ATMOS MedizinTechnik

Operating Instructions

ATMOS C 051 Thorax

English

These operating instructions are valid from software version 1.3.21.

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CE 0124

Table of contents

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

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1.0 Introduction

1.1 Notes on operating instructions

These operating instructions are valid from software version 1.3.21.

These operating instructions contain important notes on how to operate the ATMOS C 051 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 periodic tests in conjunction with professional execution provide for operational safety and readiness for use of your ATMOS C 051 Thorax and are therefore a must besides regular cleaning.

Repair work and period tests may be carried out only by expert personnel authorised by ATMOS. By applying only original spare parts you will have the guarantee that operational safety, readiness for work and the value of your ATMOS C 051 Thorax will be preserved.

- The product ATMOS C 051 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 C 051 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 starting 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 C 051 Thorax

Name: ATMOS C 051 Thorax

Main function: Digital device for mobile thoracic drainage.

Medical indication / application: Restoring 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 surgical opening of the thorax.

Specification of the main function: The ATMOS C 051 Thorax is a device for mobile, digital 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 [1], 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 thoracic drainage system 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. Not suitable for use on patients with large fistulas and coagula.

The product is: active

Sterility: Not required for the basic device. Secretion canister and hose system are sterile.

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

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

1.2.2 Intended use ATMOS C 051 Thorax secretion canister

Name: Secretion canister for the ATMOS C 051 Thorax

Main function: Transport of generated vacuum from the basic device to the patient-side hose end. Collection of secretion and air through the secretion hose into the secretion canister.

Medical indication / application: Restoring 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 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-side hose 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 thoracic drainage system may only be applied by healthcare professionals. The secretion canister and the hose system are sterile and disposable; they can be used in the sterile OT area.

Contraindication: No application with thoracic drainage systems other than the ATMOS C 051 Thorax. No separate application of the secretion canister and the hose system (i.e. 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.

Disposable product / reprocessing: Secretion canister is a disposable product.

1.2.3 Intended use ATMOS C 051 Thorax hose system

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

Main function: Transport of generated vacuum from the basic device to the patient-side hose 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: Restoring 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 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-side hose 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 thoracic drainage system may only be applied by healthcare professionals. The secretion canister and the hose system are sterile and disposable; they can be used in the sterile OT area.

Contraindication: No application with thoracic drainage systems other than 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 (i.e. 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 a disposable product.

1.3 Function

The ATMOS C 051 Thorax is an exceptionally handy, portable, 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. The secretion is collected in the secretion canister. Its capacity is 800 ml. 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. The device is equipped with a disposable strap and a carrying handle. These enable mobility and mounting of the device e.g. to the patient bed. A universal bracket or the standard rail bracket can be ordered separately as accessories.

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:	-20...+50 °C; 5...95 % air humidity without condensation at air pressure 700...1060 hPa
Operation and battery charging:	+5...+35 °C; 20...80 % air humidity without condensation at air pressure 700...1060 hPa
Operating altitude:	max. 3000 m

1.5 Explanation of pictures and symbols

Short cuts / symbols contained in these operating instructions


Follow the arrows


Please press where dot indicates


Activate the optional foot switch


Please read, important information

• General information

• Numeration

\- Subnumeration


Check


Move, plug... in this direction


Turn, shift ... in this direction


Replace

Engage, check correct fit

Graphic symbols contained in these operating instructions

Warning, special diligent notice

Important information

Symbols used for the ATMOS C 051 Thorax and its accessories

Application parts type BF

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.

SN Serial number

Protection class II

REF Order number

Fuse

Manufacturing date

Observe operating instructions!

Sterile unless package is damaged or opened.

Follow operating instructions (blue)

IP 33 Degree of protection

Manufacturer

Eurasian conformity

Professional disposal

GOST Certificate (Russia)

2.0 For your safety

2.1 Notices

Note

Damage to the device due to improperly installed protective contact socket!

- The ATMOS C 051 Thorax is designed in accordance with IEC 60601-1/EN 60601-1 and with VDE protection class ll.
- 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 C 051 Thorax fully complies with the electromagnetic immunity requirements of standard IEC 60601-1-2 / EN 60601-1-2 „Electromagnetic compatibility - Medical Electrical Devices“.

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 damage to the diaphragms of the pump 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.
- The warning message "Device in critical tilt" serves as preventive information to avoid functional impairment caused by tilting over (for example a blocked bacterial filter in the secretion canister).

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.

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 user is obliged to regularly check the functionality of the drainage system during operation.
- The control panel must be clearly visible and accessible for the operator.
- 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 C 051 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.
- 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.
- Not suitable for use on patients with large fistulas and coagula. For these patients, ATMOS recommends the use of a device with greater suction capacity (e.g. ATMOS S 201 Thorax).

Advice on disposal

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

Wrong evaluation

- Prior to using the device it is recommended to check the leak tightness at the start of therapy (see 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.

Optional functions

- The function of the leakage test, and the warning message "Device in critical tilt" are active at factory settings. If these functions are not desired, they can be deactivated in the user settings (Chapter „4.9 User settings“ on page 29).
- The leakage test is recommended for checking the leak tightness prior to each application.
- The warning message "Device in critical tilt" serves as preventive information to avoid functional impairment caused by tilting over (for example a blocked bacterial filter in the secretion canister).

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 level of the patient 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.
- 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 patients safety.
- Faulty respectively damaged components must be replaced immediately.
- Check the hose system at regular intervals. Observe the instructions from the attending physician.
- The bending of the patient hose leads to an interruption of the therapy and incorrect measurements.
- The hose system may not be clamped. Ideally clamp the thoracic catheter when changing the secretion canister.
- 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.
- Do not modify the device.
- Please pay attention to the period tests in chapter „9.0 Maintenance and Service“ on page 46.
- Assembly, repairs, modifications and period tests may only be carried out by authorized persons.

- Do not allow liquids (such as disinfectants or secretions) to enter the device or recharging unit.
- If disinfectant has penetrated the device, then it must be dried thoroughly and subsequently an efficiency control must be conducted. It should be tested if the target vacuum can be reached in a closed system, as well as if there is a flow > 4 l/min after a short while, when the system is open. If not it may not be operated again until it has been checked by the customer service centre.
- If secretion has entered or is sucked into the device then it must be sent to the manufacturer or an authorized service partner.
- The power supply may not become damp.
- Don´t take a shower / bath with the device.

Danger of explosion due to unobserved ambient conditions!

- The ATMOS C 051 Thorax is not designed for application 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 technical data (chapter „11.0 Technical data“ on page 50) must be strictly observed.

Risk of infection

- Prior to use, check the packaging of the sterile products, the secretion canister system and the hose system for intactness. Do not use defective secretion canisters or hose systems .

- Repeated reuse of components which are marked with a ② 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.
- 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 has fallen: Check the device for visible damage. A leakage test is recommended. 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 C 051 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)

	Description		Description
	Basic device		Disposable strap
	Battery recharging unit		Carrying handle
	Mains cable		Quick - Start Guide
	Operating Instructions		

3.2 Device overview

Front side

❶ Touchscreen (touch-sensitive display)
❷ On / Off sensor
❸ Charging socket
❹ Release button of secretion canister
❺ Light sensor
❻ Clips for the carrying strap

Rear side

- ❼ Connection for secretion canister
- ❽ Connection for clips
- ❾ Type plate
- ❿ Secretion canister guide
- ⓫ Measuring and rinsing hose connection
- ⓬ Cover sticker (no function for user)
- ⓭ Connection for USB flash drive (therapy data transfer)

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.

3.3 Start up

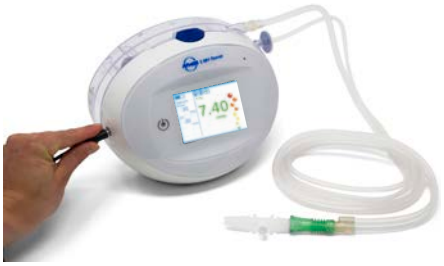
- Remove the device from the packaging. Check whether the mains current on the type plate of the recharging unit corresponds to the mains power supply.
- Peruse safety information in chapter „2.0 For your safety“ on page 9 prior to starting up the device for the first time.
- The battery must be fully charged prior to the first use. Charging time approx. 2.5 hours.
- Place the device on a safe and even surface.
- Plug in the mains cable to recharge the battery.
- Following transportation at low temperatures the appliance must be held for up to six hours at ambient temperature before first start-up. If the device is not acclimatized it may not be used as damages to the electronic components could occur.
- Always have at least one more secretion canister at hand as the device can only be operated with the specific ATMOS secretion canister.

3.3.1 Battery charging

Each bar of the symbol  represents 20% battery charge.

