Operating Instructions

ATMOS® S 201 Thorax

English

These operating instructions are valid from software version 3.0.48
# Table of contents

1.0 **Introduction** ........................................... 4  
1.1 Information on operating instructions ................................... 4  
1.2 Intended use .................................................................. 5  
  1.2.1 Intended use ATMOS® S 201 Thorax ........................................... 5  
  1.2.2 Intended use ATMOS® S 201 Thorax secretion canister ............... 5  
  1.2.3 Intended use ATMOS® S 201 Thorax hose system .................... 6  
1.3 Function ..................................................................... 7  
1.4 Transport and storage .................................................. 7  
1.5 Explanation of pictures and symbols .................................. 8  
2.0 **For your safety** .................................................. 9  
  2.1 Details .................................................................... 9  
  2.2 Caution ................................................................... 11  
  2.3 Warning ................................................................... 12  
3.0 **Setting up and starting up** ....................................... 13  
  3.1 Scope of delivery ...................................................... 13  
  3.2 Device overview ....................................................... 14  
  3.3 Start up ..................................................................... 15  
    3.3.1 Battery charging ................................................... 15  
    3.3.2 Secretion canister ............................................... 16  

Further information, accessories, consumables and spare parts are available from:

**ATMOS**

MedizinTechnik GmbH & Co. KG  
Ludwig-Kegel-Straße 16  
79853 Lenzkirch  
Germany

Phone  + 49 7653 689-0  
Fax:  + 49 7653 689-190  
    + 49 7653 689-292 (Service Center)

atmos@atmosmed.de  
www.atmosmed.com
4.0 Operation ...................................................... 19
4.1 Explanation of the display .......................................... 19
4.2 Buttons and display symbols ....................................... 20
  4.2.1 Buttons ....................................................... 20
  4.2.2 Display symbols ............................................... 21
4.3 Switching on ...................................................... 21
4.4 Leakage test ...................................................... 22
4.5 Function ......................................................... 23
  4.5.1 Target vacuum ............................................... 23
  4.5.2 Suction ........................................................ 23
4.6 Keylock .......................................................... 24
4.7 Therapy progress .................................................. 25
  4.7.1 Short time ..................................................... 25
  4.7.2 Long time ..................................................... 25
  4.7.3 Transfer of therapy data .................................... 26
  4.7.4 Reading out the therapy data ................................ 27
4.8 Switch off the device ............................................. 28
4.9 User settings ..................................................... 28
5.0 Warning messages .............................................. 30
6.0 Function ....................................................... 32
6.1 Hose rinsing ..................................................... 32
7.0 Accessories and consumables .................................... 33
  7.1 Attachment of the universal bracket (Accessories) ............ 33
  7.2 Attaching the carrying strap .................................. 34
  7.3 Hose holder at the canister .................................... 34
8.0 Cleaning and care ............................................... 35
  8.1 General information on cleaning and disinfection ............ 35
  8.2 Cleaning of the device surface ................................ 36
  8.3 Recommended disinfectants ................................... 36
  8.4 Hygienic plan .................................................. 37
9.0 Maintenance and Service ........................................ 38
  9.1 General advice ................................................ 38
  9.2 Repairs ........................................................ 38
  9.3 Sending in the device ......................................... 39
  9.4 Handling of batteries ......................................... 39
  9.5 Fuse exchange ................................................ 39
10.0 Troubleshooting ................................................ 40
11.0 Technical data .................................................. 41
12.0 Disposal ........................................................ 43
13.0 Notes on EMC (Electromagnetic compatibility) .............. 44
1.0 Introduction

1.1 Information on operating instructions

These operating instructions are valid from software version 3.0.48.

These operating instructions contain important notes on how to operate the ATMOS® C 201 Thorax safely, correctly and effectively. Their reading helps to avoid risks, and also to reduce repair costs and down-times. This increases, amongst other things, the reliability and service-life of the device.

These operating instructions serve not only for new operating personnel to be instructed in its use, but also for use as a reference manual. Reproduction, even partial, is only permitted with written permission from ATMOS.

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

Care and period tests in conjunction with professional execution provide for operational safety and readiness for use of your ATMOS® S 201 Thorax and are therefore a must besides regular cleaning.

Maintenance, repairs and period tests may only be carried out by persons who have the appropriate technical knowledge and are familiar with the product. To carry out these measures the person must have the necessary test devices and original spare parts.

- The product ATMOS® S 201 Thorax 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 appendix I of the directive.
- The product ATMOS® S 201 Thorax complies with all applicable requirements of the directive 2011/65/EC restricting the use of certain hazardous substances in electrical and electronic equipment (“RoHS”).
- The declaration of conformity and our general standard terms and conditions can be obtained on our website at www.atmosmed.com.
- The quality management system applied at ATMOS has been certified according to international standards EN ISO 13485.
- Prior to start-up please peruse chapter „2.0 For your safety“ on page 9, in order to be prepared for any possible dangerous situations.
1.2 Intended use

1.2.1 Intended use ATMOS® S 201 Thorax

Name: ATMOS® S 201 Thorax
Main functions: Digital device for mobile thoracic drainage.

Medical indications / application:
Creating the (natural) vacuum in the pleural cavity after a pneumothorax or a pleural effusion by draining off air and secretion.
Drainage of secretion and air after a surgical opening of the thorax.

Specification of the main function: The ATMOS® S 201 Thorax drainage suction unit is a digital device for mobile thoracic drainage. The device is meant for the short-term (< 30 days) application on humans. It is portable, mains independent and has an electronic monitoring system with optical and acoustic status display. The device is applied unsterile. However, the hose system and the secretion canister, which have to be applied with the device, are sterile single use products. All thoracic catheter / drains can be applied, which are intended for thoracic drainage in the intended use of the manufacturer.

User profile: Doctor, medical staff

Patient groups: Patients of all ages with and without restrictions
Application organ: Thorax
Application time: Short-term use on the patient (< 30 days).
Application site: The application site is the clinical area. The application of the device may only be applied by healthcare professionals. The secretion canister and the drainage hose are sterile and disposable, and can be applied in the sterile OT area.

Contraindications:
No separate application of the secretion canister and the hose system (this means without basic device) as gravity drainage.
No application under emergency conditions and in the home care field which is not supervised by healthcare professionals.
No suction of flammable, corrosive or explosive fluids / gases.
The product is: active

Sterility: Not in case of the basic device. Secretion canister and hose system are sterile.

Single-use product / reprocessing:
 Reprocessing for the basic device see notes in the operating instructions. Secretion canister and hose system are disposables.

1For detailed information about the secretion canister and hose system please refer to the separate intended uses.

1.2.2 Intended use ATMOS® S 201 Thorax secretion canister

Name: Secretion canister for the ATMOS® S / E 201 Thorax
Main functions:
Transport of generated vacuum from basic device to patient-sided tube end.
Collection of secretion and air through the secretion hose into the secretion canister.

Medical indications / application:
Creating the (natural) vacuum in the pleural cavity after a pneumothorax or a pleural effusion by draining off air and secretion.
Drainage of secretion and air after a surgical opening of the thorax.
**Specification of the main function:** Generation of a vacuum from the thoracic drainage system through the secretion canister and hose system to the patient-sided tube end. In this way secretion and air can be sucked through the hose system or transported into the secretion canister. A bacterial filter in the secretion canister protects the basic device from possible contamination with bacteria and the suction of secretion. The vacuum which is at the patient-side is measured with the measuring- and rinsing hose. Furthermore after a defined period a valve opens and flushes secretion, coagulum and other blockages from the hose to the secretion canister.

**User profile:** Doctor, medical staff

**Patient groups:** Patients of all ages with and without restrictions

**Application organ:** Thorax

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

**Application site:** The application site is the clinical area. The application of the device may only be applied by healthcare professionals. The secretion canister and the drainage hose are sterile and disposable, and can be applied in the sterile OT area.

**Contraindications:**
No application with other thoracic drainage systems as the ATMOS® E / S 201 Thorax.
No separate application of the secretion canister and the hose system (this means without basic device) as gravity drainage.
No application under emergency conditions and in the home care field which is not supervised by healthcare professionals.
No suction of flammable, corrosive or explosive fluids / gases.

**The product is:** not active

**Sterility:** Secretion canister is sterile.

**Single-use product / reprocessing:** Secretion canister is disposable.

### 1.2.3 Intended use ATMOS® S 201 Thorax hose system

**Name:** Hose system for the ATMOS® S / E 201 Thorax and ATMOS® C 051 Thorax

**Main functions:**
Transport of generated vacuum from basic device to patient-sided tube end.
Suction of secretion and air through the secretion hose into the secretion canister.
Transport of the patient-sided vacuum to the vacuum sensor for detecting the current vacuum, which is at the patient side.

