.5 Close / open the secretion canister handle

- To close, secure the snap-in hooks under the edge of the secretion canister, and then press the clips towards the middle of the canister 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 Mounting the DDS secretion canister

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

*Fig. 11a.*

## 4.7 DDS hose holder

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

*Fig. 12.*

## 4.8 Insert DDS hose adapter

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

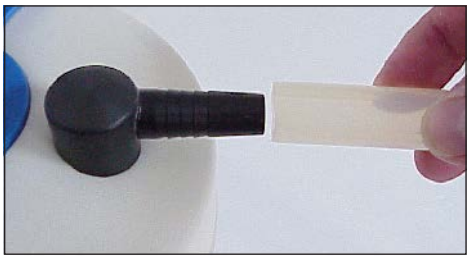

*Fig. 13.*

## 4.9 Connect hose

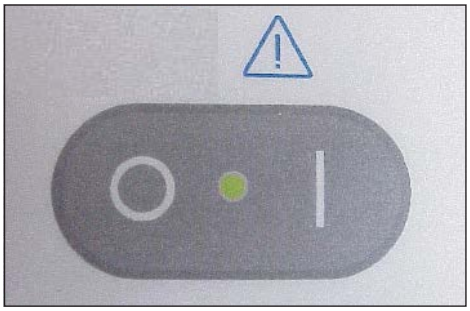

*Fig. 14.*

## 4.10 On / Off switch

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


*Fig. 15.*

## 4.11 Set vacuum

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

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

- Check 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, canisters must be checked for cracks. Damaged canisters may not be used.

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

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

## 4.13 Check the DDS bacterial and viral filter / oversuction stop

- The DDS bacterial and viral filter / oversuction stop is intended for single use.

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

☞ Only use original ATMOS DDS bacterial and viral filters!

☞ **Never operate the device without a DDS bacterial and viral filter / oversuction stop!**

☞ Replace the DDS bacterial and viral filter every time you clean or disinfect the DDS secretion canister system.

*Fig. 16.*

## 5.1 Trolley with standard rail

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

### 5.1.1 Securing the unit

*Fig. 17.*

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

- The suction device is placed on the trolley so that its feet lock into place in the holes of the trolley then it can be firmly secured from underneath by means of a knurled screw.

☞ It is imperative that the device is securely attached to the trolley to ensure safe operation and safe mobility!

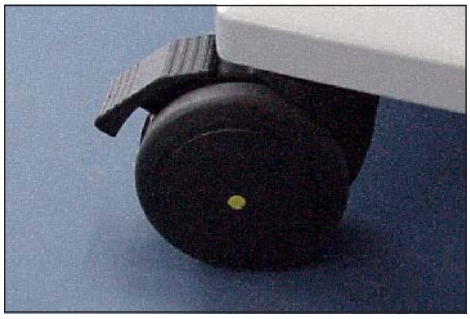

*Fig. 18.*

- Use the lockable castors if necessary.

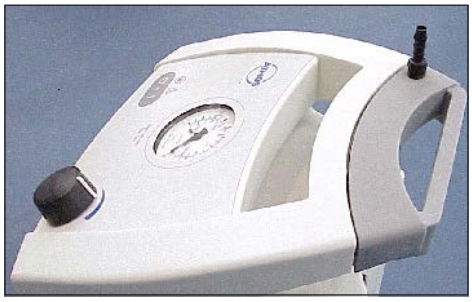

*Fig. 19.*

## 5.2 Use of suction device with disposable systems

- Optionally, the suction device can also be used as a tabletop unit with disposable suction systems that can be attached to a standard rail.
- This requires the standard rail adapter of the respective disposable system.
- Optionally, the suction device may also be used on the trolley with a disposable suction system that can be attached to a standard rail.
- When using the Receptal canisters the following supports must 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 and care

## 6.1 General information on cleaning and disinfection

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

☞ A number of disinfectants may cause discolouration to the secretion canister, etc.,; however this has no effect upon the parts' 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 canister handle
– suction hose

- Release all the hose connections, remove the DDS hose adapter from the DDS canister lid, open the lid, empty the rinsing canister and dispose of the suction material properly.
- Remove the DDS bacterial and viral filter from the DDS canister handle and dispose of it.
- Rinse all the parts under running water (except for the DDS bacterial and viral filter). You may also use a washing-up liquid that does not contain the following ingredients:

  Organic solvents, fats, alcohols or amines, acetates, esters, acids and alkaline aqueous solutions.