Attention! Prior to first start up of the ATMOS C 051 Thorax, the battery must be fully charged. Only the battery recharging unit supplied by ATMOS should be used. Please note the information on how to handle rechargeable batteries in chapter „9.4 Handling of batteries“ on page 47. 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: The battery can no longer be charged if the battery temperature is above 35°C .

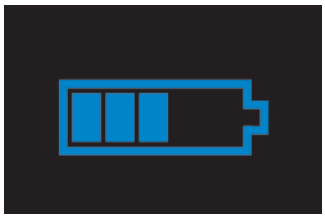


1. Insert the charging plug of the charger into the charging socket on the device.
2. Connect the battery recharging unit with the supplied country-specific power cable.
3. Plug the power plug into the power socket.
   ↳ The ATMOS C 051 Thorax displays the symbol on the display. The bar at the right flashes.As long as the power plug is plugged in, the icon is green.

When the battery is fully charged the icon stops flashing.

4. Disconnect the power plug from the socket.
5. Remove the charging plug from the charging socket.

As soon as the battery charge level is less than 20%, the drainage unit displays a warning window and triggers an audible warning message (chapter „5.0 Warning messages“ on page 32) Charge the battery in order to continue the therapy without interruption. If the battery is too low for further operation, the ATMOS C 051 Thorax switches off automatically.



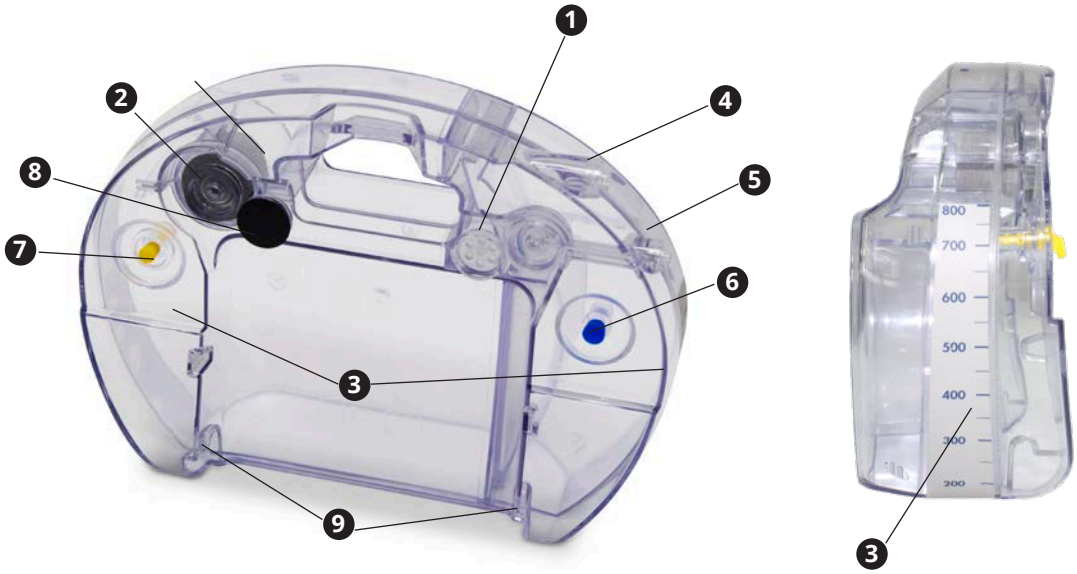
The battery of the ATMOS C 051 Thorax can also be charged when the device is switched off. The state of charge can be seen on the display.

3.3.2 Secretion canister

Important safety information on the secretion canister system

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

3.3.2.1 Secretion canister overview



❶ Pop-off valve (10 mbar high pressure)
❷ Connection to the drainage unit (protected by a hydrophobic bacterial filter)
❸ Scales (in ml)
❹ Connection towards patient (secretion channel)
❺ Connection to patient (measuring and rinsing system)
❻ Cover lid of the secretion channel ❹
❼ Cover lid for the connection to the suction unit ❷
❽ Cover lid for the pop-off valve ❶
❾ Secretion canister guide

3.3.2.2 Pop-off valve

The pop-off valve ❶ is a protection against the occurrence of high pressure which could lead to a tension pneumothorax. The valve opens at a high pressure of ≥ 10 mbar within the canister.

3.3.2.3 Insert secretion canister

Attention! Prior to use check the packaging of the sterile products, the secretion canister system and the hose system for intactness. Do not use defective secretion canisters or hose systems .

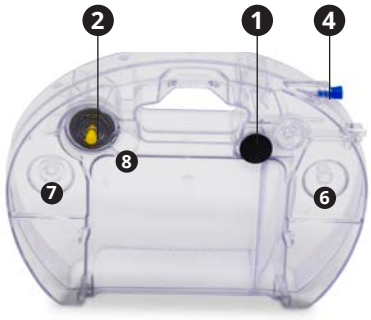
1. Wear disposable gloves and observe the regulations when handling sterile products.
2. Carefully remove the secretion canister from the packaging.
3. Place the secretion canister securely on a horizontal surface.
4. Connect the hose system (Chapter „3.3.3 Connecting the hose system“ on page 18).
5. Insert the canister guides ❾ of the secretion canister into the canister guides (❿ see Device overview) on the rear side of the device. Hold the secretion canister slightly angled to the device.
6. Press the secretion canister against the device until it audibly enganges. The release button returns to its initial position.
7. Slightly pull on the secretion canister to ensure that it is tightly fitted to the device.
8. Switch on the device. A leakage test is recommended.
9. Start the therapy.

3.3.2.4 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 blue secretion canister by pressing the blue release button (❹ see Device overview), angle the secretion canister slightly to the rear and remove it upwards from the guides.
7. Place the secretion canister on a horizontal surface.

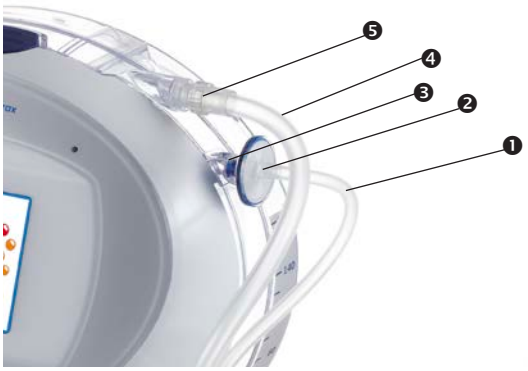


8. Release the 2 Luer-Lock connections by a counter-clockwise rotation to separate the secretion canister from the hose system. Pay attention as secretion could be found in the connection space.
9. Remove the blue cover cap ❻ and cover the upper Luer-Lock connection with it (secretion channel ❹).
10. Remove the black cover lid ❽ and cover the pop-off valve with it ❶.
11. Remove the yellow cover cap ❼ and cover the connection to the drainage unit with it (bacterial filter ❷).
12. Correctly dispose of the secretion canister.

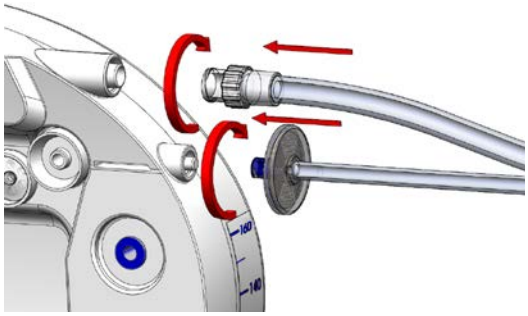
Reinserting the secretion canister

13. Insert the new secretion canister (see chapter „3.3.2.3 Insert secretion canister“ on page 17).
14. Open the clamp at the thoracic catheter.

3.3.3 Connecting the hose system



❶ Measuring and rinsing channel
❷ Hydrophobic bacterial filter
❸ Luer-Lock 4 mm
❹ Secretion channel
❺ Luer-Lock 6 mm



Attention! Prior to use check the packaging of the sterile products, the secretion canister system and the hose system for intactness. Do not use defective secretion canisters or hose systems .

1. Carefully remove the sterile hose system from the sterile packaging.
2. Connect the Luer-Lock with the bacterial filter ❷ to the lower canister connection (❸ on the secretion canister) by a clockwise rotation.
3. Connect the Luer-Lock with the larger diameter to the upper connection of the canister (❷ on the secretion canister) by a clockwise rotation.
4. It is recommended to carry out a leakage test (see chapter „4.4 Leakage test“ on page 22).
5. 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.