**Medical indications / application:**
Creating the (natural) vacuum in the pleural cavity after a pneumothorax or a pleural effusion by draining off air and secretion.
Drainage of secretion and air after a surgical opening of the thorax.

**Specification of the main function:** Generation of a vacuum from the thoracic drainage system through the secretion canister and hose system to the patient-sided tube end. In this way secretion and air can be sucked through the hose system or transported into the secretion canister. The vacuum which is at the patient-side is measured with the measuring- and rinsing hose. Furthermore after a defined period a valve opens and flushes secretion, coagulum and other blockages from the hose to the secretion canister.

**User profile:** Doctor, medical staff

**Patient groups:** Patients of all ages with and without restrictions

**Application organ:** Thorax

**Application time:** Short-term use on the patient (< 30 days).
Application site: The application site is the clinical area. The application of the device may only be applied by healthcare professionals. The secretion canister and the drainage hose are sterile and disposable, and can be applied in the sterile OT area.

Contraindications:
No application with other thoracic drainage systems as the ATMOS® E / S 201 Thorax and ATMOS® C 051 Thorax and corresponding secretion canister.
No separate application of the secretion canister and the hose system (this means without basic device) as gravity drainage.
No application under emergency conditions and in the home care field which is not supervised by healthcare professionals.
No suction of flammable, corrosive or explosive fluids / gases.

The product is: not active
Sterility: Hose system is sterile.
Single-use product / reprocessing: Hose system is disposable.

1.3 Function
The ATMOS® S 201 Thorax is an exceptionally handy, mobile, digital thoracic drainage suction device. The device is operated with an electrical, maintenance-free diaphragm pump. During operation the pump creates a vacuum within the suction hose and the secretion canister by means of which secretion and air can be sucked off by the hose system. The pump is controlled digitally and therefore ensures that the chosen required vacuum value is stable. The air flow, which is measured in real-time, is displayed in numbers. At one key press flow data from up to 12 days is shown in graphic.
The secretion is collected in the secretion canister. Its capacity is 2 l. With the aid of the measuring and rinsing hose the vacuum at the end of the hose system is measured. Via the touch screen display the required vacuum can be set manually. The suction power is regulated automatically.
The hose system is rinsed with air at regular intervals to prevent the collection of debris in the secretion channel. This measure also prevents secretion from intruding into the measuring and rinsing hose or that a syphon effect is created.
The device is equipped with a rechargeable battery. A charging unit which is located within the suction device guarantees for the secure charging of the battery. Therefore it is impossible to overcharge the battery.
Bacteria filters in the secretion canister and in the measuring channel prevent the ingress of contaminated secretion into the device. As an accessory a universal connection can be ordered separately.

Essential requirements:
• Create and maintain a regulated vacuum between -5 and -100 mbar.

1.4 Transport and storage
• The device may only be transported in a upholstered and protective shipping box.
• Please note down and immediately report any damages which occurred during shipping. Please make use of the attached QD 434 delivery complaint / return shipment form when complaining or sending back. This form can also be downloaded from our website www.atmosmed.com.
• After the transport of the unit in temperatures below 0°C or prior to first start up it should be kept at room temperature for at least six hours. If the device is not acclimatized it may not be used as damages to the electronic components could occur.
• Ambient conditions:
  - Transport / storage:
    -10...+50 °C;
    30...95 % air humidity without condensation at air pressure 700...1060 hPa
  - Operation and battery charging:
    +10...+35 °C;
    30...95 % air humidity without condensation at air pressure 700...1060 hPa
  - Operation altitude: max. 3000 m

1.5 Explanation of pictures and symbols

Short cuts / symbols contained in these operating instructions

- Follow the arrows
- Numeration
- Move, plug in this direction
- Please press where dot indicates
- Check
- Turn, shift... in this direction
- Please read, important information
- Replace
- Engage, check correct fit

Graphic symbols contained in these operating instructions

- Warning, special diligent notice
- Important information

Symbols of ATMOS® S 201 Thorax & Accessories

- Application parts type CF defibrillator proof; Application part is the hose system.
- The CE sign shows that this product meets the appropriate requirements of the EC Directives.
- Repeated reuse of components which are marked with a is forbidden. This product is not re-sterilizable. In case of repeated reuse these components lose their function and there is a high infection risk.
- Professional disposal
- Protection class II
- Eurasian conformity
- The US Federal Law restricts this product to sale by or on the order of a physician.

- Order number
- Fuse
- Follow operating instructions (blue)
- Observing operating instructions!
- Serial number
- Degree of protection
- Sterile unless package is damaged or opened.
- GOST Certificate (Russia)
2.0 For your safety

2.1 Details

Note

Damage to the device due to improperly installed protective contact socket!
• The ATMOS® S 201 Thorax was produced in accordance with IEC 60601-1/EN 60601-1 and with VDE-safety class II.
• The device may only be connected to a properly installed protective contact socket.
• Prior to first starting up, check whether the mains voltage specified on the type plate matches the local mains voltage.

Exclusion of liability and warranty
If
• no original ATMOS parts are being used,
• the advice for use in these operating instructions is not being observed,
• improper use,
• assembly, new settings, alterations, extensions and repairs have been carried out by personnel not authorised by ATMOS.

Electromagnetic compliance, damage to the device!
• The ATMOS® S 201 Thorax fully complies with the electromagnetic immunity requirements of standard IEC 60601-1-2 / EN 60601-1-2 „Electromagnetic compatibility- Medical Electrical Equipment“.

Damage to the device due to low temperatures
• After the transport of the unit in temperatures below 0°C or prior to first start up it should be kept at room temperature for at least six hours. If the device is not acclimatized it may not be used as damages to the electronic components could occur.

Damage to the device due to tilting
• The device and the canister must be used upright at all times. If the device should tilt it must be placed upright again in order to guarantee faultless operation.
• If you are unsure whether the canister works properly we advise you to replace the canister so as to ensure the patients’ safety.

Damage to the device due to heat
• The device and the canister should not be dried in a microwave oven.
• The mains cable and the device must be kept away from hot surfaces.
• The device may only be operated at room temperature and should not be subjected to direct solar irradiation as this could lead to errors.
• Do not close the ventilation slots on the bottom of the unit. Otherwise the device could overheat.

Legal advice
• US law restricts sale of the device to physicians or ordering through them.
**Appropriate operation**

- Compliance with proper surgical procedures and techniques is the responsibility of the treating physician. Observe the instructions from the attending physician.
- The control panel should always be clearly in view for the operators and be easy to reach.
- The canister may not be used without the device (gravity drainage).
- The device may only be operated by qualified personnel.
- The removal of the canister from the device during the therapy may only be performed by trained professionals who act in conformity with guidelines.
- The ATMOS® S 201 Thorax is a medical device which is subject to special safety regulations. It must to be set up and put into operation in accordance with the EMC regulations. Portable and mobile RF communication devices (mobile phones) may affect the performance of the device.
- A second functioning device (consumables included) must be available for every patient whose condition could become critical if the device in use should get damaged.
- The device may not be operated in MRI scanners (magnetic resonance imaging).
- The device cannot be carried at the hose system.
- Maximum flow of the pump 18 l/min +/- 2 l/min pump performance.
- The device supports the therapy of the patient it is not a substitute for the doctors’ diagnosis.
- The patient should be supervised constantly in accordance with the internal rules of the hospital.
- Prior to the removal of the hose connector the patient hose must be pinched off.

**Advice on disposal**

- Dispose of wrappings accordingly.
- Attention must be paid to all hospital protocols regarding disposal and infection control.

**Wrong evaluation**

- Prior to each application the device should be checked for leakages (peruse chapter „4.4 Leakage test“ on page 22).
- Leaking connections could lead to a wrong evaluation of the patient’s status and could prolong the therapy. Thus do check all connections for leakages to prevent the intrusion of additional air.

**Leakage in the system**

- Minimal leakages can indicate small leaks in the system or to irregularities in the course of therapy. This can be excluded by clamping the patient catheter and as a result the flow value is reduced to zero. If not, check all the connections on the device, the connectors as well as the Luer-Lock cap for leakage. If there is still only a minimal flow value illustrated then there is an internal leakage in the system which cannot be rectified by the user. This will be compensated by the system but illustrated as a minimal flow value.
2.2 Caution

⚠️ CAUTION ⚠️

Risk of injury!
- A misplaced drainage system and a misplaced thoracic catheter could hinder the drainage of air and liquids.
- A complete blocking of the system during the drainage of liquids and air could cause a rise in pressure and thus lead to a tension pneumothorax.
- Always place the drainage system at the same height as the patient's catheter and check the patient hose for any bends or clogging which could hinder the drainage of liquid and air. Never place the drainage system on the floor.
- Immediate reaction is required in case of the "vacuum too low" alarm.
- Prior to exchanging the secretion canister the thoracic catheter must be clamped so that a continuous vacuum is always available at the patient.

