ATMOS MedizinTechnik

Operating Instructions

ATMOS C 051 Thorax

English

These operating instructions are valid from software version 1.3.22.

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℞ Only

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1.0 Introduction

1.1 Notes on operating instructions

These operating instructions are valid from software version 1.3.22.

These operating instructions contain important notes on how to operate the ATMOS C 051 Thorax safely, correctly and effectively.

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 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 12, in order to be prepared for any possible dangerous situations.

These operating instructions are valid for the following devices:

ATMOS C 051 Thorax 317.0200.0

1.2 Explanation of pictures and symbols

In the operating instructions

⚠ DANGER Warning of a danger that will result in immediate fatal or serious injury. Observe the necessary measures.
⚠ WARNING Warning of a danger that can cause death or serious injury. Observe the necessary measures.
⚠ CAUTION Warning of a danger that can cause minor injury. Observe the necessary measures.
NOTICE Notice of a danger that can damage the product or other objects. Observe the necessary measures.

	Warning of a danger that can cause injury or death.
	Notice of potential material damage.
	Useful information on the handling of the device.
1.	Action. Proceed step by step.
»	Result of an action.
•	General information, numeration
–	Subnumeration
	Engage, check correct fit.
	Follow the arrows
	Move, plug in this direction.
	Please press where dot indicates
	Replace
	Check

On device, type plate, and packaging

	Follow operating instructions (blue)
	Consult operating instructions
	Warning; pay special attention
CE 0124	This device complies with the relevant requirements of EU regulations.
CE	This device complies with the relevant requirements of EU regulations.
℞ Only	U.S. Federal Law restricts this device to sale to or on the order of a physician.
	Manufacturer
	Date of manufacture Country of manufacture
REF	Reference number
UDI	Unique Device Identifier of a medical device
MD	Medical device
SN	Serial number
LOT	Batch code
IP 33	Specification of the degree of protection against the ingress of solids and moisture
	Type BF applied part
	Professional disposal
	Use-by date
	Do not reuse
STERILE EO	Sterilized using ethylene oxide
	Single *sterile* barrier system with protective packaging inside

	Single *sterile* barrier system with protective packaging outside
	Protection class II device
	Do not use if the packaging is damaged and follow the operating instructions.
	Fragile, handle with care
	Keep dry
	Keep away from sunlight
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation

UDI application identifier

(01)	UDI-DI: Identification of the manufacturer and the device
(10)	Batch code
(11)	Date of manufacture
(13)	Packing date
(17)	Expiry date
(21)	Serial number

1.3 Intended purpose ATMOS C 051 Thorax

Product name:	ATMOS C 051 Thorax
Main functions:	The ATMOS C 051 Thorax is a device for mobile, digital thoracic drainage. The system generates a controlled vacuum close to the patient and has an electronic monitoring system which shows the actual vacuum measured on the patient's side and the air leak. The objective therapy data are shown in colour on the display in real time and in a graph of therapy process. Error conditions are automatically indicated by visual and acoustic warning messages.
Intended use:	The ATMOS C 051 Thorax is intended for the aspiration and removal of surgical fluids, tissue, gases, bodily fluids, or infectious material from a patient's respiratory system after surgery. The general indication of the ATMOS C 051 Thorax is thoracic drainage.
Intended users / user profile:	• Physicians • Healthcare professionals • Lays with mandatory training by a qualified healthcare professional *Users must not be hard of hearing or deaf and must have adequate visual faculty.*
User training:	The product may only be used by persons who have received medical training or lays with mandatory training by a qualified healthcare professional.
Intended patient target groups:	Patients who are at least 21 years old with and without restrictions.
Medical conditions to be diagnosed, treated or monitored:	Accumulated air and fluids in the thorax that must be drained, monitored and balanced in a controlled manner.
Organ(s) applied to:	Thorax
Duration of application:	For short-term use (< 30 days) on patients.
Use environment:	• Hospital/clinic environment • Home use environment
Patient selection criteria:	Patients who require a thoracic drainage.
Indications:	• Thoracic drainage
Medical contra-indications:	• Not suitable for use on patients with large air leaks (≥4.5 l/min) and coagula • Not for thoracic drainage therapy in which no negative pressure should be applied to the patient
Other contra-indications:	• No separate use of the secretion canister and the hose system (i.e. without the device) for gravity drainage. • No application in preclinical emergency use. • No drainage of flammable, corrosive or explosive fluids/ gases.

Undesirable side-effects:	The following complications may occur during thoracic drainage: • Pain due to irritation of the intercostal nerves • Injury of lung parenchyma / air leak • Reexpansion pulmonary oedema • Effusion retention • Tension pneumothorax • Cutaneous/subcutaneous emphysema
Warnings:	• see chapter „2.0 For your safety“ on page 12 in the valid instructions for use of the product.
The product is:	active
Sterility / specific microbial state:	• The device is used in non-sterile condition. • Secretion canister and hose system are sterile.
Single-use device / reprocessing:	• The device is intended for multiple use. • The device and parts of the accessories are reusable. For information on reprocessing, cleaning and disinfection, please see the operating instructions • Secretion canister and hose system are single-use devices.

For detailed information on the secretion canister and hose system, please refer to the separate information about accessories.

1.4 Information about accessories

1.4.1 Secretion canister 800 ml (home use)

Product name:	Secretion canister 800 ml
Main functions:	The secretion canister passes on the controlled vacuum generated by the ATMOS C 051 Thorax. Fluids and air are drained through the secretion hose and collected in the secretion canister. Via balancing scales, the amount of fluid in the secretion canister is readable and documentable. An integrated bacterial and viral filter protects the device against possible contamination and oversuction. For protection purposes, the pop-off valve opens in case of overpressure in the secretion canister. Cover caps ensure proper closure and disposal.
The product is:	not active
Sterility/specific microbial status:	Secretion canister is sterile
Single-use device / reprocessing:	Secretion canister is a single-use device

1.4.2 Hose system (home use)

Product name:	Hose system Hose system with connector small Hose system with connector medium Hose system with connector large Hose system with Y-connector medium Hose system with Y-connector large
Main functions:	The double-lumen hose system passes on the controlled vacuum generated by the device. The secretion hose drains fluids and air into the secretion canister. The measuring and rinsing hose measures and regulates the vacuum existing on the patient's side. A bacterial and viral filter on the measuring and rinsing hose protects the device against contamination with bacteria and viruses. At defined intervals, a valve opens to conduct air through the measuring and rinsing hose into the secretion hose and to flush fluids, coagula, and other blockages into the secretion canister. Patient-related chest tubes are attached to the hose system by a connector. The sealing plug is used to ensure that the leakage test is carried out safely. The hose clamp is used for clamping the hose system, i.e. when changing canisters.
The product is:	not active
Sterility/specific microbial status:	Hose system is sterile.
Single use device / reprocessing:	Hose system is a single-use device

1.5 Function

General description

This product 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.

Principles of operation and its mode of action

The device is an electrical driven device and takes medical effect as a system in combination with a secretion canister and a hose system.

The system creates the (natural) vacuum in the pleural cavity by draining off air and secretion. The system is for drainage of secretion and air after surgical opening of the thorax.

The hose system is rinsed with air at regular intervals to prevent the collection of debris in the secretion hose. 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. The charging electronics located within the suction device ensures safe charging of the battery. Therefore, it is impossible to overcharge the battery.

Bacterial and viral filters in the secretion canister and measuring and rinsing hose prevent contaminated secretions from entering 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.

Key features:

- Generate and maintain a vacuum

1.6 Transport and storage

The device may only be transported in a upholstered and protective shipping box.

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 diaphragm of the pump could occur.

If damage occurs during transport:

1. Document and report damages in transit.
2. Fill in form QD 434 “Customer complaint/return shipment”.
3. Send the device to ATMOS (chapter „9.3 Sending in the device“ on page 52).

Ambient conditions for transport and storage see „11.0 Technical data“ on page 56

2.0 For your safety

The safety of the ATMOS C 051 Thorax complies with all the recognized rules of technology and the guidelines of the Medical Devices Act.

2.1 General safety instructions

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

Familiarise yourself with the device in good time so that you are capable of operating it at any time.

Never operate the device if it shows any obvious safety defects.

Only a fully functional product meets the safety requirements of users, patients and third parties. Therefore, please observe the following instructions on your product:

2.2 Danger for users, patients and third parties

⚠ WARNING

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

Burns, cardiac arrhythmias and even fatal injury are possible.

- Do not operate the device if it has been dropped. In this case, clean and disinfect the device and send it to ATMOS for repair.
- 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. In this case, clean and disinfect the device and send it to ATMOS for repair.
- Prior to each use, check for damage to the device and the power cable. Do not operate the device if you notice any damage. In this case, clean and disinfect the device and send it to ATMOS for repair.
- Damaged cables must be replaced.
- You can only disconnect the device from the power supply by pulling out the power plug.
- Position the device in such a way that you can easily disconnect it from the mains power supply at any time.
- When disconnecting the device from the mains power supply, pull the power plug first and then the device plug.
- Disconnect the device from the mains power supply before cleaning or disinfecting it.
- Never touch the power plug or power cable with wet hands.
- Never immerse the device in water or other liquids.
- Do not take a shower / bath with the device.
- The device is not sterilisable.
- Use the power cable only in dry surroundings. The surroundings must be non-conductive.
- Do not allow liquids (such as disinfectants or secretions) to enter the device or power supply unit.
- Ensure that no liquid enters the device. If liquid gets into the device, operation of the device must cease immediately. In this case, clean and disinfect the device and send it to ATMOS for repair or an authorised service partner.
- If disinfectant has penetrated the device, then it must be dried thoroughly and subsequently an efficiency control must be conducted. A check should be carried out to see whether the target vacuum is reached when the system is closed and whether a flow > 4 l/min is established after a while when the system is open. If not, it must not be operated until it has been checked by an authorised service partner or ATMOS Service centre.