4.0 Operation

4.1 Explanation of the display

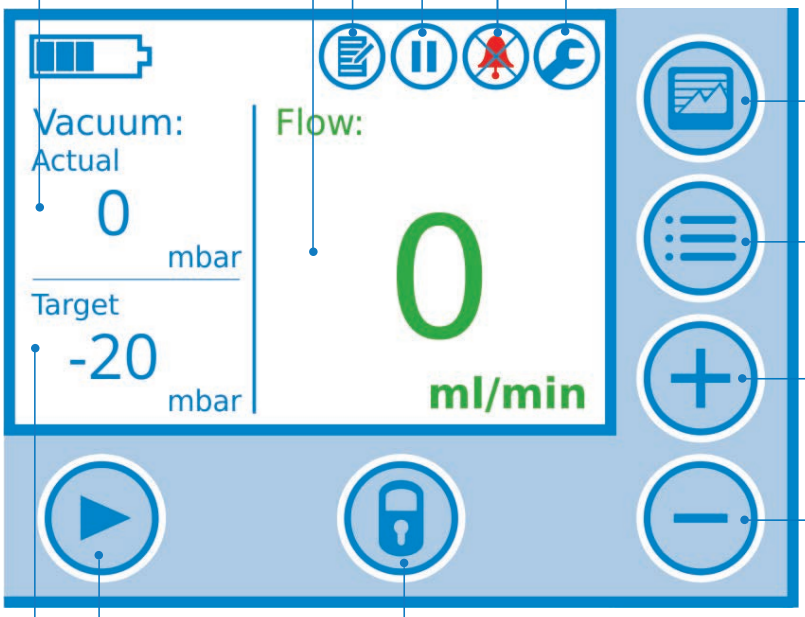
Display of the actual fistula

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.

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

Key lock manual

Target vacuum

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

Key lock activated

Flow displayed as bubbles

Each additional coloured bubble represents an additional flow.

None: 0 - < 50 ml/min

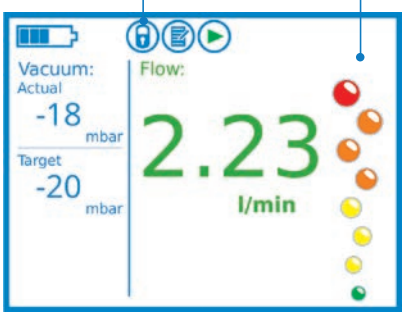
Green: 50 - < 100 ml/min

Yellow: 100 - < 630 ml/min

Orange: 630 ml - < 2.01 l/min

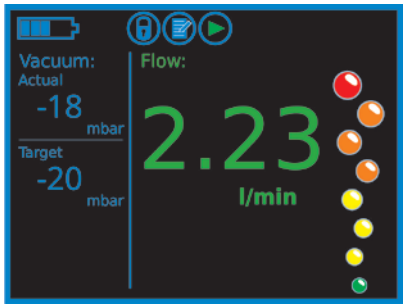
Red: >2.01 l/min to maximum

Up to 1.00 l/min the flow is displayed in ml/min.



Day/Night Mode

The ATMOS C 051 Thorax has a day/night mode, i.e. the device adjusts automatically to the light conditions in a room.



Under low ambient light conditions display has dark background illumination.

4.2 Buttons and display symbols

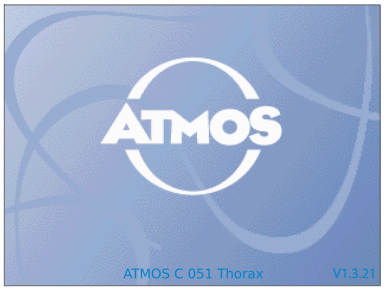
4.2.1 Buttons

Figure	Function
	Decrease the target vacuum/ in the menu: Decrease selected value
	Increase the target vacuum / in the menu: Increase selected value
	Graphic diagram of the therapy
	Open the user settings
	Save entry
	Confirm information
	Back / Exit menu
	Warning / suppress the warning
	Changeover to vacuum scaling
	Changeover to time scaling
	Changeover to flow scaling
	Start therapy
	Stop therapy
	Hold / restart graphic
	Increase maximum of axis
	Decrease maximum of axis
	Scroll up the list
	Scroll down the list
	Activate key lock

4.2.2 Display symbols

Figure	Function
	Battery status display / charging indicator
	Key lock activated
	Therapy recording in progress
	Therapy on hold
	Therapy in progress
	Upcoming warning suppressed
	Annual inspection is required

4.3 Switching on

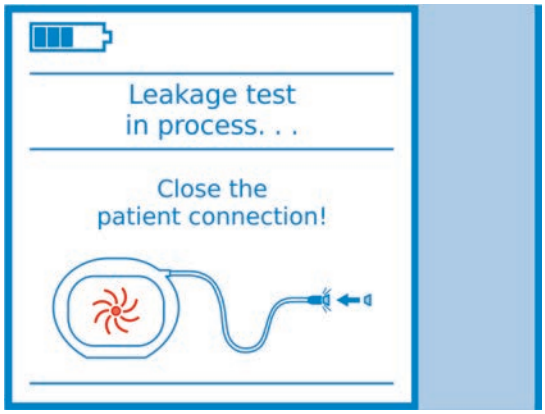


1. To switch on the ATMOS C 051 Thorax, touch the sensor above the symbol for 2 seconds.
2. The ATMOS logo appears with the software version number in the bottom right corner.
3. After a short time, depending on the user settings the leakage test starts automatically (Chapter „4.4 Leakage test“ on page 22).
4. Subsequently "Therapy progress" will appear in the display. By pressing the buttons you can start a new therapy recording or continue recording.
5. The main display appears.
6. The device is now ready for use.

4.4 Leakage test

The leakage test checks the entire system tightness. The function of the leakage test is active at factory settings. The leakage test can be deactivated (Chapter „4.9 User settings“ on page 29).

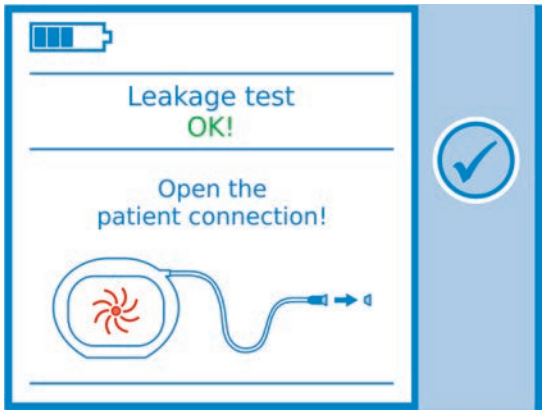
Generally the leakage test is recommended for checking the leak tightness before each start of therapy.



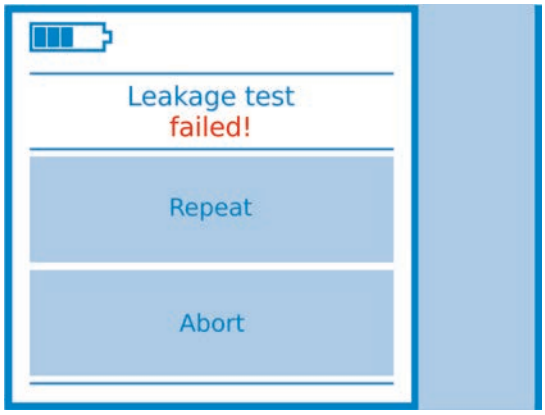
If the leakage test is activated, it will start automatically after the device has been started.

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.

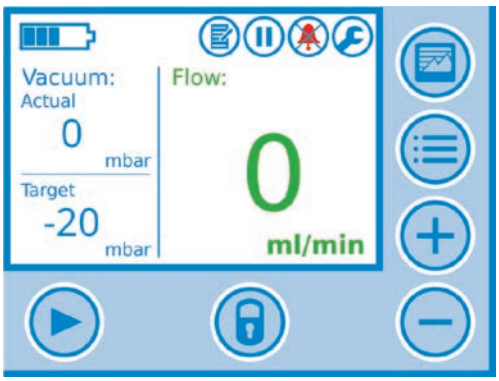
ATTENTION: If the leakage test is operated accordingly, the leakage must not be ignored. If the device dropped down it must not be operated.

Send in the device for repair. Treatment with defective equipment can cause fatal injuries to the patient.

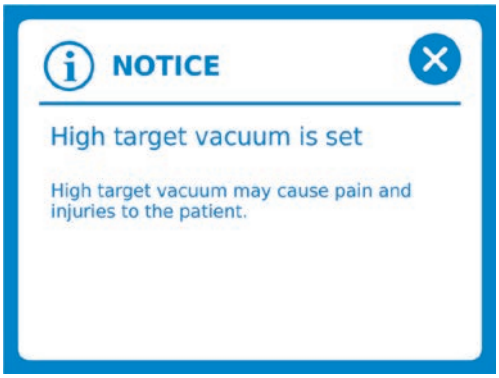
The intention of "abort the leakage test "is to skip the test if a standard test under given condition is not possible.

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 in the target vacuum takes effect immediately. 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 target vacuum of -20 mbar is preset when starting the device.



If target vacuum is adjusted over -50 mbar the notice appears ,,High target vacuum is set".