Risk of injury!
- If the fluid level in the canister is too high it could cause a blockage and thus a tension pneumothorax.
- Check the secretion canister at regular intervals and exchange the canister when the maximum filling level is reached to secure the patient's safety.
- Check device, secretion canister, power cable, accessories, connection cables and hoses for damage before start-up. Faulty respectively damaged components must be replaced immediately.
- Check the hose system at regular intervals. Observe the instructions from the attending physician.

Risk of injury!
- The hose system may not be clamped. Ideally clamp the thoracic catheter when changing the secretion canister.
- The bending of the patient hose leads to an interruption of the therapy and incorrect measurements.

Risk of injury!
- A vacuum over -50 mbar could cause pain and injury to the patient. A vacuum over -50 mbar may only be adjusted under medical indication.
2.3 Warning

**WARNING**

Electric shock due to damaged connecting cables
- Check the device and connection lines for defects prior to the use of the device.
- Damaged cables must be replaced!

Electric shock due to voltage!
- To disconnect the device from the mains supply, first remove the plug from the wall outlet. Disconnect the connection line on the device afterwards only.
- The device can be disconnected from the power supply only by pulling the plug out. The device does not have a mains switch. Ensure that the mains cable is easily accessible and can be disconnected from the power supply at all times.
- Do not modify the device.
- Please pay attention to the period tests in chapter „9.0 Maintenance and Service“ on page 38.
- Assembly, repairs, modifications and period tests may only be carried out by authorized persons.

Electric shock due to voltage!
- Do not allow liquids (such as disinfectants or secretions) to enter the device or power cable.
- If secretion has entered or is sucked into the device then it must be sent to the manufacturer or an authorized service partner.
- Don’t take a shower / bath with the device.

Danger of explosion due to unobserved ambient conditions!
- The ATMOS® S 201 Thorax is not designed for the use in medical areas with an explosion hazard or which are oxygenated. Explosion-hazardous areas may be caused by the use of flammable anaesthetics, skin cleansing products and skin disinfectants.
- The ambient conditions specified in the „11.0 Technical data“ on page 41 must be strictly observed!

Risk of infection
- Repeated reuse of components which are marked with a ☒ is forbidden. This product is not re-sterilizable. In case of repeated reuse these components lose their function and there is a high infection risk.
- The suction hose must never come into direct contact with the suction place but only through a sterile drain.
- Repeated reuse of canister and hose systems can lead to infections.
- Canister and hose system should only be used once on every patient.
- For hygienic reasons we recommend an exchange of both canister and hose system at the same time.

Risk of injury by damaged device
- If the device was dropped: Check the unit for visible damage and perform a leakage test. If the leakage test fails or the housing is damaged, the device is defective and must not be operated. Send in the device for repair. Treatment with defective equipment can cause fatal injuries to the patient.
3.0 Setting up and starting up

3.1 Scope of delivery

The ATMOS® S 201 Thorax was subjected to an extensive functional test and was carefully packed prior to dispatch.

On receipt of the goods please check the package for any possible damage and compare the contents for completeness. (see bill of delivery)

<table>
<thead>
<tr>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Basic device</td>
</tr>
<tr>
<td>Mains cable</td>
</tr>
<tr>
<td>Operating Instructions</td>
</tr>
<tr>
<td>Quick-Guide</td>
</tr>
</tbody>
</table>
3.2 Device overview

Front side

1 On / Off sensor
2 Touchscreen (touch-sensitive display)
3 Handle
4 Light sensor
5 Release button
6 Connection for USB flash drive

Only use the USB-connection for the transfer of therapy data. A software update may only be performed by ATMOS or an authorized service person.

7 Measuring and rinsing channel
8 Secretion channel

Rear side

9 Type plate
10 Nut for mains supply
11 Fixture for device attachment
3.3 Start up

• Remove the device from the packaging.
• Peruse safety information in part „2.0 For your safety“ on page 9 prior to starting up the device for the first time.
• The battery must be fully charged prior to the first use. Charging time approx. 2.5 hours.
• Place the device on a safe and even surface.
• After the transport of the unit in temperatures below 0°C or prior to first start up it should be kept at room temperature for at least six hours. If the device is not acclimatized it may not be used as damages to the electronic components could occur.
• The device can only be operated with the ATMOS® secretion canister.
• Always have at least one more ATMOS® secretion canister at hand.

Mains voltage and fuse:
• Mains voltage: 100 - 240 V; 50/60 Hz
• Fuse: 1x T 1.25 A / H, 250 V

3.3.1 Battery charging

Each bar of the symbol represents 20% battery charge.

Attention!
Prior to the first start up of the ATMOS® S 201 Thorax the battery must be fully charged.
The battery is recharged by the integrated recharging electronics as soon as you connected the device to the mains supply with the power cord.
Please note the information on how to handle rechargeable batteries in chapter „9.4 Handling of batteries“ on page 39.
Correct handling of the rechargeable batteries prolongs their maximum service life.

Batteries are wearing parts and therefore excluded from the general warranty.
The device should be recharged in a cool place without direct solar irradiation. At ambient temperatures above 25°C the charging time could be prolonged drastically. Defects which occur due to improper handling of the device are not covered by the guarantee.

Attention: If the battery temperature is higher than 50° C it can no longer be charged.
• Plug the power cable into the charging socket of the ATMOS® S 201 Thorax.
• Plug the mains plug into the socket. The ATMOS® S 201 Thorax displays the symbol on the display. The bar on the right side flashes.
• As long as the mains plug is connected, the symbol is green.
• When the battery is fully charged (the symbol does not blink anymore) remove the mains plug from the socket.
• After that remove the power plug from the charging socket of the ATMOS® S 201 Thorax.

As soon as the battery charge level is less than 20%, the drainage unit displays a warning window and triggers an audible warning message (peruse chapter „5.0 Warning messages“ on page 30 for further information). Charge the battery in order to continue the therapy without interruption. If the battery is too low for further operation of the device the ATMOS® S 201 Thorax switches off automatically.

The battery of the ATMOS® S 201 Thorax can also be charged when the device is switched off. The state of charge can be seen on the display.
3.3.2 Secretion canister

- Always use the original ATMOS disposable secretion canister.
- Vacuum connection system: The vacuum connection between device and secretion canister is set up immediately after connection!
- For hygienic reasons we recommend an exchange of both canister and hose system at the same time.

Secretion canister overview

1. Pop-off-valve
2. Filler for water lock
3. Hydrophobic bacterial filter
4. Filling level for water lock function
5. Indicator scale for balancing in ml
6. Protective cap for sealing the pop-off valve
7. Protective cap for sealing the secretion channel
8. Connection towards patient (secretion channel)

Filling the water lock

The water lock is on the right side of the secretion canister. A bacterial filter and a riser are included. The water lock is filled with water through the riser. For filling the water lock a sterile cannula 20 G, a sterile syringe and 50 ml sterile water are required. With the cannula you may puncture the silicone seal above the riser and then fill the water lock.

Prior to use the water lock must be filled to prescribed level (not above the 2 cm fill line) and it should be checked regularly to confirm proper operation.

Use only pre-packaged sterile fluid for filling the water lock.

Reconnect the filled container to the device.

During normal operation the filling of the water lock is optional.

The canister may only be removed when the pump is switched off.

Prior to inserting the secretion canister into the device, make sure that the filler of the water lock is sealed with the plug.

Pop-off-valve

The pop-off valve 1 is a protection against the occurrence of high pressure which could lead to a tension pneumothorax (e.g. a fit of coughing). The valve opens at a high pressure of ≥10 mbar within the canister.
Exchanging the secretion canister

Prior to exchanging the secretion canister the thoracic catheter must be clamped so that a continuous vacuum is always available at the patient.