- Use only original accessories and original spare parts from ATMOS. This applies to the power cable in particular.
- Follow the instructions regarding periodic tests in chapter „9.0 Maintenance and Service“ on page 52.
- Assembly, new settings, alterations, extensions, and repairs may only be carried out by authorized persons.
- Do not modify the device without the manufacturer’s permission.

⚠ WARNING

Risk of infection from non-sterile products!

Deadly diseases can be transmitted.

- Never use components marked with ⓧ more than once. These components are intended for single use only.
- 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.
- Only use sterile packaged parts when the packaging is undamaged.
- 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 secretion canisters and hose systems can lead to infections.
- Secretion canisters and hose system should only be used once on every patient.
- For hygienic reasons we recommend an exchange of both secretion canister and hose system at the same time.

⚠ WARNING

Risk of infection due to patient secretion on the device!

Deadly diseases can be transmitted.

- Always wear disposable gloves if you could come into contact with secretion.
- Clean and disinfect the device after every use.
- Clean and disinfect the device according to the operating instructions.
- The device must not be used following oversuction.

⚠ WARNING

Ensure that the device is always functional and ready for use!

Your patient can be severely injured.

- Ensure that the device is always ready for use.
- Place the device where it is easily accessible.
- Perform a function check after each use.
- Before each use, check that the security seal is undamaged.
- ATMOS recommends always having another suction device ready at hand. This allows you to treat the patient and perform suctioning even in the event of device failure.
- Please observe the notes on the electromagnetic compatibility (EMC) of the 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. In this case, clean and disinfect the device and send it to ATMOS for repair.
- The device and the secretion canister must always be used vertically. If the device should tilt it must be placed upright again in order to guarantee faultless operation. If you are unsure whether the secretion canister works properly we advise you to replace the secretion canister to ensure the patients’ safety.
- The device cannot be carried at the hose system.

- Prior to every use, the device should be checked for leakages at the start of therapy (see chapter „4.5 Leakage test“ on page 28). 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.
- 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 malfunction caused by the device tilting over (for example, a blocked bacterial and viral filter in the secretion canister).
- The leakage test function and the warning message ‘Device in critical tilt’ are activated in the factory settings. If these functions are not desired, they can be deactivated in the user settings (chapter „4.9 User settings“ on page 36).
- Minimal leakages can indicate small leaks in the system or to irregularities in the course of therapy. This can be excluded by clamping the chest tube 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.
- The device may not be operated in MRI scanners (magnetic resonance imaging).
- 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.

⚠ WARNING

Avoid improper use.

Your patient can be severely injured.

- A misplaced drainage system and a misplaced chest tube 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.
- Employ the device only according to its intended use.
- 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).
- The product may only be used by medically trained persons or trained lays who have been instructed in the handling of the medical suction system. Training of lay users by qualified healthcare professional is mandatory.
- Please select the vacuum according to the patient and the application.
- Observe the valid guidelines.
- Observe the notes on hygiene and cleaning.
- Always place the drainage system at the level of the chest tube 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.
- Do not use the device in aircraft.
- Respond immediately to warning message "Secretion canister full or hose blocked" / "Vacuum too low". Prior to exchanging the secretion canister the chest tube must be clamped so that a continuous vacuum is always available at the patient.
- If the fluid level in the secretion canister is too high it could cause a blockage and thus a tension pneumothorax.
- Check the secretion canister at regular intervals and always replace it when the maximum filling level is reached to ensure the patients safety.
- 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 chest tube when changing the secretion canister.

- Prior to the removal of the hose connector the chest tube must be clamped.
- Faulty respectively damaged components must be replaced immediately.
- A set vacuum over -50 mbar may cause pain and injury to the patient. Set a vacuum of more than -50 mbar only if clinically necessary.
- When using a Y-connector, ensure that the chest tubes do not kink and that there is no pulling at the tube insertion sites.

⚠ WARNING

Explosion and fire hazard.

Burns and injuries are possible.

- Use only original accessories and original spare parts from ATMOS. This applies to the power cable in particular.
- Never operate the product in potentially explosive areas or in areas that 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 56) must be strictly observed.

⚠ WARNUNG

Risk of suffocation or strangling for children and animals through accessory parts!

Small parts may cause children or animals to suffocate or be injured.

- Hoses or power cables may strangle people or animals, especially if the hoses or cables are particularly long.
- Keep unauthorised persons away from the device during therapy.
- Keep children away from swallowable small parts.
- Keep the device and all its accessories out of reach of children when not using it.

⚠ CAUTION

Contact may cause adverse biological reactions!

Your patient can be injured.

- The materials used have been tested for their tolerability. In very rare cases, contact with accessible materials on the device and its accessories may cause adverse biological reactions. This applies in particular to contact injuries in conjunction with prolonged contact. Caretakers should assess patients for adverse reactions on the skin where the device has contact, such as redness (erythema), swelling (edema), irritation, sensitization (delayed Type IV hypersensitivity), allergy, immune response, or other reactions.

⚠ CAUTION

Tripping hazard due to cables.

Injuries and fractures are possible.

- Lay the power cable properly.

2.3 Avoiding damage to the device

NOTICE

Damage to the device due to improper use!

The device may become damaged.

- Ensure that no liquid enters the device. If liquid gets into the device, operation of the device must cease immediately. In this case, clean and disinfect the device and send it to ATMOS for repair or an authorised service partner.
- Always place the device on a firm, level surface. The device must always be in a vertical position when you use it.
- Use only power cables which are fully functional.

2.3.1 General information

- 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 secretion canister may not be used without the device (gravity drainage).
- The device may only be operated by qualified personnel.
- The removal of the secretion canister from the device during the therapy may only be performed by trained professionals or trained lays who act in conformity with guidelines. Training of lay users by qualified healthcare professional is mandatory.
- A ready to use spare device incl. consumables must always be available.
- 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.

Electromagnetic compliance - damage to the device!

The device may become damaged.

- 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 improperly installed protective contact socket!

The device may become damaged.

- The ATMOS C 051 Thorax is designed in accordance with IEC 60601-1/EN 60601-1 and with protection class ll.
- The device may only be connected to a properly installed protective contact socket.
- Prior to first starting up, compare the mains voltage of the device (see rear of the power supply unit) with the local mains voltage.

Storage and operation in an unsuitable environment.

The electronics can become damaged.

- Please observe the ambient conditions regarding transport, storage, and operation.
- Always place the device on firm, level ground. The device must always be in a vertical position when you use it. Otherwise, secretion may enter the device.
- The device can be used in road vehicles, rail vehicles and watercraft as long as the other safety regulations are observed. The device must not be used in aircraft.

Damage to the device due to low temperatures!

The device may become damaged.

- 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 device due to heat build-up!

The device may become damaged.

- Do not cover the device during suction.

- Keep the device and the power cable away from other heat sources.
- Do not place the device directly next to other devices as this may cause excessive heating of the device.
- The device and the secretion 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.

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 authorized by ATMOS.

Advice on disposal

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

2.4 Special safety instructions for home use

⚠ WARNING

Avoid improper use.

Your patient can be severely injured.

If the patient is to use the device at home, please ensure the following points:

- The device must be fully charged.
- Give the patient the power supply unit and power cable.
- Provide the patient with sufficient secretion canisters, hose systems and disposable gloves.
- Give the patient the Quick Guide Home Use and the supplementary sheet " Essential Information at a Glance".
- Provide the patient with an emergency contact number for the responsible doctor and nurse and make sure that this number is always available.
- Carry out the mandatory training of the patient by the qualified healthcare person. The training contents are the contents of the Quick Guide Home Use.

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).

317.0200.0 ATMOS C 051 Thorax

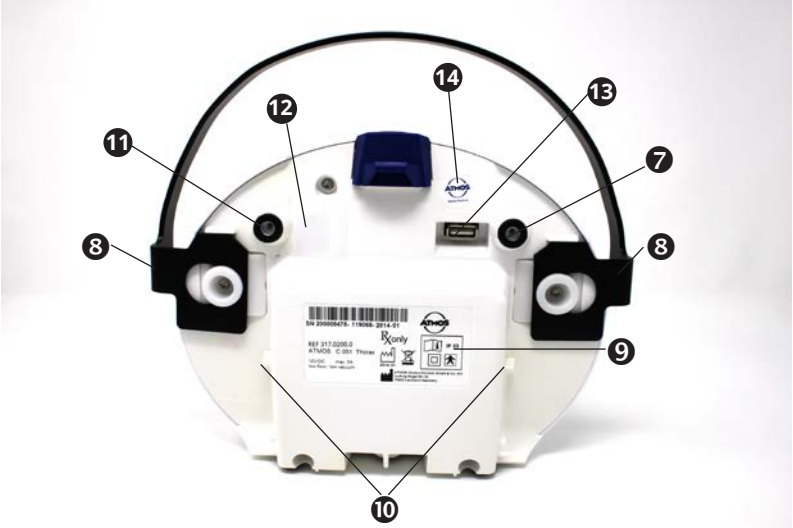
1x Basic device	
1x Carrying handle	317.0090.0
5x Disposable strap	316.1200.0
1x Recharging unit	313.0089.0
1x Power cable Type A (NEMA 1-15P), L = 4m	008.1014.0
1x Operating instructions	GA1US.710102.0
1x Quick guide	GA2GB.710101.0
1x Quick Guide Home Use	GA2US.710102.0
1 x Supplementary sheet "Essential Information at a Glance"	GA3US.710101.0

3.2 Device overview

Front side - with carrying handle

1. Touchscreen (touch-sensitive display)
2. On- / Off sensor
3. Charging socket
4. Release button of secretion canister
5. Light sensor
6. Attachment for carrying handle

Rear side



❼ Connection for secretion canister
❽ Mount for carrying handle
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)
⓮ Security seal

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 power supply unit corresponds to the mains power supply.
- Peruse safety information in chapter „2.0 For your safety“ on page 12 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 power supply 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 53. 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 .