  Using the cleaning agent Neodisher AN (manufactured by Dr. Weigert, Hamburg) cleaning in an automatic cleaner and disinfecter is also possible.
  Thermal disinfection is carried out at 93 °C.
- After disinfection reassemble the parts (Chapter 4.0 "Operation").
- Autoclave all the parts referred to above (134 °C, 3 bar, 5 min, 3x fractionated pre-vacuum).

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

## 6.3 Cleaning and sterilizing the unit surface

☞ Always disconnect the the mains plug, 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 instrument disinfectants

| Disinfectant | Contents | (in 100 g) | Manufacturer |
|---|---|---|---|
| GIGASEPT FF new (Application concentrate) | succinic acid dialdehyde<br>dimethoxy tetrahydrofurane<br>corrosion inhibitors non-ionic tensides and scents | 11.0 g<br>3.0 g | Schülke & Mayr, Norderstedt |
| Sekusept active | sodiumpercarbonate, phosphonates<br>non-ionic tensides | | Ecolab, Düsseldorf |

# 6.0 Cleaning and care

## 6.5 Recommended surface disinfectants

| Disinfectant | Contents | (in 100 g) | Manufacturer |
|---|---|---|---|
| Mikrobac forte | Benzyl - C12 - C18 - alkyl dimethyl - ammonium chloride<br>N- (3-Aminopropyl) - N - dodecylpropane- 1.3 - diamine | 19.9 g<br>5.0 g | Bode Chemie, Hamburg |
| Green & Clean SK (Application concentrate) | Alkyldimethylbenzylammoniumchloride<br>Dialkyl-dimethyl-ammonium chloride | < 1 g | Metasys, Rum (Austria) |

## 6.6 Recommended cleaning agents

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

# 7.0 Maintenance

- Before putting the device into operation, visually check the device, secretion canister and power cable, accessories, connection cables and hoses for signs of damage. Damaged cables and hoses must be replaced immediately!
- Prior to each use check whether the DDS bacterial and viral filter is dry and clean. Replace the DDS bacterial and viral filter with a new DDS bacterial and viral filter if it is discoloured, contaminated or oversucked. The DDS bacterial and viral filter must not be dried and not reused.
- 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. In this context, ATMOS recommends conducting an inspection in accordance with 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.

- Liquid has 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 “Troubleshooting”

## 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 authorised 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 neither guarantees for fault-free operation nor for personal injuries and damage to property if

- no original ATMOS parts are being used,
- the advice for use in the operating instructions is not being observed,
- assembly, new settings, alterations, extensions and repairs have not been executed by ATMOS authorised personnel.

# 7.0 Maintenance

## 7.1 Replacing the fuse

- Remove power cable.
- Press the two-sided spring clips of the fuse holder with a screwdriver and pull out the fuse holder.
- Replace the fuse and insert the holder until both spring clips engage again.
- Then reconnect the power cable.

## 7.2 Sending in the device

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

  This form is enclosed with each product and can be found atwww.atmosmed.com.
- The product must be well padded and packed in suitable packaging.
- Place the QD 434 "Delivery complaint / return shipment" form and the respective decontamination certificate in an envelope.
- Affix the envelope to the outside of the package.
- Send the product to ATMOS or your dealer.

# 8.0 Troubleshooting

The **ATMOS C 361** was subjected to a thorough quality control in the factory. If there is, nevertheless, some malfunction, you possibly might solve this problem yourself 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 neccessary |
| | – Hydrophobic bacterial and viral filter is clogged (vacuum gauge indicates a vacuum) | – Replace hydrophobic bacterial and viral filter, check filling level in secretion canister; evacuate canister, if neccessary |
| | – Secretion or blood has been sucked in and the valve plates of the aggregate are stuck together | – Unit has to be returned for repair |