Removing the secretion canister

1. Always wear disposable gloves, pay attention to the regulations for the handling of sterile products.
2. Provide a sterile secretion canister.
3. Check whether the target vacuum is reached.
4. Clamp the suction hose near the step connector close to the patient in order to prevent loss of vacuum.
5. Stop the therapy and switch off the device.
6. Remove the secretion canister by pressing the blue release button 1 and take the secretion canister from the guides on the left side.
7. Place the secretion canister on a horizontal surface.
8. Release the 2 Luer-Lock connections by a counter-clockwise rotation to separate the secretion canister and the device from the hose system. Pay attention as secretion could be found in the connection space.
9. Remove the cover cap 2 from the Luer-Lock connection of the secretion channel.
10. Separate the cover cap by rotating and pulling it simultaneously.
11. Close the Pop-off valve 3 with the bigger cover cap.
12. Close the Luer-Lock connection 4 of the secretion channel with the smaller cover cap. The connection on the rear of the secretion canister must not be sealed.
13. Correctly dispose of the secretion canister.

Insert secretion canister

14. Remove the secretion canister from the packaging and place in the guides on the left side.
15. Press in the secretion canister on the right side until it clicks into place in.
16. Connect the hose system (see chapter „Connecting the hose system“ on page 18.
17. Switch on the device. The leakage test starts automatically. The patient-sided hose end must be closed.
18. Start the therapy.
19. Reopen the clamp at the thoracic catheter.
Connecting the hose system

- Remove the sterile hose system from the sterile wrapping.
- Connect the Luer-Lock with the bacterial filter 1 to the upper canister connection on the secretion canister by a clockwise rotation.
- Connect the second Luer-Lock connection to the lower connection of the canister 3 by a clockwise rotation.
- Perform a leakage test (see chapter „4.4 Leakage test“ on page 22).
- Use the sterile hose connector, supplied with the hose system, to connect the hose system to any drainage catheter of your choice. Alternatively you can also use conventional sterile y-connectors or hose connectors.

⚠️ The vacuum is measured directly at the drain with the measuring and rinsing channel. A bacterial filter at the measuring and rinsing channel prevents the penetration of bacteria into the device.

The double-lumen hose system must be connected to the device on both channels (measuring-, rinsing- and secretion channel). The hose system is a single-use product for use with one patient only.

⚠️ The use of other hose systems may lead to damage of the device.
4.0 Operation

4.1 Explanation of the display

Flow
Display of the actual fistula
ATTENTION: This is the current value. In the case of a discontinuous fistula, the value can decline temporarily to zero although the fistula still exists.

Actual vacuum
Display of the actual vacuum value.

Target vacuum
Display of the preadjusted target vacuum to which the pump adjusts.

System information

Therapy progress
Changeover to the graphic diagram

User settings

Setting button
Increases the target vacuum

Setting button
Decreases the target vacuum

Start / Stop therapy

Keylock manual

Flow displayed as bubbles
Each additional coloured bubble represents an additional flow.

None: 0 - < 30 ml/min
Green: 30 - < 60 ml/min
Yellow: 60 - < 630 ml/min
Orange: 630 ml - 5.51 l/min
Red: > 5.51 l/min to maximum.

Up to 1,000 l/min the flow is displayed in ml/min.

Keylock activated

Day/Night Mode
The ATMOS® S 201 Thorax has a day/night mode, the device adjusts automatically to the environmental lighting.
Under low ambient light conditions display has dark background illumination.
## 4.2 Buttons and display symbols

### 4.2.1 Buttons

<table>
<thead>
<tr>
<th>Figure</th>
<th>Function</th>
</tr>
</thead>
</table>
| ![Decrease](image) | Decrease target vacuum  
In the menu: decrease selected value |
| ![Increase](image) | Increase target vacuum  
In the menu: increase selected value |
| ![Graph](image) | Graphic diagram of the therapy |
| ![Open Settings](image) | Open the user settings |
| ![Save](image) | Save entry |
| ![Confirm](image) | Confirm information |
| ![Back](image) | Back / Exit menu |
| ![Warning](image) | Warning / suppress the warning |
| ![Vac](image) | Changeover to vacuum scaling |
| ![Time](image) | Changeover to time scaling |
| ![Flow](image) | Changeover to flow scaling |
| ![Start](image) | Start therapy |
| ![Stop](image) | Stop therapy |
| ![Hold](image) | Hold / restart graphic |
| ![Increase Axis](image) | Increase maximum of axis |
| ![Decrease Axis](image) | Decrease maximum of axis |
| ![Scroll Up](image) | Scroll up the list |
| ![Scroll Down](image) | Scroll down the list |
| ![Activate](image) | Activate keylock |
4.2.2 Display symbols

<table>
<thead>
<tr>
<th>Figure</th>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td>🍃️</td>
<td>Battery status display / charging indicator</td>
</tr>
<tr>
<td>🎁️</td>
<td>Keylock activated</td>
</tr>
<tr>
<td>📦</td>
<td>Therapy recording in progress</td>
</tr>
<tr>
<td>⏳️</td>
<td>Therapy on hold</td>
</tr>
<tr>
<td>🔰</td>
<td>Therapy in progress</td>
</tr>
<tr>
<td>🚨</td>
<td>Upcoming warning suppressed</td>
</tr>
<tr>
<td>📰</td>
<td>Annual inspection is required</td>
</tr>
</tbody>
</table>

4.3 Switching on

- To switch on the ATMOS® S 201 Thorax please touch the sensor above of the symbol 🍃️ for 2 seconds.
- The ATMOS logo appears with the software version number in the bottom right corner.
- After a short while the leakage test (chapter „4.4 Leakage test“ on page 22) starts automatically.
- Subsequently "Therapy progress" will appear in the display. By pressing the buttons you can start a new therapy recording or continue recording.
- The main display appears. The device is now ready for use.
4.4 Leakage test

Following device start up the leakage test starts automatically.
The hose attachment towards the drainage catheter should already be sealed with a sterile plug when starting up the device. Alternatively the thorax catheter can be clamped near to the patient. Do not clamp the ATMOS hose system.

If the leakage test is error-free, the message “Leakage test OK” appears. Now you can remove the plug from the hose. By pressing the button you will reach the main menu.

If the leakage test is faulty, the message „Leakage test failed“ appears. Check the hose connections and whether the secretion canister is correctly clicked into place. You now have the possibility to
a) repeat the test
b) abort the test by pressing the respective buttons on the screen.
ATTENTION: If the leakage test is operated accordingly the leakage must not be ignored. If the device dropped down it must not be operated. Send in the device for repair. Treatment with defective equipment can cause fatal injuries to the patient.
The intention of "abort the leakage test" is to skip the test if a standard test under given condition is not possible.
4.5 Function

4.5.1 Target vacuum

- Please note, an adjusted target vacuum over -50 mbar may cause pain and injuries to the patient.
- On the main screen the target vacuum can be set directly by pressing the + and - buttons.
- ATTENTION: The change of the target vacuum is immediately effective. There is no confirmation necessary.
- The target vacuum can be freely selected between -5 and -100 mbar in steps of 1 mbar.
- If the buttons + and - are pressed permanently, the increase / decrease will be accelerated.
- The default value is -20 mbar vacuum at delivery. The standard vacuum value can be individually set in the user menu.

If target vacuum is adjusted over -50 mbar the notice appears „High target vacuum is set“.

4.5.2 Suction

- When the device is switched on the pump is not activated. This is visible due to the symbol in the right upper corner. By pressing the button the pump starts.
- The symbol in the right upper corner of the main screen shows that the pump is running.
- By pressing the button the pump will be stopped.
- The ATMOS® S 201 Thorax has a vacuum controller. This means, that the integrated pump only starts, if the actual vacuum doesn't correspond to the target vacuum. On the other hand the pumps performance depends on the difference between the actual vacuum and the target vacuum.
- The vacuum is measured at the patient side of the hose system.
- The bacterial filter is a safe protection against liquid or bacteria penetrating the pump.
4.6 Keylock

The ATMOS® S 201 Thorax has an automatic keylock.

**Automatic activation of the keylock**

If the settings are not changed for a defined time, the keylock will be activated automatically (default factory setting 1 minute, individually adjustable in the user settings). This will prevent unintentional operation.

**Manually activate the keylock**

The keylock can be manually activated after all the therapy values are set and the therapy is started.

Press the symbol to activate the keylock.

The display symbol appears above the Flow-display and shows an activated keylock.

**Deactivate the keylock**

A quick touch to the display and then the first contact point appears.

By touching the contact point the second contact point appears.

By a repeated touching of this contact point the key lock symbol above is deactivated (see first display image). Now you can operate the system again.

If you do not touch both the symbols and within 6 seconds the key lock remains activated. The deactivation process can be started by a repeated touching to the screen.
4.7 Therapy progress

The ATMOS® S 201 Thorax has 2 graphical diagrams to simplify the analysis of the air-flow and actual vacuum progress.

Selection menu
By selecting the button you reach the graphical diagram modus. By pressing the buttons you can select the modus of your choice e.g. long / short time.