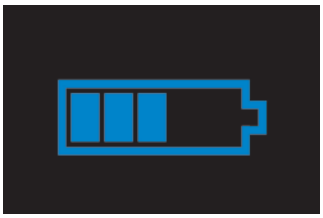
1. Insert the plug of the power supply unit to the charging connector of the device.
2. Connect the power supply unit with the supplied country-specific power cable.
3. Plug the power plug into the power socket.

☞ The ATMOS C 051 Thorax displays the symbol on the display. The bar on the far right flashes. As long as the power plug is inserted, the symbol is green .

As soon as the battery is fully charged the last bar of the symbol stops blinking .

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 thoracic drainage system displays a warning window and triggers an audible warning message (chapter „5.0 Warning messages“ on page 39). 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.



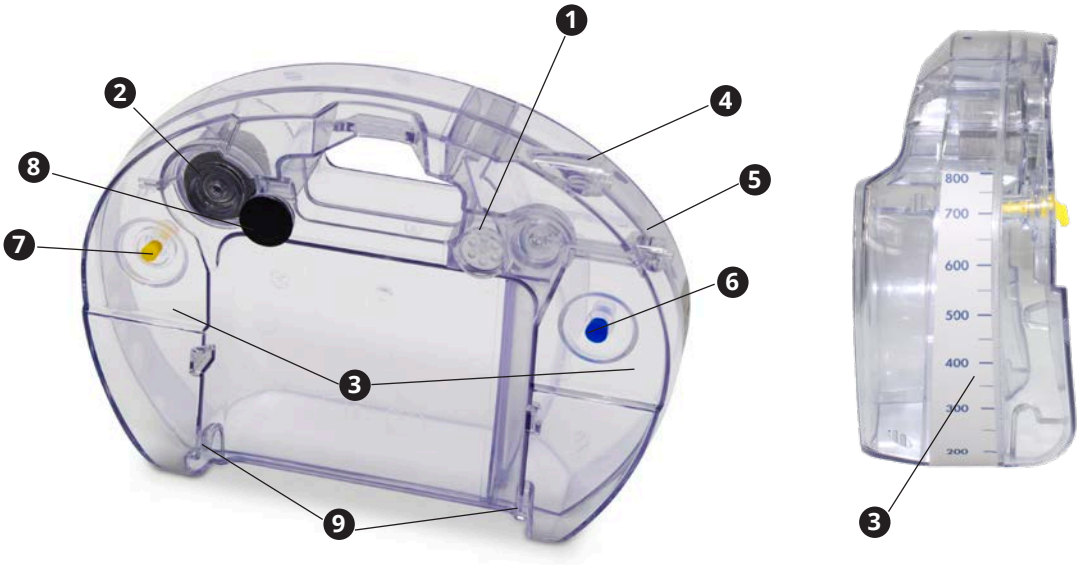
The battery of the ATMOS C 051 Thorax can also be charged when the device is switched off. The state of charge can be seen on the display.

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 is engaged!
- 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



1. Pop-off valve (10 mbar overpressure)
2. Connection to the thoracic drainage system (protected by hydrophobic bacterial and viral filter)
3. Scaling (in ml)
4. Patient connection (secretion hose)
5. Patient connection (measuring and rinsing hose)
6. Protection cap of the secretion hose 4
7. Protection cap for the connection to the suction device 2
8. Protection cap for the pop-off valve 1
9. Secretion canister guide

3.3.2.2 Pop-off valve

The pop-off valve is a protective device against the occurrence of overpressure which could lead to a tension pneumothorax. The valve opens at an overpressure of ≥ 10 mbar within the rinsing 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.

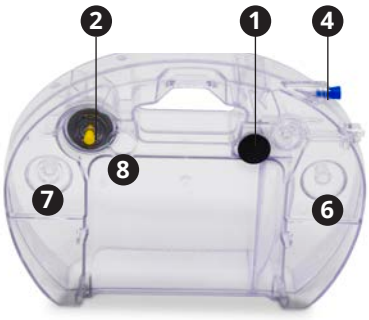
1. Wear disposable gloves and observe the regulations when handling sterile products.
2. Carefully remove the secretion canister from the packaging.
3. Insert the canister guides of the secretion canister into the canister guides on the rear side of the device (see device overview). Hold the secretion canister slightly angled to the device.
4. Press the secretion canister against the device until it audibly engages. The release button returns to its initial position.
5. Slightly pull on the secretion canister to ensure that it is tightly fitted to the device.
6. Connect the hose system (chapter „3.3.3 Connecting the hose system“ on page 23).
7. Switch on the device. A leakage test is recommended.
8. Start the therapy.

3.3.2.4 Changing the secretion canister

Prior to exchanging the secretion canister the chest tube 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.
6. Remove the secretion canister by pressing the blue release button,❹ (see device overview) slightly angle the secretion canister backwards and carefully remove it upwards from the guides.
7. Place the secretion canister securely on a horizontal surface.



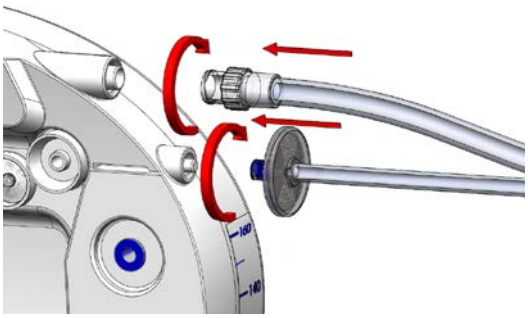
8. Release the 2 Luer lock - connections by a counter-clockwise rotation to separate the secretion canister from the hose system. Pay attention as secretion could be found in the connection space.
9. Remove the blue protection cap ❻ and use it to close the upper Luer lock connection of the secretion hose ❹.
10. Remove the black protection cap ❽ and use it to seal the pop-off valve ❶.
11. Remove the yellow protection cap and use it to close the connection to the device (Bacterial and viral) ❷.
12. Correctly dispose of the secretion canister.

Reinserting the secretion canister

1. Take the new sterile secretion canister and insert the secretion canister guides ❾ of the secretion canister into the guide ❿ on the back side of the device (see Device overview). Hold the secretion canister slightly angled to the device.
2. Press the secretion canister against the device, until it audibly engages. The release button returns to its initial position.
3. Slightly pull on the secretion canister to ensure that it is tightly fitted to the device.
4. Connect the hose system.
5. Start the therapy.
6. Open the clamp at the chest tube.

3.3.3 Connecting the hose system

❶ Measuring and rinsing hose
❷ Hydrophobic bacterial and viral filter
❸ Luer lock 4 mm
❹ Secretion hose
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 and viral filter ❷ to the lower canister connection (❸ on the secretion canister) by rotating it clockwise.
3. Connect the Luer lock with the larger diameter to the upper connection of the canister (❺ on the secretion canister) by rotating it clockwise.
4. A leakage test is recommended (see chapter „4.5 Leakage test“ on page 28).
5. Remove the blue plug from the hose system and use the sterile hose connector, supplied with the hose system, to connect the hose system to any chest tube of your choice. Alternatively you can also use conventional sterile y-connectors or hose connectors.

3.3.4 Connecting the hose system to chest tubes

The hose systems are compatible with the following chest tubes:

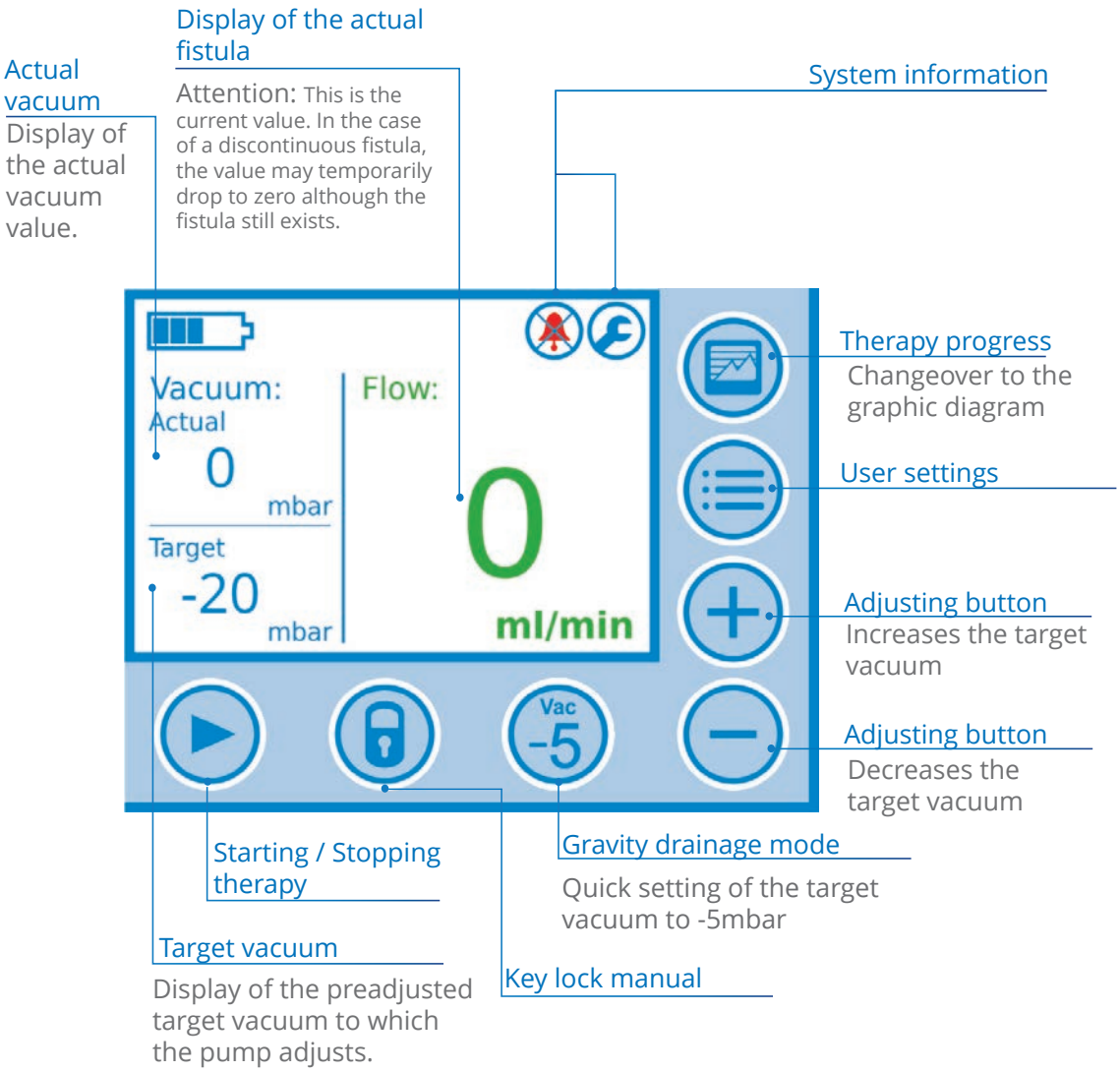
compatible
not compatible

Chest tube			312.1170.0	312.1201.0	312.1202.0	312.1203.0	312.1204.0	312.1205.0
Outer diameter		shape	Hose system	Hose system with connector small	Hose system with connector medium	Hose system with connector large	Hose system with Y-connector medium	Hose system with Y-connector large
mm	CH							
4.0	12	conical						
		Not conical						
4.7	14	conical						
		Not conical						
5.3	16	conical						
		Not conical						
6.7	20	conical						
		Not conical						
8.0	24	conical						
		Not conical						
9.3	28	conical						
		Not conical						
10.7	32	conical						
		Not conical						
12	36	conical						
		Not conical						

4.0 Operation

Ambient conditions during operation see „11.0 Technical data“ on page 56

4.1 Explanation of the display



4.2 Buttons and display symbols

4.2.1 Buttons

Figure	Function
	Decrease target vacuum
	Increase target vacuum
	Gravity drainage mode
	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

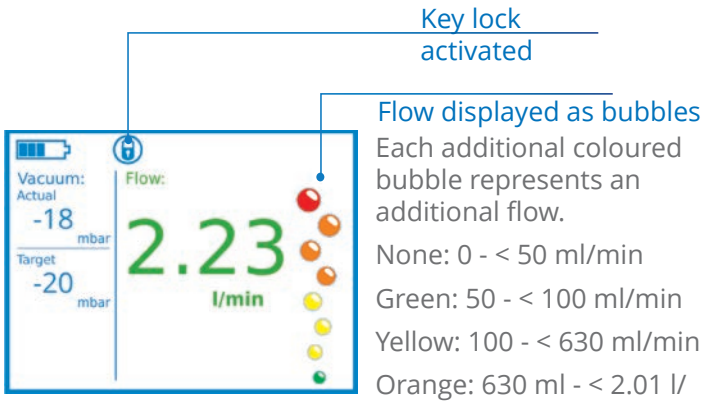
4.2.2 Display symbols

Figure	Function
	Battery status display / charging indicator
	Key lock activated
	Upcoming warning suppressed
	Annual inspection is required

4.3 Explanation of the display in key lock modes

4.3.1 Key lock mode with bubbles

In the key lock mode the flow is additionally displayed in traffic light coloured bubbles for at least one hour.



Each additional coloured bubble represents an additional flow.

None: 0 - < 50 ml/min

Green: 50 - < 100 ml/min

Yellow: 100 - < 630 ml/min

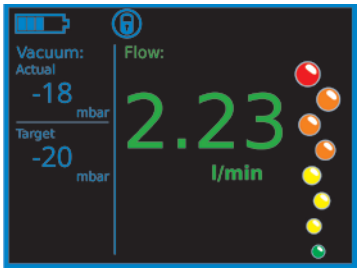
Orange: 630 ml - < 2.01 l/min

Red: >2.01 l/min to maximum

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

Day/Night Mode

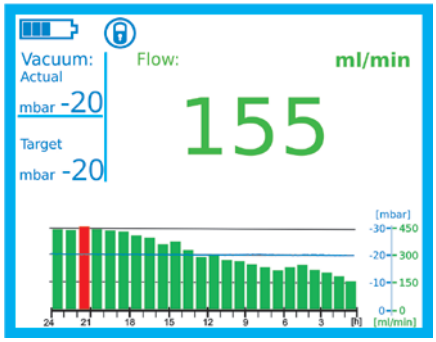
The ATMOS C 051 Thorax has a day/night mode, i.e. the device adjusts automatically to the light conditions in a room.



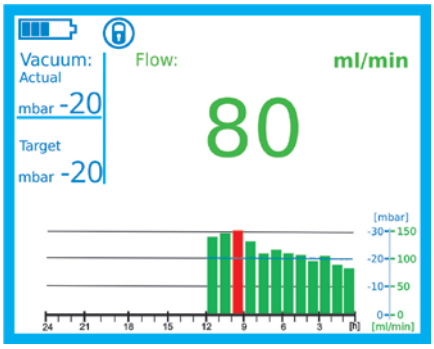
Under low ambient light conditions display has dark background illumination.

4.3.2 Key lock mode with bar chart

If the key lock is active and the average flow value is less than 450 ml/min for at least one hour, the therapy process is displayed in a bar chart over 24 hours. The flow is visualised as an average value in bars on an hourly basis. The vacuum is displayed as a gradient line.



The bar chart appears with a max. flow scaling of 450 ml/min if the average flow value is less than 450 ml/min for at least one hour.



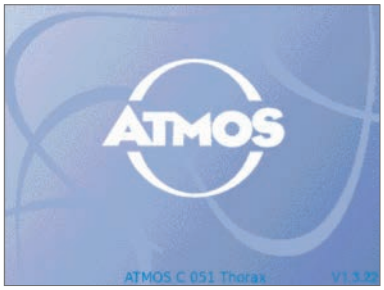
The bar chart appears with a max. flow scaling of 150 ml/min if the average flow value is less than 150 ml/min for at least one hour.

A change of the bar chart with flow scaling from 450 ml/min to 150 ml/min takes place automatically as soon as the hourly average value is less than 150 ml/min. The recording is restarted in the process.

If the hourly flow value exceeds the maximum of the flow scale, when the bar chart display is already active, then this bar is displayed in red.

If the vacuum exceeds -30 mbar the vacuum lines are no longer displayed.

4.4 Switching on

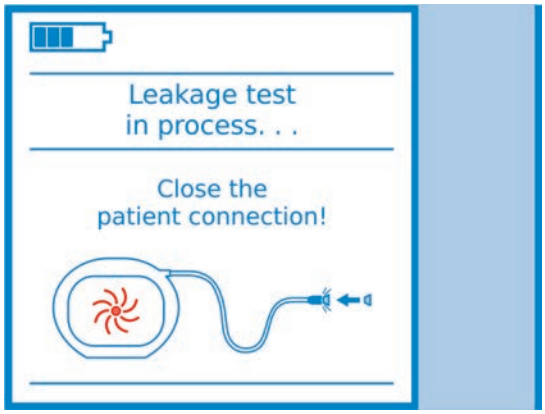


1. To switch on the ATMOS C 051 Thorax, touch the sensor above the ⏻ symbol for two seconds.
2. The ATMOS logo appears with the software version number in the bottom right corner.
3. After a short time, depending on the user settings the leakage test starts automatically (see next chapter).
4. Subsequently "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.

4.5 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 36).

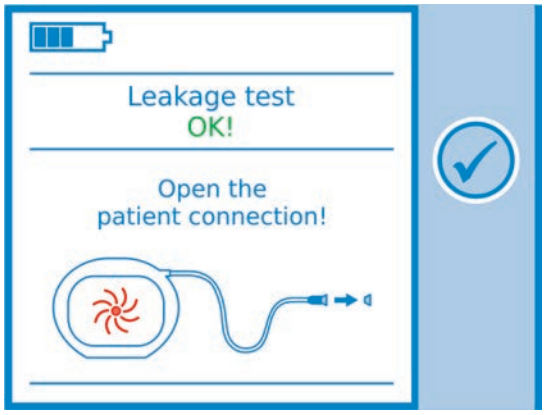
Generally the leakage test is recommended for checking the leak tightness before each start of therapy.



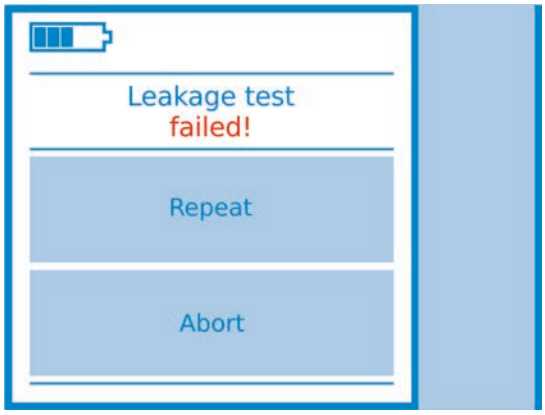
If the leakage test is activated, it will start automatically after the device has been started.