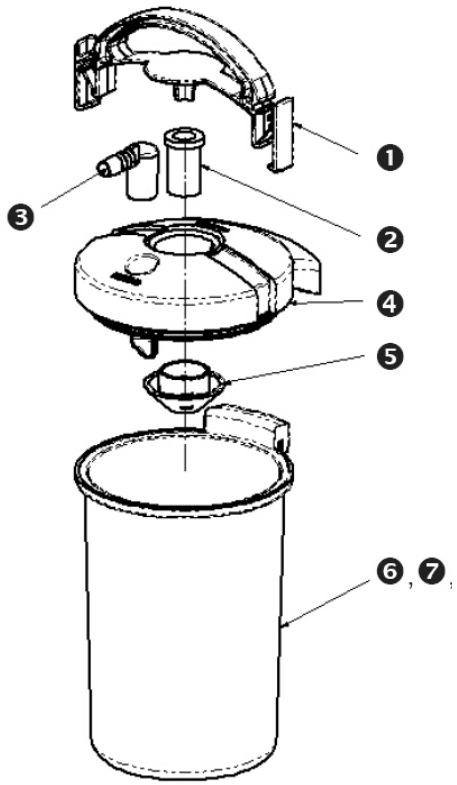


*Fig. 20.*

## 9.1 Spare parts

| *Description* | *Article-No* |
|---|---|
| ❶ DDS-canister handle, grey | 340.0055.0 |
| ❶ DDS-canister handle, blue | 340.0326.0 |
| ❷ Hydrophobic DDS-bacterial and viral filter/over-suction stop, disposable part, 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 |
| Suction hose, silicone, Ø 10 mm, 2 m | 000.0243.0 |
| Suction hose, silicone, Ø 6 mm, 2 m | 000.0361.0 |
| Suction hose, silicone, Ø 6 mm, 1.30 m | 000.0013.0 |
| Suction hose, for single use only, Ø 6 mm, 1.30 m | 006.0057.0 |
| Suction hose, for single use only, Ø 6 mm, 2.10 m | 006.0059.0 |
| Expansion bellows, silicone | 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 |
| Power 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 Accessories for the 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 secretion canister, 3 l glass | 000.0040.0 |
| Holder for secretion canister, 5 l glass | 000.0041.0 |
| Disposable suction system Receptal® canister set, | |
| Receptal® outer canister 1.5 l | 310.0221.0 |
| Receptal® outer canister 2 l | 443.0256.0 |
| Receptal® outer canister 3 l | 444.0157.0 |
| Receptal® suction bag 1.5 l, not autoclavable, 50 pcs | 310.0222.2 |
| Receptal® suction 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 attachment to a standard rail (white plastic) | 444.0450.0 |

# 10.0 Technical data

| | |
|---|---|
| Suction capacity of pump | 36 ± 4 l/min |
| Max. vacuum | -91 kPa (- 910 mbar or 682.5 mmHg)* @ sea level |
| Vacuum display | −1…0 bar ± 16 mbar (class 1.6), ø 63 mm |
| Secretion canister System, | 1.5 l or 3 l canisters made of polysulphone or 1.5 l, 2 l, 3 l Receptal®-<br>also 2 canisters on trolley |
| Hose connections | Ø 6 mm or Ø 10 mm |
| Nominal voltage | 230V~ 50/60 Hz |
| Nominal current | Ca. 0.45 A at 230 V~ |
| Nominal capacity | Ca. 100 W |
| Protection class | (IEC 601) |
| Applied part type BF |  |
| Type of protection | IPX 1 |
| Periodic test | Repeat test of electrical safety every 24 months. Recommended: inspection according to manufacturer's specifications. |
| Classification acc. to Annex IX EC Directive 93/42/EEC | IIa |
| Fuse | T 630 mA/H for 230 V~ |
| Operating time | > 8 h Continuous operation without interruption, within 24 h |
| Ambient conditions: | |
| Transport/storage | -30…+50 °C<br>5...90% air humidity without condensation<br>at air pressure 700...1060 hPa |
| Operation | +5...+35 °C<br>20…80% air humidity without condensation<br>at an air pressure of 700...1060 hPa |
| Dimensions | H 330 x W 240 x D 360 mm (incl. secretion canister)<br>H 900 x W 410 x D 450 mm (incl. trolley) |
| Weight | 6.3 kg (incl. secretion canister) |
| Noise level: | < 50dB (A) @ 1 m (ISO 7779) |
| GMDN-Code: | 36777 |
| CE-marking | CE 0124 |
| UMDNS-Code | 10-217 |
| Hydrophobic bacterial and viral filter: | |
| Degree of separation against bacteria (BFE) | 99.999778%** |
| Degree of separation against viruses (VFE) | 99.73%** |
| Overall degree of separation | >99.95%** |
| Filter class | H13 (High-Efficiency Particulate Air/Arrestance)** |

*Subject to technical changes!*

* dependent on daily air pressure ** external test report (test laboratory)

Issue of the technical data December 2020

# 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, thorough cleaning and disinfection of the device and the application parts respectively the operation of the device in line with the operating instructions are assumed.

## 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 goods.
- The materials of the housing can be recycled completely.
- Prior to disposal, device and accessories must be decontaminated, as secretion residues containing pathogens can be hazardous.
- The materials are to be separated carefully.
- Pay attention to country-specific regulations for disposal (e.g. waste incineration).