4.7.1 Short time

The graphical diagram starts by selecting the menu. In this modus the real measurements (flow, vacuum) from the last 30 seconds can be shown. Therefore you can visualise cough tests and other proceedings.

By pressing the button the diagram can be frozen to enable a graphical interpretation. When you press the button again the short time diagram is restarted.

By pressing the button you will return to the main menu.

4.7.2 Long time

In the longtime modus the complete therapy progress can be visualised.

• The scaling can be switched between time, flow and vacuum.
• You can reach the different scalings by pressing the or button.
• The scale can be increased or decreased by pressing the or button.

Time scaling:
• The endpoint on the right side of the graphic is always the actual point of time.
• The scaling can be selected in 7 steps, between the display of the past 60 minutes and the last 12 days.
• A vertical line shows when the therapy was interrupted.

Flow scaling:
• The scaling can be selected between 0 – 1 l/min and 0 – 15 l/min in 4 steps.

Vacuum scaling:
• The scaling can be selected between 0 - 110 mbar (= cmH2O) and 0 - 22 mbar (= cmH2O) in 3 steps.
4.7.3 Transfer of therapy data

You may transfer the therapy data to a USB flashdrive. The therapy data is saved as a PDF- and Excel-file. If you continue the therapy after the data transfer, the data will still be recorded. The transmitted data will not be deleted. If you are starting a new therapy, the previous data will be overwritten. ATMOS recommends: Perform the therapy data transfer at the end of a patients therapy.

Suitable USB flash drives for therapy data read-out

- Manufacturer: SanDisk, Kingston, ATMOS flash drive
- System: USB 2.0
- Capacity: ≤ 8 GB
- Formatting: FAT 32
- No stored encryption

ATMOS recommends: Use USB flash drive without content. Different USB flash drives may not be detected.

Start transfer

- Press the release button. The secretion canister swivels forward to the right.
- Connect the USB flash drive, see chapter page 14.
- The device prepares for the therapy data transfer.

- In order to start the transfer confirm the query on the device with „Yes“.
- To abort the transfer confirm the query on the device with „No“.

Termination

Remove the USB flash drive. Now you return to the main screen.

Therapy data transfer

- The USB flash drive must stay connected during the whole data transfer.
- The software indicates the duration and status of the transfer. The transfer can take up to 3 minutes. Do not abort the transfer even if the percentage reading does not increase.
Complete data transfer

• As soon as the therapy data is transferred then the USB flash drive may be removed. Now you return to the main screen.

If the therapy data should be transferred during a patients therapy, follow the steps below:
• Clamp the thoracic catheter
• Stop the current therapy
• Remove the secretion canister.
Perform the therapy data transfer as described.
• Connect the secretion canister.
• Continue the therapy
• Reopen the clamp at the thoracic catheter.

4.7.4 Reading out the therapy data

• Connect the USB flash drive to PC.
• Open the folder on the USB flash drive. This folder contains a PDF file and an excel file.
• Open the PDF file.
• Fill in the desired Information:
  - Patient data
  - Diagnosis
  - Description of the secretion

Following information can be seen in the report:
  - Beginning and end of recording, flow at beginning and end of recording
  - File name und device ID
  - Graphic diagram of the therapy data
4.8 Switch off the device

- To switch off the ATMOS® S 201 Thorax stop the therapy and touch the sensor for 2 seconds.
- The ATMOS logo appears on the screen and the device shuts down.

4.9 User settings

For accessing the user menu please press the button. Please press the buttons and for moving up and down in the menu selection.
For entering a selection menu press on the text box.

These buttons can be found in every settings menu:
- For accessing the user menu please press the button.
- ATTENTION! The selected data are only saved if you press the memory key.

In the user settings the following positions can be selected:

<table>
<thead>
<tr>
<th>Language</th>
<th>System language</th>
<th>The system language can be adjusted with and .</th>
</tr>
</thead>
<tbody>
<tr>
<td>English</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Vacuum unit</th>
<th>Vacuum unit</th>
<th>The vacuum unit can be adjusted with and .</th>
</tr>
</thead>
<tbody>
<tr>
<td>mbar</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Setting</td>
<td>Description</td>
<td></td>
</tr>
<tr>
<td>------------------------------</td>
<td>-----------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>Standard vacuum</td>
<td>When the device is started the standard-vacuum is automatically pre-adjusted.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>The standard-vacuum can be adjusted with + and −.</td>
<td></td>
</tr>
<tr>
<td>Period time of hose rinsing</td>
<td>The period time of hose rinsing can be adjusted with + and −.</td>
<td></td>
</tr>
<tr>
<td>Keylock activation time</td>
<td>The keylock activation time can be adjusted with + and −.</td>
<td></td>
</tr>
<tr>
<td>Keytone</td>
<td>The keytone can be activated or deactivated by pressing + and −.</td>
<td></td>
</tr>
<tr>
<td>Date</td>
<td>By pressing one of the three control panels (Day, Month, Year) you may enter the individual settings. Now adjust the Date with + and −.</td>
<td></td>
</tr>
<tr>
<td>Time</td>
<td>By pressing one of the two control panels (hour or minute) you may enter the individual settings. Now adjust the Time with + and −.</td>
<td></td>
</tr>
</tbody>
</table>
5.0 Warning messages

In the event of a warning message the keylock is removed automatically!

⚠️ In the event of a warning message the system switches to the warning-menu automatically. An error indication is displayed. This indication contains advice for the removal of the cause of error. The acoustic warning message is triggered at the same time. No warning message appears during the start up and the data transfer.

⚠️ The cause of error must always be removed in the case of an alarm message!

<table>
<thead>
<tr>
<th>Display</th>
<th>Cause of error</th>
<th>Troubleshooting</th>
</tr>
</thead>
</table>
| ![Vacuum too low](image) | If the required vacuum cannot be reached an acoustic alarm and optical display of the warning message „vacuum too low“ is displayed. Possible reasons for this error indication are: Leakage, blockage of the bacterial filter in the measuring and rinsing channel, clogging, a bend in the drainage hose, liquids were sucked into the pump. | • Check for leakages and / or blockages:  
  - Connections  
  - Secretion canister  
  - Drainage hose  
  • Contact the ATMOS service! |
| ![Vacuum too high](image) | The measurement of an excessively high vacuum results in the display of the warning message “vacuum too high”. Possible reasons for this error indication are:  
  • Ventilation valve is defect.  
  • There are further vacuum sources in the drainage area. | • Remove vacuum sources  
  • Contact the ATMOS service! |
<p>| <img src="image" alt="Low battery" /> | If the voltage of the battery falls below a specific value the error indication for “battery low” is displayed. | Connect device to the supply network. The battery is charged and the soc (state of charge) is indicated in the display. |
| <img src="image" alt="Device in critical tilt" /> | If the device is in a tilted position the warning „Device in critical tilt“ appears. | Place the device in an upright position. The warning signal is automatically deactivated. |</p>
<table>
<thead>
<tr>
<th>Display</th>
<th>Cause of error</th>
<th>Troubleshooting</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="warning.png" alt="Warning Icon" /> <strong>WARNING</strong>&lt;br&gt;Inactive therapy&lt;br&gt;Start therapy by pressing the button!</td>
<td>If the therapy has not been started after initial operation the warning &quot;Inactive therapy&quot; appears.</td>
<td>Start therapy by pressing the button.</td>
</tr>
<tr>
<td><img src="warning.png" alt="Warning Icon" /> <strong>WARNING</strong>&lt;br&gt;Faulty battery&lt;br&gt;The device can not be operated! Battery must be replaced by the service!</td>
<td>• Battery is defective. The device can no longer be used.</td>
<td>• Please contact the ATMOS service.</td>
</tr>
<tr>
<td><img src="warning.png" alt="Warning Icon" /> <strong>WARNING</strong>&lt;br&gt;Device temperature too high&lt;br&gt;Provide sufficient ventilation! Check fan!</td>
<td>Device temperature too high.&lt;br&gt;• Device is in the sun or near a heater.&lt;br&gt;• Ventilation slots are covered.&lt;br&gt;• Fan is defective</td>
<td>• Place the device in a cooler location.&lt;br&gt;• Please ensure sufficient air ventilation.&lt;br&gt;• Please contact the ATMOS service.</td>
</tr>
</tbody>
</table>

An inspection according to the manufacturer's specifications is required every year. This will be displayed on the device.

Low battery capacity appears in the display. Battery must be replaced by the service.