The hose attachment towards the chest tube should already be sealed with a sterile plug when starting up the device. Alternatively the chest tube 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.

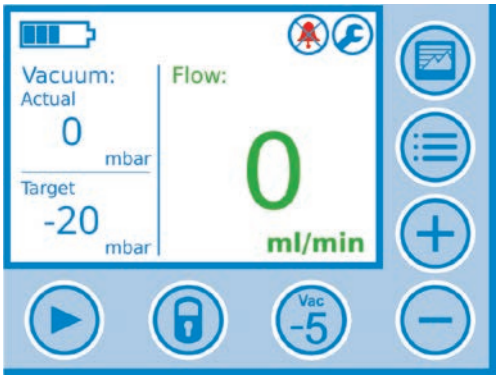
ATTENTION: If the leakage test is operated accordingly, the leakage must not be ignored. If the device dropped down it must not be operated.

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

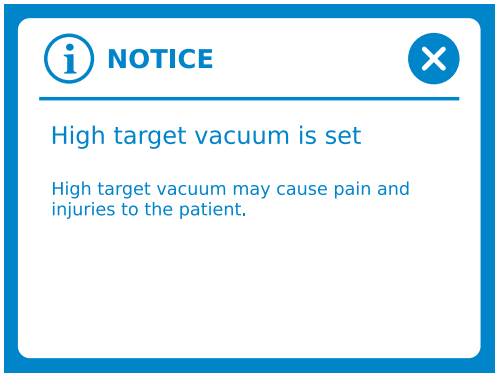
The intention of "abort the leakage test "is to skip the test if a standard test under given condition is not possible.

4.6 Function

4.6.1 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 ⊕, ⊖ or Vac -5 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.
- The Vac -5 button can be used to set the target vacuum directly to -5 mbar. For more information see „4.6.2 Gravity drainage mode“ on page 30.



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

4.6.2 Gravity drainage mode

- On the main screen the target vacuum can be set directly to -5 mbar by pressing the Vac -5 button.
- If the Vac -5 symbol is touched during inactive therapy, the target vacuum is set to -5 mbar. To start the therapy, it must be started manually by pressing the symbol ▶.
- If the Vac -5 symbol is touched during active therapy, the target vacuum is set to -5 mbar.

NOTICE

☞ The change of the target vacuum is immediately effective. There is no confirmation necessary.

- The settings of the target vacuum from the gravity drainage mode can be changed again using the symbol ⊕ .

4.6.3 Suction

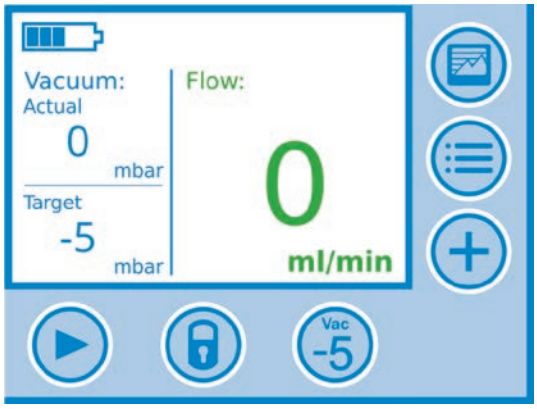
- When the device is switched on the pump is not activated. The pump or therapy will be started by pressing the ▶ button. This is visually illustrated by a symbol change from ▶ to ⏸ in the lower left of the display.
- By pressing the ⏸ button the pump will be stopped.
- The ATMOS C 051 Thorax has a vacuum regulator. 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.

4.7 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.

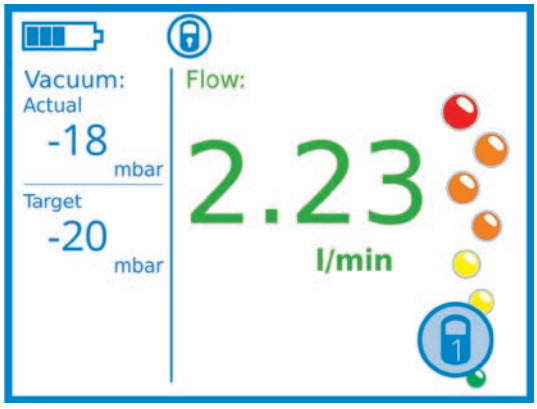


2. Manually activate the key lock

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

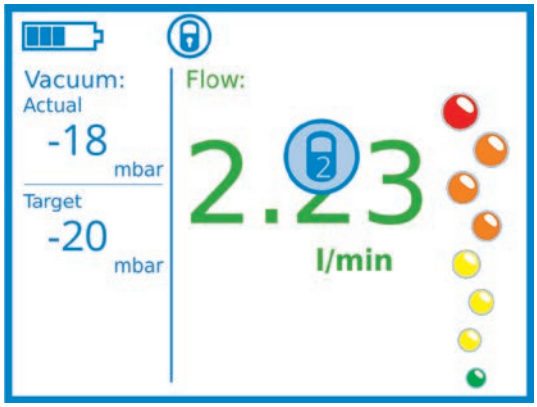
Press the symbol to activate the key lock.

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



3. Deactivate the key lock

After briefly touching the screen, the first contact point appears .

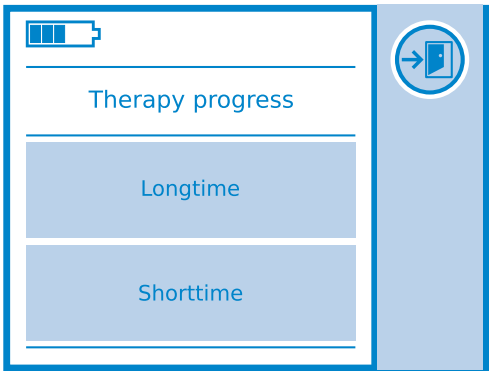


By touching the contact point the second contact point appears .

By a repeated touching of this contact point the key lock symbol on the top 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.

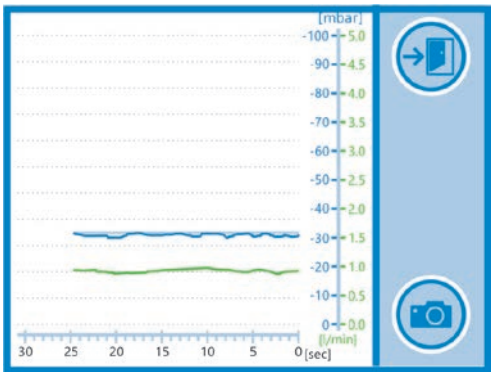
4.8 Therapy progress



The ATMOS C 051 Thorax offers 2 graphs to simplify the analysis of the flow and actual vacuum process.

Selection menu

By selecting the buttons you enter the menu for graphical diagram modus. By pressing the buttons you can select the modus of your choice e.g. long time display / short time.



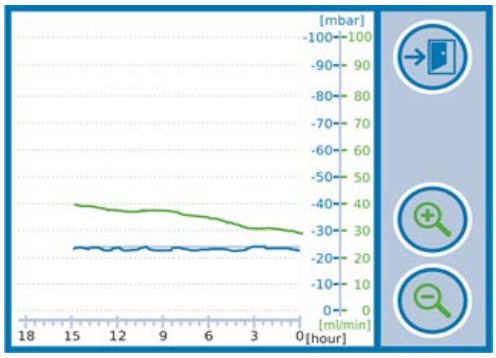
4.8.1 Short time display

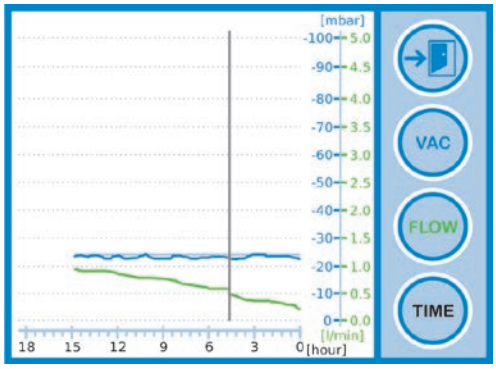
The graphical diagram starts by selecting the menu. In this modus the real measurements (flow, vacuum) from the last 30 seconds can be shown. Therefore you can visualise cough tests and other proceedings.

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

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

☞ Set the period duration of the hose rinsing to > 5 minutes if you want to use the short time display for real-time display of the flow, such as for cough tests, to detect blocked chest tubes, etc.

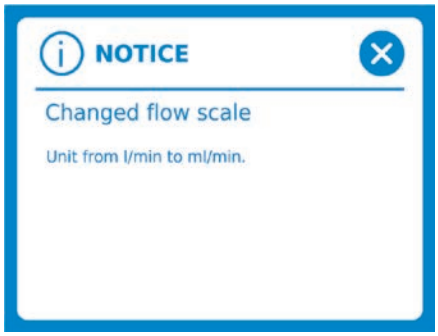




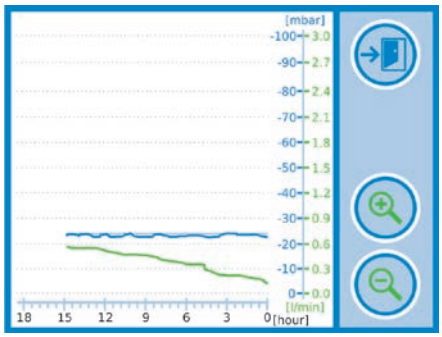
4.8.2 Long time display

In the long time display the complete therapy process 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 buttons.
- The scale can be increased or decreased by pressing the ⊕ or ⊖ buttons.
- 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 and -100 ml/min and 0 – 5 l/min in 4 steps.
- Vacuum scaling:
  - The scaling can be selected between 0 -100 mbar (= cm H_2O) and 0 - 20 mbar (= cm H_2O) in 3 steps.