4.5.2 Suction

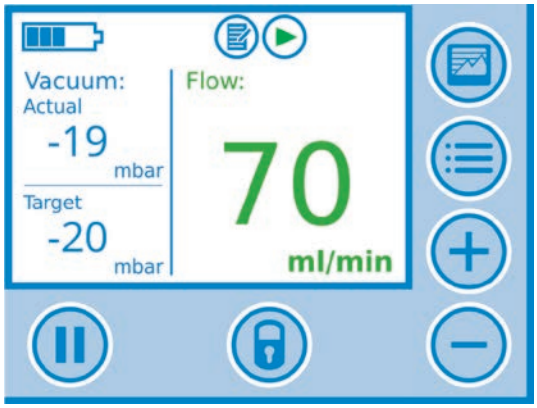
- When the device is switched on the pump is not activated. This is visible due to the ⏸ symbol in the right upper corner. By pressing the ▶ button the pump starts.
- The symbol ▶ in the right upper corner of the main screen shows that the pump is running.
- By pressing the ⏸ button the pump will be stopped.
- The ATMOS C 051 Thorax has a vacuum regulator. On the one hand this means, that the integrated pump only starts, if the actual vacuum does not correspond to the target vacuum. On the other hand the pump 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.

4.6 Key lock

The ATMOS C 051 Thorax has an automatic key lock.

1. Automatic activation of the key lock

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

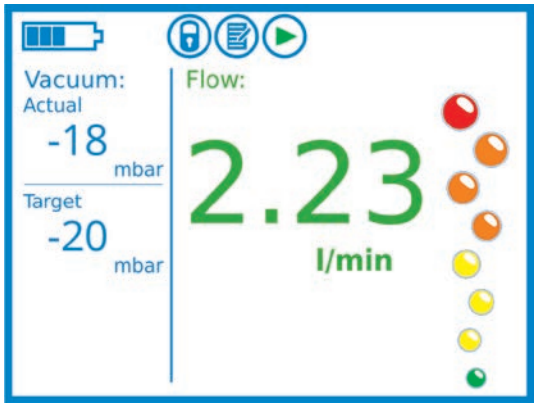


2. Manually activate the key lock

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

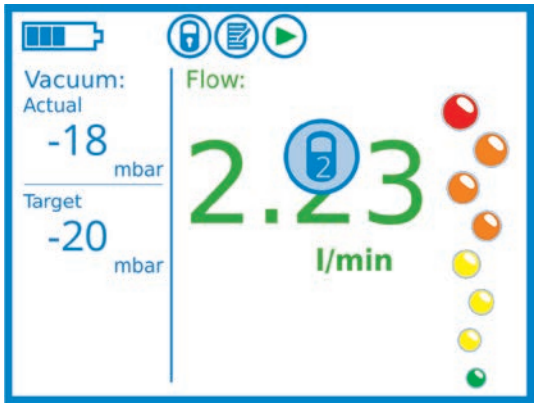
Press the symbol to activate the key lock.

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



3. Deactivate the key lock

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

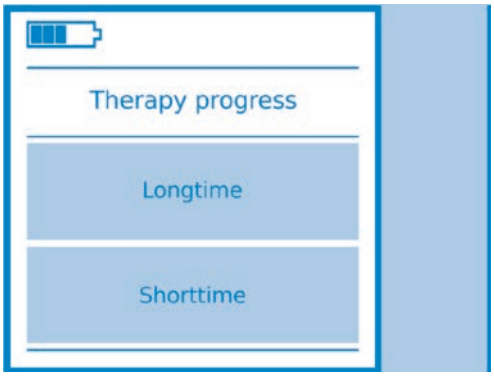


By touching the contact point the second contact point appears .

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.

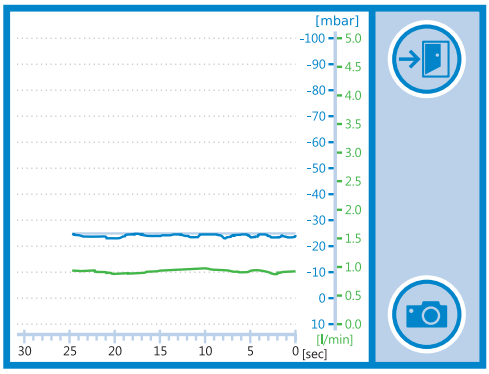
4.7 Therapy progress



The ATMOS C 051 Thorax offers 2 graphs 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 you choice e.g. long / short time.

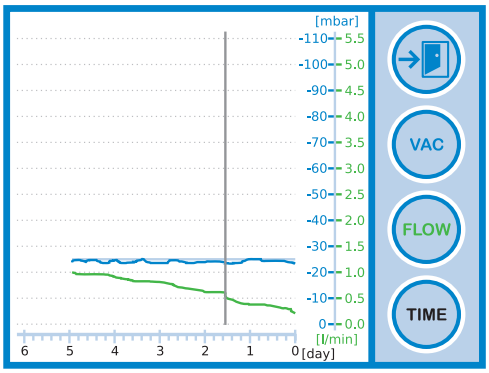


1.1.1 Short time

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.

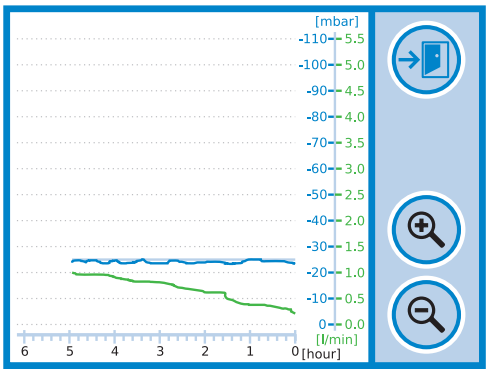
By pressing the button you will return to the main menu.



1.1.2 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 VAC, FLOW or TIME 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 – 0.55 l/min and 0 – 5.5 l/min in 4 steps.
- Vacuum scaling:
  - The scaling can be selected between 0 - 110 mbar (= cm H_2O) and 0 - 22 mbar (= cm H_2O) in 3 steps.



4.7.1 Transfer of therapy data

You may transfer the therapy data to a USB flashdrive. The therapy data is saved as a PDF- and

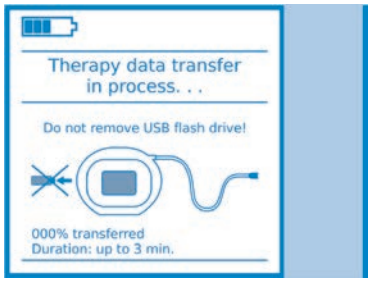
Excel-file. If you continue the therapy after the data transfer, the data will still be recorded. The transmitted data will not be deleted. If you are starting a new therapy, the previous data will be overwritten.

ATMOS recommends: Perform the therapy data transfer at the end of the patient's therapy.

Suitable USB flash drives for therapy data read-out

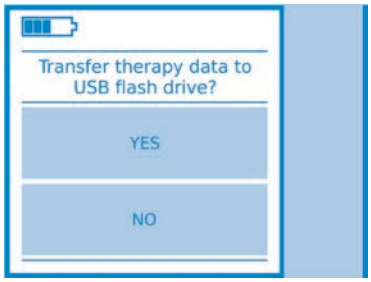
- Manufacturer: SanDisk, Kingston, ATMOS flash drive
- System: USB 2.0, 3.0, 3.1
- Capacity: ≤ 32 GB
- Formatting: FAT 32
- No stored encryption

ATMOS recommends: Use a USB flash drive without content. Other USB flash drives may not be recognized, thus the therapy data read-out does not start.



Start transfer

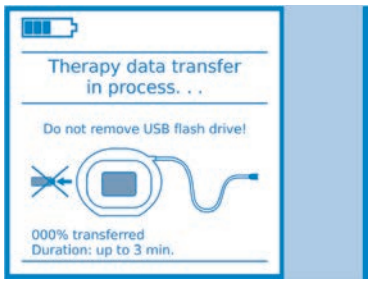
- Connect the USB flash drive, see page 14.
- The device prepares for the therapy data transfer.



- 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“.

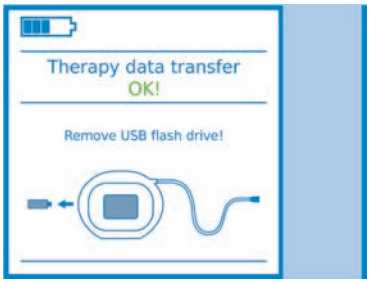
Termination

- 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.