**Disposal within the EU**

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

**Disposal within the Federal Republic of Germany**

In the Federal Republic of Germany, the law for electrical devices (ElektroG) regulates 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, according to the regulations of the EAR foundation (Used Electrical Appliances Register), this type of device is excluded from ElektroG regulations. In order to guarantee proper disposal of your old device, please either pass it on to your specialised dealer or send it directly to ATMOS Medizin-Technik GmbH & Co. KG for professional disposal.
**Prior to disposal or before transport, all secretion canisters 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 RF communication facilities can influence medical electrical equipment.
- The use of other accessories, other transducers 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 environment specified below. The customer or user of the ATMOS C 401 and ATMOS C 361 should ensure that it is used in such an environment.

| Emissions Test | Compliance | Electromagnetic Environment - Guidance |
|---|---|---|
| Emissions of harmonics acc. to IEC 61000-3-2 | Class A | The ATMOS C 401 and 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. |
| Emissions of Voltage fluctuations/flicker IEC 61000-3-3 | Corresponds | |

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 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 and ATMOS C 361 should ensure that it is used in such an environment.

| Immunity Test | IEC 60601- Test Level | Compliance Level | Electromagnetic Environment - Guidance |
|---|---|---|---|
| Electrostatic discharge (ESD) acc. to IEC 61000-4-2 | ± 6 kV Contact<br>± 8 kV Air | ± 6 kV Contact<br>± 8 kV Air | Floors should be made of wood or concrete or tiled with ceramic tiles. If floors are synthetic, the relative humidity should be at least 30 %. |
| Fast electrical transient/ bursts IEC 61000-4-4 | ± 2 kV Mains<br>± 1 kV I/Os | ± 2 kV Mains | The quality of the supply voltage should correspond to a typical commercial or hospital environment. |
| Surges IEC 61000-4-5 | ± 1 kV Differential<br>± 2 kV Common | ± 1 kV Differential<br>± 2 kV Common | The quality of the supply voltage should correspond to a typical commercial or hospital environment. |
| Magnetic field at power frequency (50/60 Hz) 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<br><br>40% $U_T$ (60% Dip of the $U_T$) For 5 cycles<br><br>70% $U_T$ (30% Dip of the $U_T$) For 25 cycles<br><br>< 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<br><br>40% $U_T$ (60% Dip of the $U_T$) For 5 cycles<br><br>70% $U_T$ (30% Dip of the $U_T$) For 25 cycles<br><br>< 5% $U_T$ (> 95% Dip of the $U_T$) For 5 sec | The quality of the supply voltage should correspond to a typical commercial or hospital environment. If the user of the ATMOS C 401 and ATMOS C 361 demands continued function even in case of interruptions of the energy supply, it is recommended to supply the ATMOS C 401 and ATMOS C 361 from an uninterruptible power 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 and ATMOS C 361 should ensure that it is used in such an environment.

| Immunity Test | IEC 60601- Test Level | Compliance Level | Electromagnetic Environment - Guidance |
|---|---|---|---|
| Conducted disturbances IEC 61000-4-6 | 3 $V_{eff}$ 150 kHz to 80 MHz | [$V_1$] V | 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.<br><br>**Recommended distances:**<br>$d = [3.5 / V_1] \sqrt{P}$<br>$d = [3.5 / E_1] \sqrt{P}$<br>$d = [7.0 / E_1] \sqrt{P}$<br><br>Where 'P' is the max. power in watts (W) and d is the recommended separation distance in meters (m).<br><br>Field strengths from fixed transmitters, as determined by an electromagnetic site (a) survey, should be less than the compliance level (b).<br><br>Interference may occur in the vicinity of equipment containing the following symbol.<br><br>  |
| Radiated HF disturbances IEC 61000-4-3 | 3 V/m 80 MHz to 2.5 GHz | [$V_1$] V | |

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

NOTE 2: These guidelines might not be applicable in all cases. The emanation of electromagnetic waves is affected by absorption and reflection of buildings, objects, and people.

## 12.4 Recommended separations between portable and mobile RF Communications equipment and the ATMOS C 401 and ATMOS C 361

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 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile HF communication equipment (transmitters) 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**<br><br>**W** | **150 kHz to 80 MHz**<br><br>$d = [3.5 / V_1] \sqrt{P}$ | **80 MHz to 800 MHz**<br><br>$d = [3.5 / E_1] \sqrt{P}$ | **800 MHz to 2.5 GHz**<br><br>$d = [7,0 / E_1] \sqrt{P}$ |
| 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 might not be applicable in all cases. The emanation of electromagnetic waves is affected by absorption and reflection of buildings, objects, and people.


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