If target vacuum is adjusted over -50 mbar the notice appears „High target vacuum is set“. 
6.0 Function

6.1 Hose rinsing

- The ATMOS® S 201 Thorax has an automatic hose rinsing function which works periodically.
- The rinsing process transports secretion located in the secretion channel into the secretion canister.
- The rinsing is performed by opening a valve located in the measuring and rinsing channel.
- The manufacturers default setting for the period between 2 rinsing cycles is 3 minutes.

If the water lock function is being used, air bubbles are likely to appear during the hose rinsing period. Users should be aware that these air bubbles appear at regular intervals (usually 3 minutes) and are not related to the patient’s condition (e.g. Fistula).
7.0 Accessories and consumables

Accessories

<table>
<thead>
<tr>
<th>REF</th>
<th>Description</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>312.1160.0</td>
<td>Universal bracket</td>
<td>Bracket for fastening the ATMOS® S 201 Thorax on the patient bed, standard rail, wheelchair, tripod, etc.</td>
</tr>
<tr>
<td>312.0850.0</td>
<td>Carrying strap ATMOS® S 201 Thorax</td>
<td></td>
</tr>
<tr>
<td>061.0079.0</td>
<td>Hose clamp</td>
<td></td>
</tr>
<tr>
<td>312.1029.0</td>
<td>Hose holder</td>
<td></td>
</tr>
</tbody>
</table>

Consumables

<table>
<thead>
<tr>
<th>REF</th>
<th>Description</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>312.1031.0</td>
<td>Surgical kit for ATMOS® E / S 201 Thorax</td>
<td>Included in the surgical kit: 10 x secretion canister, 2 l (sterile) 10 x hose system for ATMOS® Thorax drainage systems (sterile) Exchange: once per patient</td>
</tr>
<tr>
<td>312.1170.0</td>
<td>Hose system, 10 pcs.</td>
<td></td>
</tr>
<tr>
<td>312.1150.5</td>
<td>Secretion canister, 2 l, 5 pcs.</td>
<td></td>
</tr>
</tbody>
</table>

7.1 Attachment of the universal bracket (Accessories)

The universal bracket can be mounted to infusion tripods, wheelchairs, to the bed or to the standard rail.

Align the fastening bracket:
- Pull the stop bolt.
- Rotate the fastening bracket 90°.
- Allow the stop bolt to snap into position.

Attach the universal bracket:
- Position the universal bracket to the required position.
- Turn the knob until the universal bracket is fixated.

Attach the device to the universal bracket:
- Pull the locking system and rotate it by 90°, so that the stop bolt goes in.
- Place the device on the universal bracket.
- Pull the locking system and rotate it by 90°, so that the bolt fixates the device.
7.2 Attaching the carrying strap

Fix the carrying strap with the Velcro fastening to the handle, adjust the requested length and put the device over your shoulder.

7.3 Hose holder at the canister

Pull off the adhesive strip and fix the holder as shown.
8.0 Cleaning and care

8.1 General information on cleaning and disinfection

Prior to cleaning:
Medical devices like the ATMOS® S 201 Thorax vision need to be fail safe at any time.
Therefore we recommend prior to every use:

![Diagram](image)

Handling of the drainage unit determines to a large extent its reliability and safety. The hygiene measures are necessary measures for the protection of patients and users, and to maintain functional reliability of the drainage unit.

⚠️ During all work disposable gloves must be worn.
- The described action relating to cleaning and disinfection resp. sterilisation do not substitute the relevant instructions which must be adhered to prior to operation!
- Avoid the penetration or liquid entering the drainage device, especially in the connections.

Prior to being used on a new patient all parts which come into contact with secretion e.g. secretion canister, hoses etc, must be disposed.

Prior to cleaning remove the mains cable from the device.

Prior to cleaning the device please remove and dispose of all disposable parts like secretion canister and hoses, these are disposable products and are not suitable for reprocessing.

During cleaning and disinfection the device must be switched off. Do not switch the device back on until the cleaning and disinfectants on the surface have dried completely.

Please observe the operating instructions for use prescribed by the manufacturers of disinfectants. Pay attention regarding their concentration suitability for use and the contact time.

Attention! Some disinfectants could cause discolouring to some of the plastic parts.

Do not use
- Disinfectants which contain organic or inorganic acids or bases as they could cause corrosion damage.
- Disinfectants containing chloramides or phenol derivatives, since these may cause stress cracks in the material used for the housing of the unit.

For disinfection, you may use all surface disinfectants listed in chapter „8.3 Recommended disinfectants” on page 36.

It is important that disinfectant does not enter the device. Do not use a spray disinfectant directly on the device, but spray it on a cloth (only damp not wet).

We recommend that you always document all maintenance work and exchange of parts in writing.
8.2 Cleaning of the device surface

⚠ Prior to using the device on a new patient the complete device surface must always be cleaned with a damp (not wet) cloth and disinfected with a surface disinfection solution. In case the device is being used by the same patient the surface should still be cleaned at least once every week with a damp (not wet) cloth and afterwards be disinfected with a surface disinfectant.

• Attention! The device should never be autoclaved, rinsed under running water or immersed into any liquids!

8.3 Recommended disinfectants

<table>
<thead>
<tr>
<th>Disinfectant</th>
<th>Ingredients</th>
<th>in 100 g</th>
<th>Manufacturer</th>
</tr>
</thead>
</table>
| ATMOS® 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) | Magnesium monoperoxyphthalate  
Hexahydrate | 80 g | Bode Chemie, Hamburg |
| Dismozon® plus (Granulate) | Magnesium monoperoxyphthalate  
Hexahydrate | 95.8 g | Bode Chemie, Hamburg |
| Kohrsolin® FF (Application concentrate) | glutaral  
benzyl-C12-18-alkyldimethyl-ammonium chlorides  
Didecyldimethylammonium chloride | 5 g  
3 g  
3 g | Bode Chemie, Hamburg |
| Kohrsolin® extra (Application concentrate) | (ethylenedioxy)dimethanol  
glutaral  
Didecyldimethylammonium chloride | 14.1 g  
5 g  
8 g | Bode Chemie, Hamburg |
| Perform® | Pentapotassium-bis(peroxymonosulphate)-bis(sulphate) | 45 g | Schülke & Mayr, Norderstedt |
| Bacillol® 30 Foam | ethanol  
propan-2-ol  
propan-1-ol  
n-alkyl-aminopropylglycine | 14 g  
10 g  
6 g  
< 1 g | Bode Chemie, Hamburg |
| SaniCloth® Active | didecyldimethylammonium chloride | < 1 g | Ecolab, Düsseldorf |
| Incidin® Active | peracetic acid | < 1 g | Ecolab, Düsseldorf |
| Mikrozid® Sensitive Wipes | benzyl-C12-16 alklydimethyl-, chloride;  
Didecyldimethylammonium chloride  
benzyl-C12-14-alkyl [ethylphenyl]methyl]dimethyl-, chlorides | 0.26 g  
0.26 g  
0.26 g | Schülke & Mayr, Norderstedt |

All cleaning and disinfectant agents with the above mentioned ingredients are also suitable for cleaning the basic device.

⚠ When using disinfectants containing aldehyde and amines at the same object colour changes may occur.

Do not use disinfectants with alcohol for cleaning the touch screen.
# 8.4 Hygienic plan

<table>
<thead>
<tr>
<th>WHAT</th>
<th>HOW</th>
<th>WHEN</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>E</td>
<td>C</td>
<td>D</td>
</tr>
<tr>
<td>Drainage unit</td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Canister</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hose system</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carrying strap</td>
<td>X</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

R= Removal, C= Cleaning, D= Disinfection, S= Sterilization
9.0 Maintenance and Service

9.1 General advice

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.

Maintenance, repairs and period tests may only be carried out by persons who have the appropriate technical knowledge and are familiar with the product. To carry out these measures the person must have the necessary test devices and original spare parts.

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

Carry out an inspection according to the manufacturer's specifications every 12 months. Depending on the amount of charging cycles performed we recommend an exchange of the batteries.

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

• Please observe any national and international regulations applicable for your institution.
• Prior to every use a visual inspection of the device, secretion canister and power cable, accessories, connection cables and hoses must be performed. Damaged cables must be replaced immediately!
• For repair works the device can be sent either directly to ATMOS, or via the retailer you purchased it from.
• There are no warranty claims whatsoever on defects or malfunctions which arise from the use of third party accessories or consumables.

9.2 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.
• Significant decrease of battery capacity.
• Sudden occurrence of abnormal displays on the screen.
• Sudden occurrence of unusual noises
• Operational and functional disorders which cannot be resolved by means of the hints describes in the chapter “10.0 Troubleshooting” on page 40".


9.3  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:

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 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.