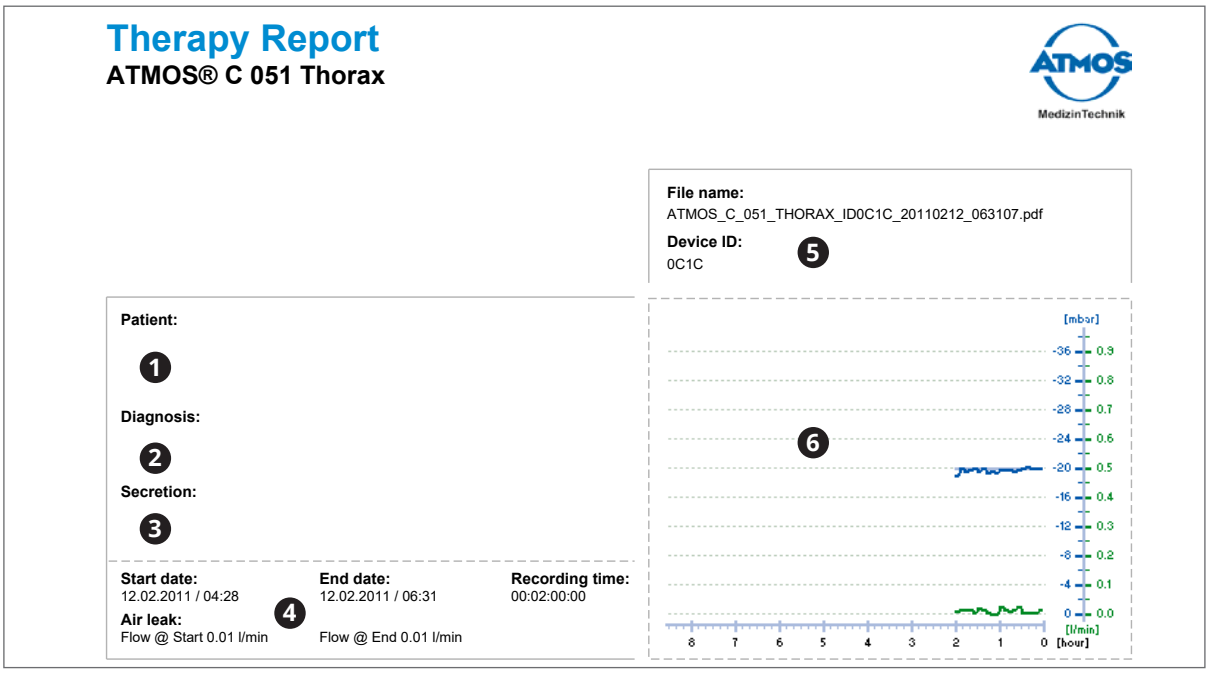
- Connect the secretion canister.
- Continue the therapy
- Reopen the clamp at the thoracic catheter.

4.7.2 Reading out the therapy data

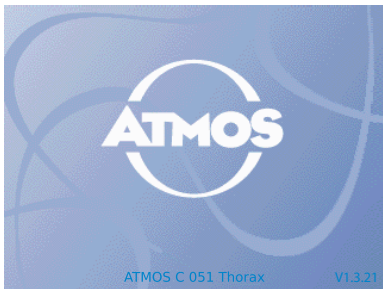
- Connect the USB flash drive to PC.
- Open the folder on the USB flash drive. This folder contains a PDF file and an excel file.
- Open the PDF file.
- Fill in the desired Information:
  - ❶ Patient data
  - ❷ Diagnosis
  - ❸ Description of the secretion

Following information can be seen in the report:

- ❹ Beginning and end of recording, flow at beginning and end of recording
- ❺ File name und device ID
- ❻ Graphic diagram of the therapy data

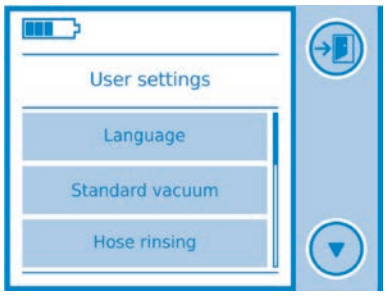


4.8 Switch off the device



- To switch off the ATMOS C 051 Thorax stop the therapy and touch the sensor for 2 seconds.
- The ATMOS logo appears on the screen and the device shuts down.

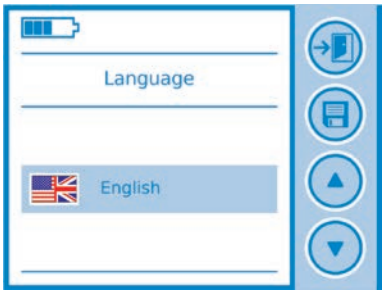
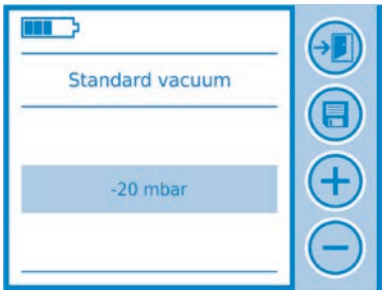
4.9 User settings

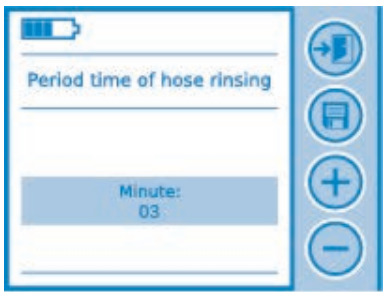
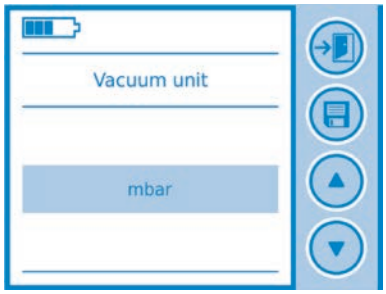
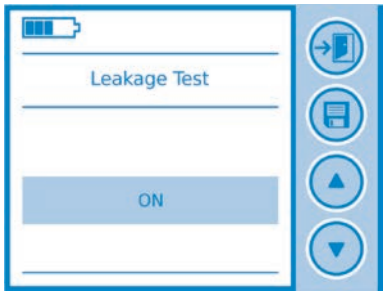
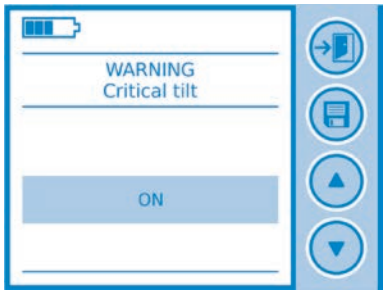
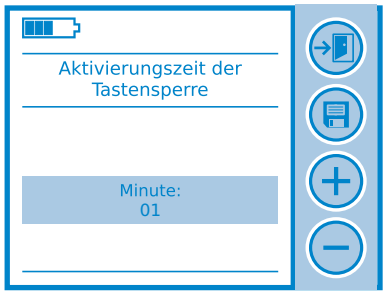


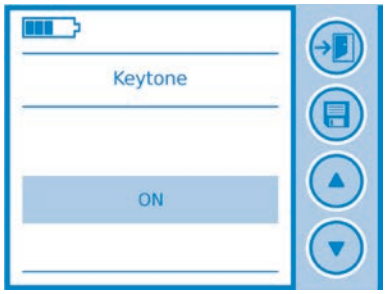
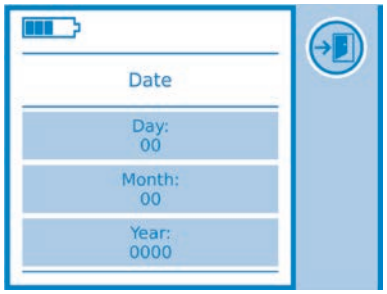
For accessing the user menu please press the button .
Please press the buttons and for moving up and down in the menu selection.
For entering a selection menu press on the text box.
These buttons can be found in every settings menu:

- For accessing the user menu please press the button .
- ⚠ The selected data are only saved if you press the memory key .

In the user settings the following positions can be selected:

	System language	The system language can be adjusted with and .
	Standard-vacuum	When the device is started the standard-vacuum is automatically pre-adjusted. You can use the standard vacuum or change it with and .

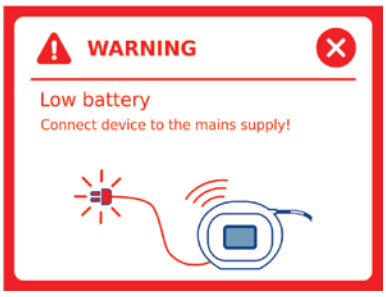
	Period time of hose rinsing	You can change the period time of hose rinsing with ⊕ and ⊖.
	Vacuum unit	The vacuum unit can be adjusted with ▲ and ▼.
	Leakage test	The leakage test can be activated or deactivated with ▲ and ▼.
	WARNING Critical tilt	The warning message device in critical tilt can be activated or deactivated with ▲ and ▼.
	Key lock activation time	You can change the period time for the hose rinsing with ⊕ and ⊖.

	Key tone	The key tone can be activated or deactivated by pressing ▲ and ▼.
	Time	By pressing one of the two control panels (hour or minute) you may enter the individual settings. Now the time can be adjusted with ⊕ and ⊖.
	Date	By pressing one of the three control panels (Day, Month, Year) you may enter the individual settings. Now the date can be adjusted with ⊕ and ⊖.