When changing the flow scaling in the long time display to the smallest scaling, the message appears that the scaling unit has changed from l / min to ml / min.



If you have initially set the zoom values and go back to the long time display, the previously set zoom values are saved, even if the device has been switched off in the meantime.

☞ If the recorded therapy data is greater than the set scaling for the long time display, they are not displayed in the usual lines.

The target vacuum is recorded in light blue.
The actual vacuum is recorded in dark blue.
The flow value is recorded in green.

4.8.3 Transfer of therapy data

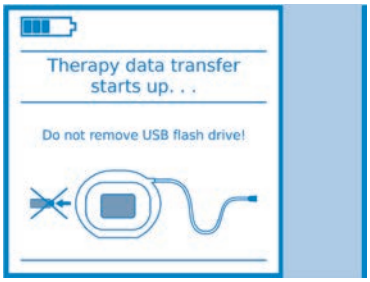
You may transfer the therapy data to a USB flashdrive. The therapy data is saved as a PDF- and Excel file. If you continue the therapy after the data transfer, the data will still be recorded. The transmitted data will not be deleted. If you are starting a new therapy, the previous data will be overwritten.

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

Suitable USB flash drives for therapy data transfer

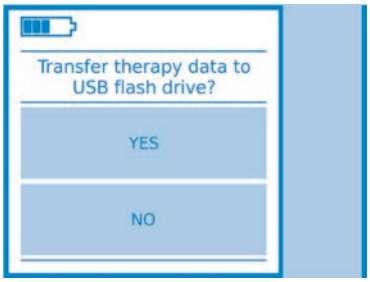
- Manufacturer: SanDisk, Kingston, ATMOS flashdrive
- System: USB 2.0, 3.0, 3.1
- Capacity: ≤ 32 GB
- Formatting: FAT 32
- No stored encryption

ATMOS recommends: Use a USB flashdrive without content. Other USB flashdrives may not be recognized, thus the therapy data transfer does not start.



Start transfer

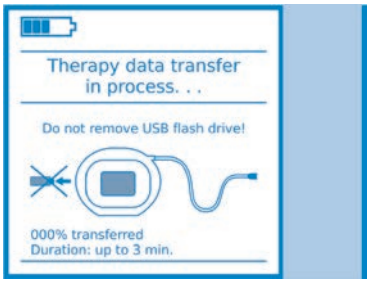
- Connect the USB flash drive, see „3.2 Device overview“ on page 18.
- The device prepares for the therapy data transfer.



- 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“.

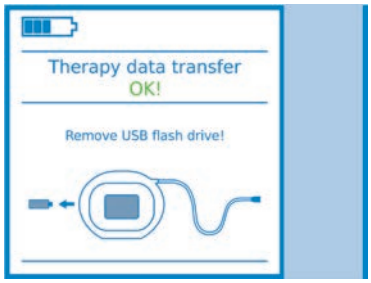
Termination

- 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 chest tube
- Stop the current therapy
- Remove the secretion canister.

Perform the therapy data transfer as described.

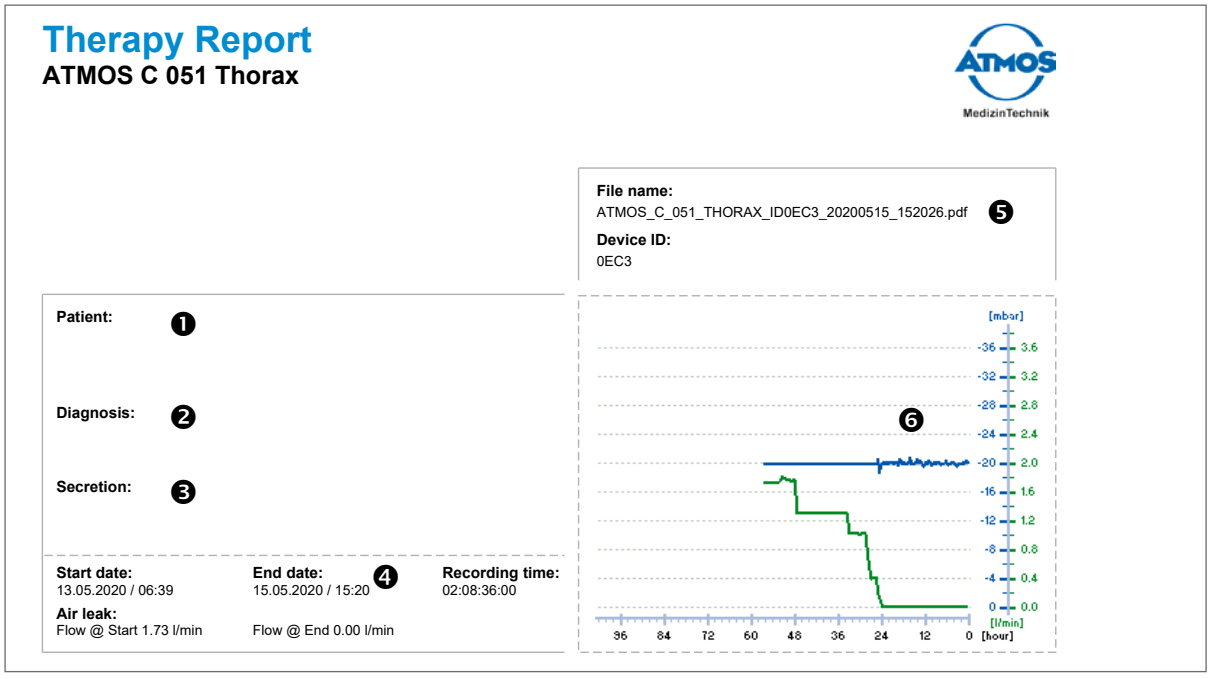
- Connect the secretion canister.
- Continue the therapy
- Reopen the clamp at the chest tube.

4.8.4 Reading out the therapy data

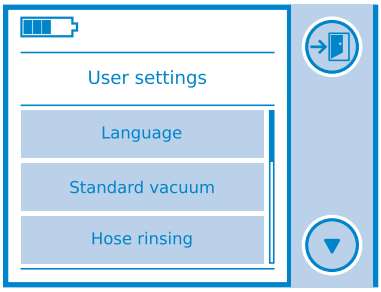
- Connect the USB flashdrive to PC.
- Open the folder on the USB flash drive. This folder contains a PDF file and an Excel file.
- Open the PDF file.
- Fill in the desired Information:
  - ❶ Patient data
  - ❷ Diagnosis
  - ❸ Description of the secretion

Following information can be seen in the report:

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



4.9 User settings



Press the button to access user settings.

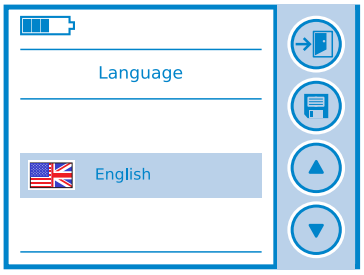
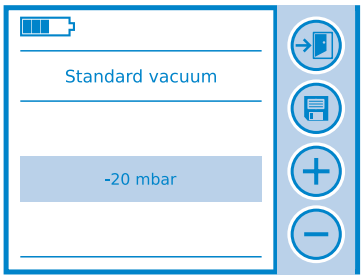
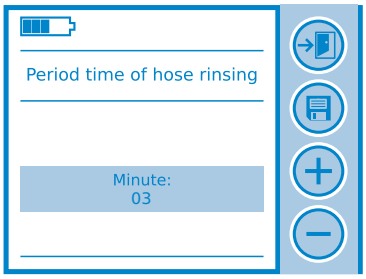
Press the buttons and for moving up and down in the menu selection.

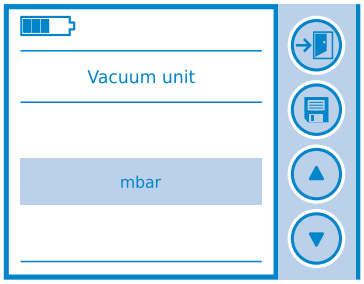
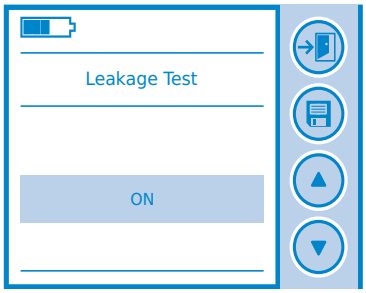
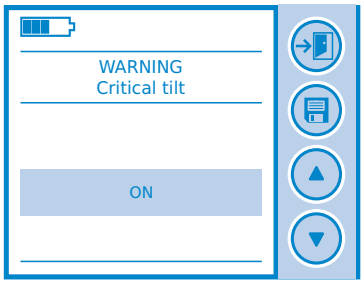
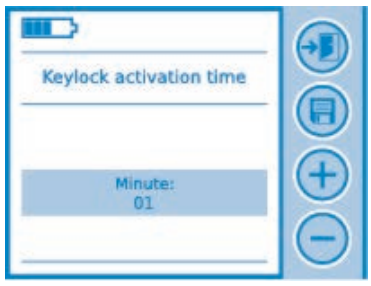
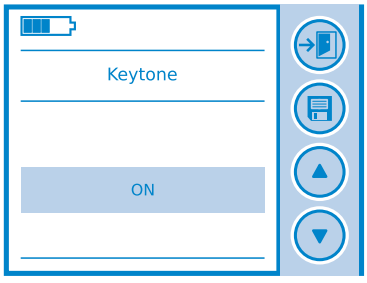
For entering a selection menu press on the text box.