9.4  Handling of batteries

Rechargeable batteries are wear parts with a limited lifetime. Under optimal condition of use, lithium-ionic batteries are usually worn after approx. 500 charge cycles and should then be replaced. Handling of the device and the batteries significantly affects lifetime of the batteries. Non-observance of the following recommendations may significantly decrease lifetime.

- Always store device with batteries in a cool and dry place (room temperature 18 - 25° C).
- Always store device with batteries at a charge status of 20 - 40 %.
- Due to self-discharge, the batteries should be recharged every 4 - 5 months.
- Never cover the device, never expose the device to direct sunlight and never charge, operate or store the device in close vicinity to heaters.
- Always charge the batteries using the respective charging equipment. Overcharging will destroy the batteries.
- The lifetime of lithium-ionic batteries mainly depends on the ambient temperature. On principle batteries are depleted after 2.5 years.
- New batteries should be fully charged prior to first use.

⚠️ Using other charging accessories may result in risk of explosions!
ATMOS has no influence on the use of the device therefore batteries are excluded from the guarantee. There is a function guarantee of 6 months.

9.5  Fuse exchange

<p>| | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>2.</td>
<td>3.</td>
<td>4.</td>
<td>5.</td>
</tr>
<tr>
<td>6.</td>
<td>7.</td>
<td>8.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## 10.0 Troubleshooting

<table>
<thead>
<tr>
<th>Description</th>
<th>Possible causes</th>
<th>Remedy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device cannot be switched on.</td>
<td>Battery is completely empty.</td>
<td>Connect the power cable to the device to recharge the battery, note that the progress can be checked in the upper left hand corner of the display.</td>
</tr>
<tr>
<td>Battery does not recharge and charging symbol does not light up despite proper connection to the power cable.</td>
<td>Fuse is defective.</td>
<td>Check the fuses.</td>
</tr>
<tr>
<td></td>
<td>Mains cable defective or not connected properly.</td>
<td>Check the mains cable.</td>
</tr>
<tr>
<td></td>
<td>Recharging unit, charging electronics or battery are internally defective.</td>
<td>Contact the ATMOS service or a certified service partner. The device must be checked.</td>
</tr>
<tr>
<td>„Vacuum too low“</td>
<td>Leakage</td>
<td>Check all the hoses and the secretion canister for leakages.</td>
</tr>
<tr>
<td></td>
<td>Blockage in the hose system. Hose is kinked.</td>
<td>Remove the blockage if necessary. Remove the measuring and rinsing channel from the connection to the secretion canister. If the filter in the measuring and rinsing channel is blocked exchange the hose system.</td>
</tr>
<tr>
<td></td>
<td>Bacterial filter at the measuring channel / filter in the secretion canister blocked.</td>
<td>Check the bacterial filter at the measuring channel and the bacterial filter in the secretion canister. If the bacterial filter at the measuring channel is blocked change the secretion canister.</td>
</tr>
<tr>
<td></td>
<td>Liquids sucked into pump.</td>
<td>Contact the ATMOS service or a certified service partner. The device must be checked.</td>
</tr>
<tr>
<td>„Vacuum too high“</td>
<td>Excessively high vacuum applied from the outside.</td>
<td>Check for correct hose connections.</td>
</tr>
<tr>
<td></td>
<td>Ventilation valve is defect.</td>
<td>Contact the ATMOS service or a certified service partner. The device must be checked.</td>
</tr>
<tr>
<td>„Battery low“</td>
<td>Battery almost empty.</td>
<td>Connect device to the supply network. The battery is charged and the soc (state of charge) is indicated in the display.</td>
</tr>
<tr>
<td>„Service required“</td>
<td>Watch Dog Jumper not set.</td>
<td>Contact the ATMOS service or a certified service partner. The device must be checked.</td>
</tr>
<tr>
<td>System shut down.</td>
<td>Battery empty.</td>
<td>Connect device to the supply network. The battery is charged and the soc (state of charge) is indicated in the display.</td>
</tr>
<tr>
<td>High temperature of the device</td>
<td>Ventilation slots are covered.</td>
<td>Please ensure sufficient air ventilation. Contact the ATMOS service or a certified service partner. The device must be checked.</td>
</tr>
<tr>
<td>Leakage test failed.</td>
<td>Internal error</td>
<td>Contact the ATMOS service or a certified service partner. The device must be checked.</td>
</tr>
<tr>
<td></td>
<td>Secretion canister is leaking.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Hose system is not completely closed.</td>
<td></td>
</tr>
<tr>
<td>Flow readout is always in 0 l/min.</td>
<td>Component error</td>
<td>1) Check whether the flow is also 0 l/min when the system is open.</td>
</tr>
<tr>
<td></td>
<td>Secretion has entered the device.</td>
<td>2) Contact the ATMOS service or a certified service partner. The device must be checked.</td>
</tr>
</tbody>
</table>
## 11.0 Technical data

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Voltage</strong></td>
<td>100-240 V~/; 50/60 Hz</td>
</tr>
<tr>
<td><strong>Power consumption</strong></td>
<td>Max. 70 VA</td>
</tr>
<tr>
<td><strong>Integrated battery</strong></td>
<td>Lithium-Ionic, 14,4 V nominal, 2150 mAh nominal</td>
</tr>
<tr>
<td><strong>Fuses</strong></td>
<td>1 x T 1,25 A/H, 250 V</td>
</tr>
<tr>
<td><strong>Other safety equipment</strong></td>
<td>Pressure control valve „Pop-off valve“ in the canister</td>
</tr>
<tr>
<td></td>
<td>Vacuum limitation in the device to approx. 150 mbar</td>
</tr>
<tr>
<td></td>
<td>Acoustic and optical error warnings</td>
</tr>
<tr>
<td><strong>Pump performance</strong></td>
<td>Free flow 18 +/- 2 l/min</td>
</tr>
<tr>
<td></td>
<td>Vacuum adjustable from -5 mbar to -100 mbar, step size -1 mbar</td>
</tr>
<tr>
<td><strong>Display</strong></td>
<td>Graphic display, colour, with background lighting</td>
</tr>
<tr>
<td></td>
<td>Display of target vacuum and actual vacuum in mbar, cmH₂O, kPa and flow in l/min.</td>
</tr>
<tr>
<td><strong>Data memory</strong></td>
<td>Internal memory for therapy data: 2,5 MB. Up to 12 days recording possible.</td>
</tr>
<tr>
<td><strong>Canister</strong></td>
<td>ATMOS® secretion canister, transparent, with integrated water lock, pressure control valve, graduation. Max. volume of 2 l, connection to the device with „Direct-Docking-System“</td>
</tr>
<tr>
<td></td>
<td>Material: PC</td>
</tr>
<tr>
<td><strong>Suction hose</strong></td>
<td>ATMOS® disposable suction hose for thoracic, double lumen with integrated bacterial filter in the measuring channel, 180 cm length</td>
</tr>
<tr>
<td><strong>Operating time</strong></td>
<td>Continuous operation in the specified temperature range. Simultaneous battery recharging and operation possible.</td>
</tr>
<tr>
<td><strong>Battery operation time at maximum continuous suction.</strong></td>
<td>1 h</td>
</tr>
<tr>
<td><strong>Battery operation time in normal operation (without fistula)</strong></td>
<td>12 h</td>
</tr>
<tr>
<td><strong>Battery recharging time</strong></td>
<td>Fully recharged (at least 95 %) in approx. 2.5 h</td>
</tr>
<tr>
<td><strong>Earth leakage current</strong></td>
<td>Max. 0.5 mA</td>
</tr>
<tr>
<td><strong>Patient leakage current</strong></td>
<td>Max. 0.01 mA</td>
</tr>
<tr>
<td><strong>Ambient conditions for transport/delivery</strong></td>
<td>-10...+50°C</td>
</tr>
<tr>
<td></td>
<td>30...95 % humidity without condensation at air pressure 700...1060 hPa</td>
</tr>
<tr>
<td><strong>Operation</strong></td>
<td>+10...+35°C</td>
</tr>
<tr>
<td></td>
<td>30...95 % humidity without condensation at air pressure 700...1060 hPa</td>
</tr>
<tr>
<td><strong>Maximum operating altitude</strong></td>
<td>3000 m (NN)</td>
</tr>
<tr>
<td><strong>Contamination level</strong></td>
<td>2</td>
</tr>
<tr>
<td><strong>Overvoltage category</strong></td>
<td>II</td>
</tr>
<tr>
<td><strong>Dimensions (HxWxD)</strong></td>
<td>Ca. 365 x 250 x 168 mm (H x W x D)</td>
</tr>
<tr>
<td><strong>Weight</strong></td>
<td>3,7 kg (device with canister)</td>
</tr>
<tr>
<td><strong>Housing material</strong></td>
<td>ABS/PC UL 94 V0, grey-white and dove blue</td>
</tr>
<tr>
<td><strong>Noise level</strong></td>
<td>Max. 31 dB (A) @ 1 m (as per ISO 7779)</td>
</tr>
<tr>
<td><strong>Period tests</strong></td>
<td>Inspection according to the manufacturers specifications every 12 months.</td>
</tr>
<tr>
<td>Safety class (EN 60601-1)</td>
<td>II, protective earth conductor only for EMC protection</td>
</tr>
<tr>
<td>---------------------------</td>
<td>------------------------------------------------------</td>
</tr>
<tr>
<td>Degree of protection</td>
<td>Type CF, defibrillator-proof, recovery time 10 seconds</td>
</tr>
<tr>
<td>Type of protection</td>
<td>IP X0</td>
</tr>
</tbody>
</table>
| Applied standards         | EN 60601-1:  
                            | EN 60601-1/-2: 
                            | EN ISO 10079-1             |
| Classification in         | II a                                                  |
| accordance with Appendix IX EC Directive 93/42/EEC |                                                      |
| CE marking                | CE 0124                                               |
| GMDN code                 | 36787, suction unit thoracic                          |
| UMDNS code                | 10-218 Suction device, thoracic                      |
| REF                       | 312.1000.0 ATMOS® S 201 Thorax                        |