5.0 Warning messages

⚠ In the event of a warning message the key lock is removed automatically!

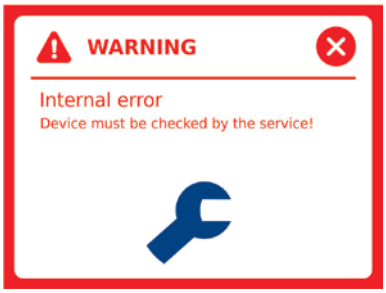
ⓘ In the event of a warning message the system switches to the warning-menu automatically. An error indication is displayed. This indication contains advice for the removal of the cause of error. The acoustic warning message is triggered at the same time. No warning message appears during the start up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

Display	Cause of error	Troubleshooting
	If the required vacuum cannot be reached an acoustic alarm and optical display of the warning message „vacuum too low“ is displayed. Possible causes for this error message: Leakage, blockage of the bacterial filter in the measuring and rinsing hose, 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
	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!
	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 state of charge is indicated in the display.

⚠ The warning message "Device in critical tilt" serves as preventive information to avoid malfunction caused by tilting over (for example a blocked bacterial filter in the secretion canister).

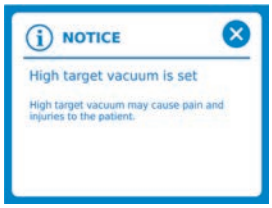
The function of the warning message is active at factory settings. If the warning message "Device in critical tilt" is not required, it can be deactivated (Chapter „4.9 User settings“ on page 29).

Generally the warning message "Device in critical tilt" is recommended to avoid malfunction caused by tipping over.

Display	Cause of error	Troubleshooting
	If the device is in a tilted po-sition the warning „Device in critical tilt" appears.	Place the device in an upright position. The warning signal is automatically deactivated.
	If the therapy has not been started after initial operation the warning "Inactive therapy" appears.	Start therapy by pressing the button.
	Defective battery. The device can no longer be used.	Contact the ATMOS service!

Perform an inspection according to the manufacturer's specifications every 12 months. 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 C 051 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.

6.2 Gravity drainage mode while using the drainage system

A physiological vacuum can be generated by setting the target vacuum to -5 mbar:

The automatic warning messages as well as all measuring functions and the hose rinsing are retained. Thus the physiological vacuum in the thorax is maintained while preserving the digital security features.

⚠ The drainage system must be positioned at the same height as the patient catheter.

7.0 Accessories, consumables and spare parts

Accessories	REF
Universal bracket for the ATMOS C 051 Thorax	316.0200.0
Carrying strap for the ATMOS C 051 Thorax	316.1100.0
Hose clamp	061.0079.0
Carrying handle for the ATMOS C 051 Thorax	317.0090.0
Support for the ATMOS C 051 Thorax	317.1160.0
Power supply unit support for the ATMOS C 051 Thorax	317.1170.0

Consumables	REF
OT set for the ATMOS C 051 Thorax included in the OT set are: 10 x secretion canister 800 ml (sterile) 10 x hose system 800 ml (sterile)	317.1100.0
Hose system, 10 pcs.	312.1170.0
Secretion canister 800 ml, 10 pcs.	317.1000.0
Disposable strap	316.1200.0
Y-port, 50 pcs.	312.1101.0
Paediatrics-port, 1 pc.	312.1102.0
Fir tree port (without Luer-Lock), 1 pc.	312.1103.0
Connection set for thoracic catheter, 50 pcs.	312.1104.0

Spare parts	REF
2-pin power cord	008.0941.0
Power supply unit with ATMOS logo	313.0089.0
Strap hook right for the ATMOS C 051 Thorax	999.2272.0
Strap hook left for the ATMOS C 051 Thorax	999.2273.0
Strap holder for the ATMOS C 051 Thorax	317.0008.0

7.1 Attaching the universal bracket (Accessories)

Turning the universal bracket:

The universal bracket may be attached – horizontally and vertically - to plates (e.g. table boards), pipes and stands with a diameter up to 40 mm.

1. Pull the fixing pin from the fixing at the bottom side of the universal bracket.

2. Turn the holder clamp until the fixing pin clicks into place at the next fixing.

⚠ Ensure that the fixing pin is correctly clicked into place before attaching the thoracic drainage unit on the universal bracket.

Attachment of the universal bracket:

1. Turn the turning knob of the universal bracket counter-clockwise until the clamp can be attached to the desired fixture.
2. Turn the turning knob clockwise to fix the universal bracket.

⚠ Ensure that the universal bracket is firmly attached to the desired fixture.

7.2 Attaching/removing the device to/from the universal bracket

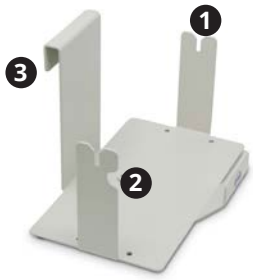
⚠ Firmly hold the ATMOS C 051 Thorax during the whole process.

1. Place the device on the universal bracket. Ensure that the thread at the bottom of the thoracic drainage unit is directly above the fixing screw of the universal bracket.
2. Turn the fixing screw clockwise to mount the device.

To remove the ATMOS C 051 Thorax release the fixing screw by turning anticlockwise.

The thoracic drainage unit must always be attached horizontally.

7.3 Attaching the support to a standard rail



❶ Lateral guides for placement / removal of the device
❷ A recess for connecting the power supply cable to the device
❸ Mounting to a standard rail

7.3.1 Attaching the support directly to a standard rail

1. Attach the support to a standard rail.

☞ Check that the support is properly locked in place before placing the device onto the support.

7.3.2 Attaching / removing the support to / from the universal bracket

☞ Firmly hold the support during the entire process.

1. Attach the universal bracket (Chapter „7.1 Attaching the universal bracket (Accessories)“ on page 35).
2. Place the support on the universal bracket by positioning the thread on the bottom of the support over the fixing screw of the universal bracket
3. Turn the fixing screw on the universal bracket in a clockwise direction in order to mount the support to it.

☞ The support with the device must always be affixed in a horizontal position.

4. To remove the support loosen the fixing screw on the universal bracket by turning it counter-clockwise.

7.4 Placing / removing the device on / from support (accessory)

1. Place the device on the support.

☞ Make sure that the guides of the carrying handles or the lateral strap holders are inserted into the guides on the support.

2. Remove the device from the support by the carrying handle or on the canister recess.

7.5 Attaching and removing the power supply unit (accessory)

❶ Assembly recesses

❷ Recess for storage of power supply unit and power supply cable

7.5.1 Attaching and removing the power supply unit to the support

1. Place the support on the power supply unit by placing the mounting recesses of the support over the power supply unit mounting recesses.
2. Tighten the support with the provided screws and the recommended screwdriver (TORX - screwdriver - T10).
3. Remove the support with the provided screws and the recommended screwdriver (TORX - screwdriver - T10).

7.5.2 Attaching and removing the power supply unit with support to the universal bracket

☞ Firmly hold the power supply unit which is attached to the support during the entire process.

1. Attach the universal bracket (Chapter „7.1 Attaching the universal bracket (Accessories)“ on page 35).
2. Place the support with power supply unit to the universal bracket by positioning the thread on the bottom of the support with power supply unit over the fixing screw of the universal bracket.
3. Turn the fixing screw on the universal bracket in a clockwise direction in order to mount the power supply unit support to it.

☞ The support with the device must always be affixed in a horizontal position.

4. To remove the support with power supply unit loosen the fixing screw on the universal bracket by turning it counter-clockwise.

7.6 Inserting and removing the power supply unit and cable

1. Insert the power supply unit and charging cable in the power supply unit support.
2. Remove the power supply unit and the charging cable from the power supply unit support.
3. The device can be placed or removed from the support (see chapter „7.4 Placing / removing the device on / from support (accessory)“ on page 38).

7.7 Charging the device with power supply unit support (accessory)

1. Insert the charging plug from the power cable through the recess provided on the support into the charging socket on the device (see chapter „3.3.1 Battery charging“ on page 14).

☞ Remove the charging plug from the device before you remove the device from the support.

7.8 Attaching and removing the carrying handle, disposable strap and carrying strap

7.8.1 Strap holders

- The strap holders on the back of the device are already mounted on delivery.

- If you do not require the strap holders they can be easily removed with a standard screwdriver (TORX - screwdriver T10).

❶ Strap holders
❷ Strap holder clips

7.8.2 Attaching the carrying handle

To attach the carrying handle the strap holder clips and screws are required. These are provided on the device.

1. Loosen the screws on the back of the device by 3 turns with the recommended screwdriver (TORX - screwdriver - T10).
2. If necessary remove the strap holders.