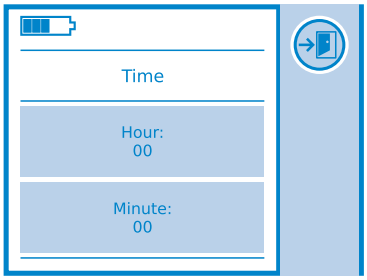
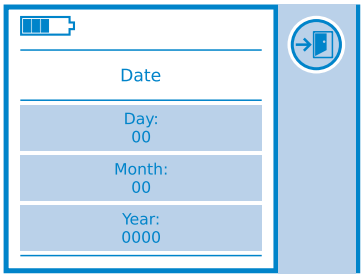
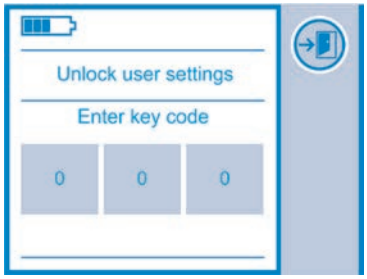
These buttons can be found in every settings menu:

- Press the button to access the user menu.
- ⚠ The selected data will only be saved when you press the Save symbol .

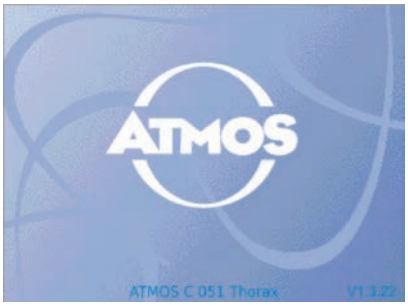
In the user settings the following positions can be selected:

	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 adjust the standard vacuum with and .
	Period time of hose rinsing	You can change the cycle duration for 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	The key lock activation time can be adjusted with ⊕ and ⊖.
	Key tone	The key tone can be activated or deactivated by pressing ▲ and ▼ .

	Time	By pressing one of the two buttons (hour or minute) you can access the individual settings. Now you can change the time with ⊕ and ⊖.
	Date	By pressing one of the three buttons (Day, Month, Year) you can access the individual settings. Now you can change the date with ⊕ and ⊖.
	Unlocking the user settings via key code	The user settings can be locked in the service menu if required. If the setting is activated, the user settings can only be unlocked and operated using a corresponding key code.

4.10 Switch off the device

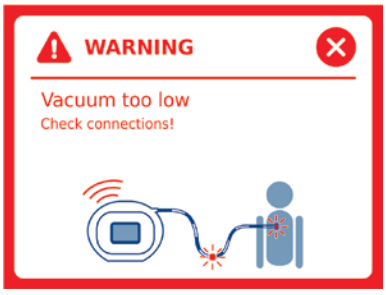
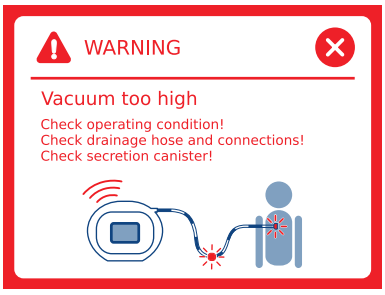
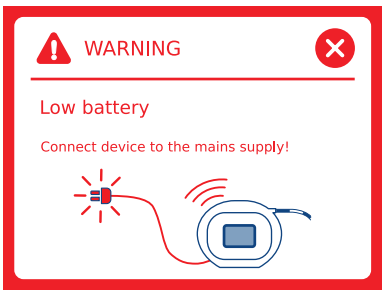


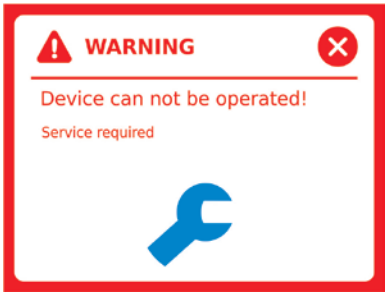
- To switch off the ATMOS C 051 Thorax stop the therapy and touch the sensor for two seconds.
- The ATMOS logo appears on the screen and the device shuts down.

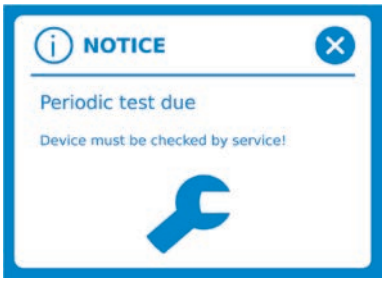
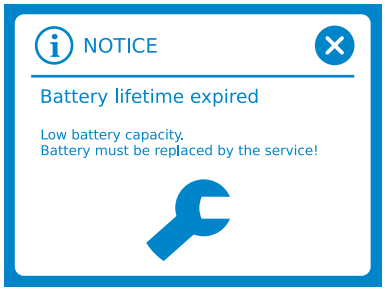
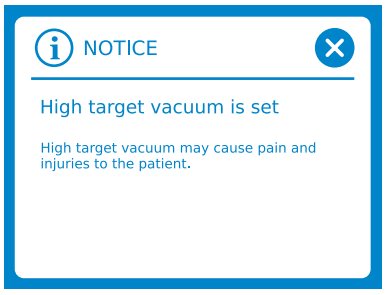
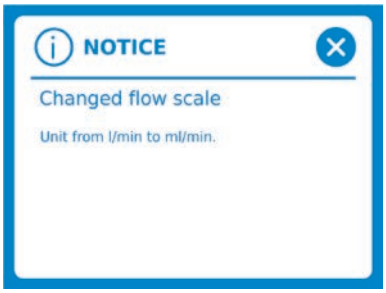
5.0 Warning messages

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

ⓘ In the event of a warning message the system automatically switches to the warning message window. 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.

Display	Cause of error	Troubleshooting
	If the target vacuum is not achieved, the warning message "Vacuum too low" and "Secretion canister full or hose blocked" is activated. Possible reasons for this error message are: Leakages	• Check for leakage: - Connection from the hose system to the chest tube - Secretion hose system to the secretion canister - Secretion canister connection • Contact the ATMOS service
	If the target vacuum is not achieved, the warning message "Vacuum too low" and "Secretion canister full or hose blocked" is activated. Possible reasons for this error message are: • Blockages	• Check for blockages: - Secretion canister - Hose - Filter in the secretion canister - Filter in the measuring 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 “Low battery” is displayed.	Connect device to the supply network. The battery is charged and the state of charge is indicated in the display.

Display	Cause of error	Troubleshooting
⚠ The warning message ‘Device in critical tilt’ serves as preventive information to avoid malfunction caused by the device tilting over (for example, a blocked bacterial and viral 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 desired, it can be deactivated (chapter „4.9 User settings“ on page 36). Generally the warning message "Device in critical tilt" is recommended to avoid malfunction caused by tipping over.		
	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.
	If the therapy has not been started after initial operation the warning message "Inactive therapy" appears without tone.	Press the play symbol to start the therapy. If the warning message is suppressed, it reappears after one minute, but without tone.
	If the therapy has already started and has been interrupted by the pause symbol, the warning message "Inactive therapy" appears with tone.	Press the Play symbol to start the therapy. If the warning message is suppressed, it appears again with tone after one minute.
	The device must no longer be operated. Possible causes • Battery or • pump defective.	Contact the ATMOS service.

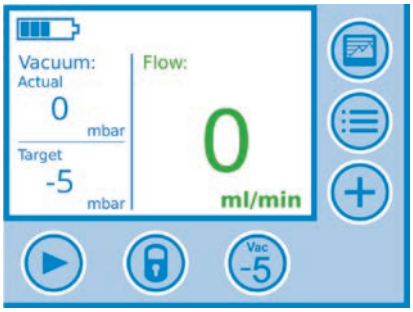
Display	Cause	Recommended actions
	The inspection after 12 months in accordance with the manufacturer's specifications is required. This will be displayed on the device.	Contact the ATMOS service.
	The device has a low battery capacity. This will be displayed on the device.	Battery must be replaced by the service.
	If the set target vacuum is over -50 mbar the notice "High target vacuum is set" appears.	
	When changing the flow scaling in the long time display to the smallest scaling, the notice indicating that the scaling unit has changed from l / min to ml / min. appears.	

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 hose into the secretion canister.
- The rinsing process is initiated by opening a valve located in the measuring and rinsing hose.
- 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 (press the button Vac -5).

The automatic warning messages as well as all measuring functions and 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 chest tube.

7.0 Accessories, consumables and spare parts

Accessories	REF
Universal bracket for the ATMOS C 051 Thorax	316.0200.0
Hose clamp	061.0079.0
Support for the ATMOS C 051 Thorax standard rail	317.1160.0
Power supply unit for the ATMOS C 051 Thorax	317.1170.0

Consumables	REF
Secretion canister 800 ml, 10 pcs.	317.1000.0
Hose system, 10 pcs.	312.1170.0
Hose system with connector small, 10 pcs.	312.1201.0
Hose system with connector medium, 10 pcs.	312.1202.0
Hose system with connector large, 10 pcs.	312.1203.0
Hose system with Y-connector medium, 10 pcs.	312.1204.0
Hose system with Y-connector large, 10 pcs.	312.1205.0
Disposable strap holder for the ATMOS C 051 Thorax	316.1200.0
Y-connector, 50 pcs.	312.1101.0
Paediatrics port, different sides, 1 pcs.	312.1102.0
Fir tree connector (without Luer lock), 1 pcs.	312.1103.0
Connection set for thorax chest tube, 50 pcs.	312.1104.0

Spare parts	REF
2-pin power cable Type A (NEMA 1-15P), L = 4 m	008.1014.0
Recharging unit for ATMOS devices with marking	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

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 has engaged correctly before attaching the thoracic drainage system to 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

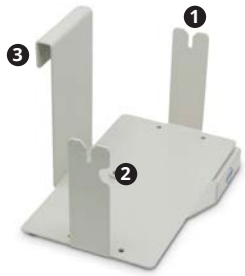
⚠ Firmly hold the ATMOS C 051 Thorax during the whole process.