Technical data unchanged since: 10.12.2015
12.0 Disposal

- Please observe national disposal regulations (e.g. waste incineration).
- Device and accessories must be decontaminated prior to disposal as secretion residuals could lead to danger of a third party.
- Pay attention to a careful separation of the different materials.
- The housing is recyclable.
- There is a lithium-ionic battery included in the ATMOS® S 201 Thorax which must be disposed of in accordance with applicable guidelines.

Disposal within the EC

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 in 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. It must be assumed that such suction devices can be contaminated. Therefore, according to the regulations of the EAR foundation (Used Electrical Appliances Register) is this type of device excluded from the ElektroG regulations. 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 canisters and tubes must be removed. The device surface must be disinfected.
13.0 Notes on EMC (Electromagnetic compatibility)

- 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 power supplies and cables than stated may lead to an increased emission or a reduced interference immunity of the equipment or system.
- The electrical medical device must not be stacked next to or with other devices. When operation is required close to or in combination with other equipment, the electrical medical equipment must be observed to verify its intended operation in this arrangement.

Guidance and manufacturer’s declaration - electromagnetic emissions

The ATMOS® S 201 Thorax is intended for use in the electromagnetic environment specified below. The customer or user of the ATMOS® S 201 Thorax should ensure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Emissions Test</th>
<th>Compliance</th>
<th>Electromagnetic Environment - Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF Emissions acc. to CISPR 11</td>
<td>Group 1</td>
<td>The ATMOS® S 201 Thorax uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td>
</tr>
<tr>
<td>Harmonic emissions according to IEC 61000-3-2</td>
<td>Class A</td>
<td>The ATMOS® S 201 Thorax is suitable for use in all establishments, including domestic, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td>
</tr>
<tr>
<td>Voltage fluctuations/flicker according to IEC 61000-3-3</td>
<td>Corresponds</td>
<td></td>
</tr>
</tbody>
</table>

Guidance and manufacturer’s declaration - electromagnetic immunity

The ATMOS® S 201 Thorax is intended for use in the electromagnetic environment specified below. The customer or user of the ATMOS® S 201 Thorax should ensure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>IEC 60601- Test Level</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment - Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge (ESD) according to IEC 61000-4-2</td>
<td>± 6 kV Contact</td>
<td>± 6 kV Contact</td>
<td>Floors should be wood, concrete, or ceramics tile. If floors are synthetic, the relative humidity should be at least 30 %.</td>
</tr>
<tr>
<td></td>
<td>± 8 kV Air</td>
<td>± 8 kV Air</td>
<td></td>
</tr>
<tr>
<td>Fast electrical transient/ burst IEC 61000-4-4</td>
<td>± 2 kV Mains</td>
<td>± 2 kV Mains</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td></td>
<td>± 1 kV I/Os</td>
<td>Inapplicable</td>
<td></td>
</tr>
<tr>
<td>Surges IEC 61000-4-5</td>
<td>1 kV Differential</td>
<td>1 kV Differential</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td></td>
<td>2 kV Common</td>
<td>2 kV Common</td>
<td></td>
</tr>
<tr>
<td>Magnetic field at power frequency 50/60 Hz acc. to IEC 61000-4-8</td>
<td>3 A/m</td>
<td>applicable</td>
<td>Power frequency magnetic fields should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3 A/m</td>
<td></td>
</tr>
</tbody>
</table>
### Guideline and manufacturer's declaration - electromagnetic immunity

The ATMOS® S 201 Thorax is intended for use in the electromagnetic environment specified below. The customer or user of the ATMOS® S 201 Thorax should ensure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>IEC 60601- Test Level</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment - Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Voltage Dips / Dropout IEC 61000-4-11</td>
<td>&lt; 5 % UT (&gt; 95 % Dip of the UT) For 0.5 cycles</td>
<td>&lt; 5 % UT (&gt; 95 % Dip of the UT) For 0.5 cycles</td>
<td>Mains power quality should be that of a typical commercial or hospital environment. If the user of the ATMOS® S 201 Thorax demands continued function even in case of interruptions of the energy supply, it is recommended to supply the ATMOS® S 201 Thorax from an uninterruptible current supply or a battery.</td>
</tr>
<tr>
<td></td>
<td>40 % UT (60% Dip of the UT) For 5 cycles</td>
<td>40 % UT (60% Dip of the UT) For 5 cycles</td>
<td></td>
</tr>
<tr>
<td></td>
<td>70% UT (30 % Dip of the UT) For 25 cycles</td>
<td>70% UT (30 % Dip of the UT) For 25 cycles</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&lt; 5 % UT (95 % Dip of the UT) For 5 sec</td>
<td>&lt; 5 % UT (95 % Dip of the UT) For 5 sec</td>
<td></td>
</tr>
</tbody>
</table>

NOTE: UT is the alternating mains voltage prior to application of the test levels.

**Conducted RF IEC 61000-4-6**

- **V1 = 3 V_{eff}**
- **150 kHz to 80 MHz**
- **3 V**

- **Recommended distances:**
  - \(d = (3.5 / V1) \ast \sqrt{P}\)
  - \(d = (3.5 / E1) \ast \sqrt{P}\) from 80 MHz to 800 MHz
  - \(d = (7.0 / E1) \ast \sqrt{P}\) from 800 MHz to 2500 MHz

  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:
NOTE 1  By 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.

a  The field strength of stationary transmitters, such as base stations of cellular phones and mobile terrain radio equipment, amateur radio transmitters, cbm broadcast and TV stations cannot be predestined exactly. To determine the electromagnetic environment in regard to stationary transmitters, a study of the location is to be considered. If the measured field strength at the location where the ATMOS® S 201 Thorax is used exceeds the above compliance level, the ATMOS® S 201 Thorax 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 ATMOS® S 201 Thorax.

b  Over the frequency range of 150 kHz to 80 MHz, field strengths should be lower than 3 V/m.

**Recommended separations between portable and mobile RF Communications equipment and the ATMOS® S 201 Thorax**

The ATMOS® S 201 Thorax is intended for use in electromagnetic environment in which radiated disturbances are controlled. The customer or user of the ATMOS® S 201 Thorax can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications equipment and the ATMOS® S 201 Thorax as recommended below, according to the maximum output power of the communications equipment.

<table>
<thead>
<tr>
<th>Safety distance, depending on transmit-frequency m</th>
<th>Nominal output of the transmitter W</th>
</tr>
</thead>
<tbody>
<tr>
<td>150 kHz to 80 MHz</td>
<td>80 MHz to 800 MHz</td>
</tr>
<tr>
<td>d = ( \frac{3.5}{3} \sqrt{P} )</td>
<td>d = ( \frac{3.5}{3} \sqrt{P} )</td>
</tr>
<tr>
<td>0.01</td>
<td>0.12</td>
</tr>
<tr>
<td>0.1</td>
<td>0.37</td>
</tr>
<tr>
<td>1</td>
<td>1.16</td>
</tr>
<tr>
<td>10</td>
<td>3.69</td>
</tr>
<tr>
<td>100</td>
<td>11.66</td>
</tr>
</tbody>
</table>

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

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

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