The curve of the carrying handle must point towards the front of the device.

Correct

Incorrect

3. Insert the recesses of the carrying handle in the provided strap holder clips and press the carrying handle inwards, until it clicks into place.

☞ Pay attention to a maximum tightening torque of 0,7 Nm.

4. Tighten the carrying handle with the provided screws and the recommended screwdriver (TORX - screwdriver - T10).

7.8.3 Removing the carrying handle

To remove the carrying handle from the device, loosen the screws by 3 turns with the recommended screwdriver (TORX - screwdriver - T10) out of the strap clips on the back of the device.

7.8.4 Attaching the disposable strap

Strap carabiner ❶+❷ for attaching to carrying handle or strap holders

7.8.4.1 Attach the disposable strap to the carrying handle

To attach the disposable strap to the carrying handle the device with the mounted carrying handle is required (Chapter „7.8.2 Attaching the carrying handle“ on page 40).

1. Click one of the carabiner in one of the recesses provided on the handle.
2. Now hook the other carabiner into the other recess.

   ↳ The device can be carried over the shoulder.

7.8.4.2 Attaching the disposable strap to the strap holders

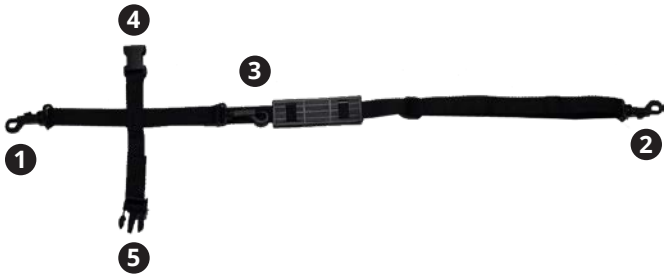
To attach the disposable strap to the strap holders, the strap holder clips are required.

1. Hook the carabiner into one of the strap holder clips.
2. Now hook the other carabiner into the second clip.

   ↳ The device can be carried over the shoulder.

7.8.5 Attaching the carrying strap

To attach the carrying strap, the strap holder clips are required.



❶+❷ Strap carabiner for attachment to the clips on the device. For use as a shoulder strap.

❶+❷ Strap carabiner for attachment to the clips on the device. For use on a patient’s bed.

❹+❺ Fastner for the bed attachment

Attaching the shoulder strap

1. Take the snap link ❶ and hook it to one of the attachment clips on your drainage unit.
2. Now hook the other snap link ❷ to the second attachment clip on your drainage unit. Now the ATMOS C 051 Thorax can be worn over your shoulder.

Attaching the drainage unit to a patient bed

1. To prepare attachment to a patient's bed hook the carabiner ❸ instead of carabiner ❷ to the device.
2. Now you only need to connect the strap ends ❹ and ❺ to each other, to attach the drainage unit to a patient's bed.

Removing the drainage unit from the patient bed

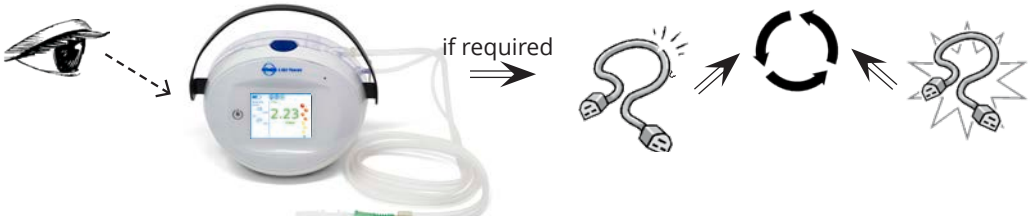
1. Press the unlocking device of the strap closure laterally and keep it pressed.
2. Now pull the two ends apart.

8.0 Cleaning and care

8.1 General information on cleaning and disinfection

Prior to cleaning

Medical devices such as the ATMOS C 051 Thorax must be operationally and functionally reliable. Therefore we recommend prior to every use:



⚠ 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.

⚠ Prior to cleaning please remove the power cable, power supply unit and charging plug from the device.

⚠ The described action relating to cleaning and disinfection resp. sterilisation do not substitute the relevant instructions which must be adhered to prior to operation!

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

⚠ Avoid the penetration or liquid entering the drainage device, especially in the connections on the rear side of the device.

⚠ 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.

⚠ 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.

During all work disposable gloves must be worn.

For disinfection, you may use all surface disinfectants listed in chapter „8.3 Recommended disinfectants“ on page 44 .

Prior to cleaning the device please remove and dispose of all disposable parts like secretion canister and hoses.

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. 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). 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.

We recommend that you always document all maintenance work and exchange of parts in writing.

8.2 Cleaning 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.

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

8.3 Recommended disinfectants

Disinfectant	Ingredients	(in 100 g)	Manufacturer
ATMOS Green & Clean SK	Alkyl dimethyl benzyl ammonium chloride Dialkyl dimehtyl ammonium chloride Alkyl dimethyl ethyl benzyl ammonium chloride	< 1 g < 1 g < 1 g	Metasys, Rum (Austria)
Dismozon pur End of product 12/2014	Magnesium monoperoxyphthalate Hexahydrate	80 g	Bode Chemie, Hamburg
Dismozon plus	Magnesium monoperoxyphthalate Hexahydrate	95.8 g	Bode Chemie, Hamburg
Kohrsolin FF	glutaral benzyl-C12-C18-alkyldimethyl-ammonium chlorides Didecyldimethylammonium chloride	5 g 3 g 3 g	Bode Chemie, Hamburg
Kohrsolin extra (Application solution)	(ethylenedioxy)dimethanol glutaral Didecyldimethylammonium chloride	14.1 g 5 g 8 g	Bode Chemie, Hamburg
Mikrozid sensitive wipes	Quaternary ammonium compounds	0.26 g	Schülke & Mayr, Norderstedt
Perform	Pentapotassium bis(peroxymonosulphate)-bis(sulphate)	45.0 g	Schülke & Mayr, Norderstedt
Sanicloth active (wipes)	Didecyldimethylammonium chloride	0.45 g	Ecolab, Düsseldorf
Incidin active (1% Application solution)	peracetic acid	0.05 g	Ecolab, Düsseldorf
Bacillol 30 foam	propan-2-ol ethanol propan-1-ol N-Alkylamino-propylglycin	10 g 14 g 6 g 21 g	Bode Chemie, Hamburg

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

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

⚠ Do not use disinfectants with alcohol (Exception: Bacillol 30 foam).

8.4 Hygiene plan

WHAT	HOW				WHEN					Details
	E	C	D	S	after each application	daily	weekly	monthly	After each patient	
Drainage unit		X					X		X	Manual wipe cleaning
			X				X		X	Manual wipe disinfection
Canister ⊗	X								X	Disposable product — not suitable for reprocessing, change after use
Hose system ⊗	X								X	Disposable product — not suitable for reprocessing, change after use
Disposable strap ⊗	X								X	Single use product -> not for reprocessing, change after use
Ports ⊗	X								X	Single use product -> not for reprocessing, change after use
Carrying handle		X					X		X	Manual wipe cleaning
			X				X		X	Manual wipe disinfection
Carrying strap		X	X						X	At 40 °C hand wash Recommendation: A new carrying strap should be used for each patient.
Support - standard rail		X					X		X	Manual wipe cleaning
			X				X		X	Manual wipe disinfection
Support for power supply unit		X					X		X	Manual wipe cleaning
			X				X		X	Manual wipe disinfection
Universal bracket		X					X		X	Manual wipe cleaning
			X				X		X	Manual wipe disinfection

R= Removal, C= Cleaning, D= Disinfection, S= Sterilization

9.0 Maintenance and Service

9.1 Basic instructions

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 authorised 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. This check should also include a check of the battery capacity as well as all parts for wear or damage.

The unit does not require any further maintenance.

A regular thorough cleaning and disinfection of the drainage unit 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.

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 drainage unit.
- 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 48.

9.3 Sending in the device

If the drainage unit 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 %.
- ☞ Avoid deep discharge: Devices with permanently installed 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.

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.

⚠ Using other charging accessories may result in risk of explosions!

10.0 Troubleshooting

Description	Possible causes	Remedy
Device cannot be switched on.	Battery is completely empty.	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.
Battery does not recharge and charging symbol does not light up despite proper connection to the power cable.	Fuse is defective.	Check main fuse.
	Mains cable defective or not connected properly.	Check the mains cable.
	Recharging unit or battery are internally defective.	Contact the ATMOS service or a certified service partner. The device must be checked.
„Vacuum too low“	Leakage	Check all the hoses and the secretion canister for leakages.
	Blockage in the hose system. Hose is kinked.	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.
	Bacterial filter at the measuring channel / Bacterial filter in the secretion canister blocked.	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 hose system. If the bacterial filter in the secretion canister is blocked change the secretion canister.
	Liquids sucked into pump.	Contact the ATMOS service or a certified service partner. The device must be checked.
„Vacuum too high“	Excessively high vacuum applied from the outside.	Check for correct hose connections.
	Ventilation valve is defect.	Contact the ATMOS service or a certified service partner. The device must be checked.
„Battery low“	Battery almost empty.	Connect device to the supply network. The battery is charged and the state of charge is indicated in the display.
System shut down.	Battery empty.	Connect device to the supply network. The battery is charged and the state of charge is indicated in the display.
Leakage test failed.	Internal error.	Contact the ATMOS service or a certified service partner. The device must be checked.
	Secretion canister is leaking.	
	Hose system is not completely closed.	

Flow readout is always in 0 l/min.	Component error	1) Check whether the flow is also 0 l/min when the system is open. 2) Contact the ATMOS service or a certified service partner. The device must be checked.
	Secretion has entered the device.	

11.0 Technical data

Voltage	100 - 240 V~, 50/60 Hz IEC jack, IEC320, type C 7, cable length 4 m
Power consumption	Max. 60 W
Direct current voltage	12 V DC +/- 2 %, max. 5 A via cable,1.8 m length with plug 5.5 x 2.5 mm
Integrated battery	Lithium ion, 14.4 V nominal, 2900 mAh nominal
Battery recharging unit	GTM 91099-6015-3.0-T2A
Other safety equipment	Pressure control valve „Pop-off valve“ in the canister Vacuum limitation in the device to approx.150 mbar Acoustic and optical error warnings
Pump performance	Free flow 5 +/- 0.5 l/min Vacuum adjustable from -5 mbar to -100 mbar, step size -1 mbar
Display	Graphic display, colour, with background lighting, display of target vacuum and actual vacuum in mbar, cmH2O, kPa and flow in l/min
Data memory	Internal memory for therapy data: 2.5 MB of up to 12 days storage is possible
Canister	ATMOS disposable canister, transparent, pop-off valve, graduation. Max. volume of 800 ml, connection to the device with „Direct-Docking-System“. Material: SAN (Styrene Acrylonitrile)
Suction hose	ATMOS disposable suction hose for thorax, double lumen, with integrated bacterial filter in the measuring channel, 180 cm length
Operating time	Continuous operation in the specified temperature range. Simultaneous battery recharging and operation possible.
Battery operation time at maximum continuous suction.	3 h
Battery operation time in normal operation (without fistula)	16 h
Battery recharging time	Fully recharged (at least 95 %) in approx. 2 h
Earth leakage current	Max. 0.5 mA
Ambient conditions Transport / storage	-20...+50°C 5...95 % air humidity without condensation at an air pressure of 700...1060 hPa
Ambient conditions operation	+5...+35°C 20...80 % air humidity without condensation at an air pressure of 700...1060 hPa
Maximum operational altitude	3,000 m (NN)
Contamination level	2
Overvoltage category	II
Dimensions (HxWxD)	164 x 206 x 95 mm, without secretion canister Depth with secretion canister: 142mm

Weight: • Drainage device (without canister) • Secretion canister • System with secretion canister • Mains cable and recharging unit	 1.06 kg 0.28 kg 1.34 kg 0.50 kg
Housing material	PC (Poly Carbonat)
Noise level	Max. 34 dB (A) @ 1m (as per ISO 7779)
Period tests	Inspection according to the manufacturers specifications every 12 months.
Safety class (EN 60601-1)	II
Degree of protection	Type BF 
Type of protection	IP 33
Applied standards	EN 60601-1: EN 60601-1/-2: EN ISO 10079-1
Classification according to Appendix IX EC Directive 93/42/EEC	IIa
CE marking	CE 0124
GMDN code	36787
UMDNS code	10-218 Suction device, thoracic
REF	317.0000.0 ATMOS C 051 Thorax

Issue of the technical data: 16.12.2016

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.
- The ATMOS C 051 Thorax has a lithium-ion battery which must be disposed of in accordance with existing directives.

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)

- ℹMedical 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.

13.1 Guidelines and Manufacturer's Declaration - Emissions

The ATMOS C 051 Thorax is intended for use in the environment specified below. The customer or user of the ATMOS C 051 Thorax should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions acc.to CISPR 11	Group 1	The ATMOS C 051 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.
RF Emissions acc.to CISPR 11	Class B	The ATMOS S 051 Thorax is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions according to IEC 61000-3-2	Class A	
Voltage fluctuations/flicker according to IEC 61000-3-3	Corresponds	

13.2 Guidance and manufacturer's declaration - electromagnetic immunity

The ATMOS C 051 Thorax is designed for operation in the electromagnetic environment specified below. The customer or user of the ATMOS C 051 Thorax should ensure that it is used in such an environment.

Immunity Test	IEC 60601- Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) according to IEC 61000-4-2	± 6 kV Contact ± 8 kV Air	± 6 kV Contact ± 8 kV Air	Floors should be wood, concrete, or ceramics tile. If floors are synthetic, the relative humidity should be at least 30 %.
Fast electrical transient/burst IEC 61000-4-4	± 2 kV Mains ± 1 kV I/Os	± 2 kV inapplicable for power cables ± 1 kV I/Os	Mains power quality should be that of a typical commercial or hospital environment.
Surges IEC 61000-4-5	1 kV Differential 2 kV Common	1 kV Differential 2 kV Common	Mains power quality should be that of a typical commercial or hospital environment.
Magnetic field at power frequency 50/60 Hz acc. to IEC 61000-4-8	3 A/m	applicable 3 A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.
Voltage Dips, dropout and fluctuations in the supply voltage acc. to IEC 61000-4-11	< 5 % UT (> 95 % Dip of the UT) for 0.5 cycles 40 % UT (60% Dip of the UT) for 5 cycles 70% UT (30 % Dip of the UT) for 25 cycles < 5 % UT (>95 % Dip of the UT) for 5 s	< 5 % UT (> 95 % Dip of the UT) for 0.5 cycles 40 % UT (60% Dip of the UT) for 5 cycles 70% UT (30 % Dip of the UT) for 25 cycles < 5 % UT (>95 % Dip of the UT) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the ATMOS C 051 Thorax requires continued operation even in case of interruptions of the energy supply, it is recommended that the ATMOS C 051 Thorax be powered by an uninterruptible power supply or a battery.

NOTE

UT is the alternating maims voltage prior to application of the test levels.

13.3 Guidelines and Manufacturer´s Declaration - Immunity

The ATMOS C 051 Thorax is designed for operation in the electromagnetic environment specified below. The customer or user of the ATMOS C 051 Thorax should ensure that it is used in such an environment.

Immunity Test	IEC 60601-Test level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	V1 = 3 Veff 150 kHz to 80 MHz	3 V	Portable and mobile communications equipment should be used no closer to the ATMOS C 051 Thorax, including cables, than the recommended separating distance as calculated/listed below. Recommended distances: d = (3.5 / V1) * √(P) d = (3.5 / E1) * √(P) from 80 MHz to 800 MHz d = (7.0 / E1) * √(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:
Radiated HF disturbances according to IEC 61000-4-3	E1 = 3 V/m 80 MHz to 2.5 GHz	3 V/m	

NOTE 1

With 80 MHz and 800 MHz the higher frequency range applies.

NOTE 2

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

a

The field strength of stationary transmitters, such as base stations of cellular phones and mobile terrain radio equipment, amateur radio transmitters, cbm broadcast and TV stations cannot be predestined exactly. To determine the electromagnetic environment in regard to stationary transmitters, a study of the location must be considered. If the measured field strength at the location where the ATMOS C 051 Thorax is used exceeds the above compliance level, the ATMOS C 051 Thorax is to be observed to verify the intended use. If abnormal performance characteristics are noted, additional measures may be necessary, such as reorienting or relocating the ATMOS C 051 Thorax.

b

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

13.4 Recommended separations between portable and mobile RF Communications equipment and the ATMOS C 051 Thorax

The ATMOS C 051 Thorax is intended for use in electromagnetic environment in which radiated disturbances are controlled. The customer or user of the ATMOS C 051 Thorax can thereby help to prevent electromagnetic interference by maintaining a minimum distance between portable and mobile HF communication equipment (transmitters) and the ATMOS C 051 Thorax - depending on the output of the communication device as indicated below.

	Safety distance, depending on transmit-frequency m		
Nominal capacity of the transmitter W	150 kHz to 80 MHz d = [3.5 / 3] √P	80 MHz to 800 MHz d = [3.5 / 3] √P	800 MHz to 2.5 GHz d = [7.0 / 3] √P
0.01	0.12	0.12	0.233
0.1	0.37	0.37	0.74

1	1.16	1.16	2.33
10	3.69	3.69	7.38
100	11.66	11.66	23.33

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

With 80 MHz and 800 MHz the higher frequency range applies.

NOTE 2

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

14.0 Notice

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