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

To remove the ATMOS C 051 Thorax release the fixing screw by turning counter-clockwise.

The thoracic drainage system must always be attached horizontally.

7.3 Attaching the support to a standard rail



1. Lateral guides for placement / removal of the device
2. A recess for connecting the power cable to the device
3. 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 43).
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.

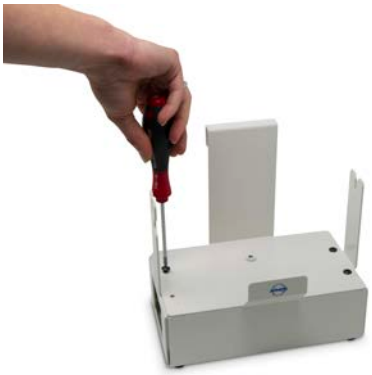
☞ Make sure that the guides of the carrying handle are inserted into the guides on the support.

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)

1. Assembly recesses
2. Recess for storage of the power supply unit and power cable

7.5.1 Attaching and removing the power supply unit to the support



1. Place the support onto the power supply unit by placing the thread at the bottom of the support over the fixing screw of the power supply unit.
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 „7.2 Attaching/ removing the device to/from the universal bracket“ on page 44).
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 support with power supply unit 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 power cable

1. Insert the power supply unit and power cable in the power supply unit.
2. Remove the power supply unit and the power cable from the power supply unit.
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 45).

7.7 Charging the device with support with power supply unit (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 19).

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

7.8 Attaching and removing the carrying handle and disposable strap

7.8.1 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.

7.8.2 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).

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

Correct **Incorrect**

2. 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.

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

7.8.3 Attaching the disposable strap

Strap carabiner ❶+❷ for attaching to carrying handle

7.8.3.1 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 „7.8.1 Removing the carrying handle“ on page 47).

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.

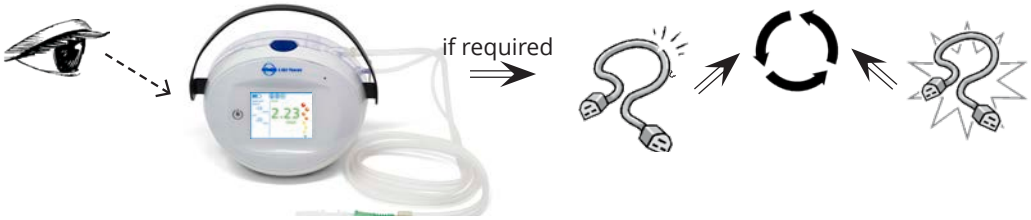
☞ The device can be carried over the shoulder.

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 thoracic drainage system 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 thoracic drainage system.

⚠ Prior to cleaning the device please remove all disposable parts such as secretion canister and hoses. Please remove the power cable, power supply unit, charging plug and if present, the carrying strap.

⚠ The described actions relating to cleaning and disinfection or sterilization 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 thoracic drainage system, 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 50 .

When the device is used on another patient, all parts which come patient’s into contact with the suction material must be , disposed of (secretion canister, hoses and carrying strap). 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.

If the device becomes contaminated or soiled during therapy, clean and disinfect it immediately.

If the device is not visually clean after cleaning and disinfection, clean and disinfect the device again.

⚠ The device must 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 dimethyl ammonium chloride Alkyl dimethyl ethyl benzyl ammonium chloride	< 1 g < 1 g < 1 g	Metasys, Rum (Austria)
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
mikrozid sensitive wipes	Alkyl(C12-16)dimethylbenzylammonium chloride Didecyldimethylammonium chloride Alkyl(C12-14)ethylbenzylammonium chloride	0.25 g 0.25 g 0.25 g	Schülke & Mayr, Norderstedt
perform	Pentapotassium bis(peroxymonosulphate) bis(sulphate)	45.0 g	Schülke & Mayr, Norderstedt
Sani-Cloth Active (wipes)	Didecyldimethylammonium chloride	0.45 g	Ecolab, Düsseldorf
Incidin active (1 % application solution)	Peracetic acid	0.05 g	Ecolab, Düsseldorf

ⓘ 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.

8.4 Hygiene plan

WHAT	HOW				WHEN					Details
	R	C	D	S	after each application	daily	weekly	monthly	After each patient	
Device		X					X		X	Manual wipe cleaning
			X				X		X	Manual wipe disinfection
Secretion canister ⓧ	X								X	Single use product -> not for reprocessing, change after use
Hose system ⓧ	X								X	Single use product -> not for reprocessing, change after use
Disposable strap ⓧ	X								X	Single use product -> not for reprocessing, change after use
Connectors ⓧ	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
Support - standard rail		X					X		X	Manual wipe cleaning
			X				X		X	Manual wipe disinfection
Power supply unit for support		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 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. 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.

Regular thorough cleaning and disinfection of the thoracic drainage system and the application parts and operation of the device in line with the operating instructions, respectively, 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 thoracic drainage system
- Significant decrease of battery capacity.
- Sudden occurrence of abnormal displays on the screen.
- Sudden occurrence of unusual noises
- Operational and functional errors that cannot be resolved by means of the measures described in the chapter '„11.0 Technical data“ on page 56'.

9.3 Sending in the device

If the thoracic drainage system has to be sent in for repair after consultation with the manufacturer or an authorised 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 keep the device and batteries cool and dry (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, observe the battery status on the upper left hand corner of the display.
Battery does not recharge; 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.
	Power supply unit or battery defective.	Contact the ATMOS service or a certified service partner. The device must be checked.
„Vacuum too low“	Leakage	Check all connections for leaks. Connection of the hose system to the chest tube, connection of the hose system to the secretion canister and connection of the secretion system.
“Secretion canister is full or the hose is blocked“	Secretion canister full.	Exchange secretion canister. See „3.3.2.4 Changing the secretion canister“ on page 22.
	Hose blocked or kinked.	Remove any blockages; if necessary, remove the measuring and rinsing hose from the connection to the secretion canister. If the bacterial filter in the measuring and rinsing hose is blocked, replace the hose system. Check the hose system for kinks and remove kinks if necessary.
	Bacterial and viral filter blocked on the measuring hose or secretion canister.	Check the bacterial and viral filter on the measuring hose and in the secretion canister. If the bacterial and viral filter on the measuring hose is blocked, replace the hose system. If the bacterial and viral filter in the secretion canister is blocked change the secretion canister.
	Liquid sucked into pump.	Contact 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.

Description	Possible causes	Remedy
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.	Hose system is not completely closed.	Check the hose system and rinsing canister for correct fit. See „3.3.2.4 Changing the secretion canister“ on page 22.
	Secretion canister is leaking.	
	Internal error.	Contact the ATMOS service or a certified service partner. The device must be checked.
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.	
"Device cannot be operated"	Internal error.	Contact the ATMOS service or a certified service partner. The device must be checked.

11.0 Technical data

11.1 ATMOS C 051 Thorax

Voltage	100-240 V; 50/60 Hz Connection socket IEC320 type C7, 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
Rechargeable battery, built-in	Lithium-ionic, 14.4 V nominal, 3350 mAh nominal
Charger	GTM 91099-6015-3.0-T2A
Other safety lugs	Pressure control valve „Pop-off valve“ in the canister Vacuum in the device limited 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, cmH_2O, kPa and flow in ml/min or l/min
Data memory	Internal memory for therapy data: 2.5 MB of up to 12 days storage is possible
Mode of operation	Continuous operation in the specified temperature range Simultaneous battery recharging and operation possible
Battery operation time at maximum continuous suction.	6 h
Battery operation time in normal operation (without fistula)	16 h
Battery recharging time	Fully recharged (at least 95 %) in approx. 2 h
Ambient conditions: for transport	
• Temperature	−10... +50 °C
• Air humidity without condensation	20...85 %
• Air pressure	700...1060 hPa
Ambient conditions: for storage	
• Temperature	−10... +35 °C
• Air humidity without condensation	20...85 %
• Air pressure	700...1060 hPa
Ambient conditions: Operation	
• Temperature	+5... +35 °C
• Air humidity without condensation	20...80 %
• Air pressure	700...1060 hPa
Maximum operational altitude	3,000 m (NN)
Contamination level	Class 2
Overvoltage category	II

Dimensions H x W x D	164 x 206 x 95 mm, without secretion canister Depth with rinsing canister: 142mm
Weight: • Drainage device (without canister) • Secretion canister • System with secretion canister • Power cable and recharging unit	 1.16 kg 0.28 kg 1.44 kg 0.50 kg
Housing material	PC (polycarbonate)
Noise level • @ 0.2 l/min and −15mbar • @ 1 l/min and −15mbar • @ free flow and −15mbar	 max. 39 dB(A) @ 1 m max. 39 dB(A) @ 1m max. 47 dB(A) @ 1m
Alarm sound	max. 61 dB(A) @ 1m
Period tests	Inspection by ATMOS authorized service personnel every 12 months in accordance with the manufacturer's specifications.
Protection class against electric shock (according to EN 60601-1)	II
Classification of applied parts	Type BF applied parts
Type of protection	IP33
Reference number (REF)	317.0200.0 ATMOS C 051 Thorax

11.2 Secretion canister 800 ml

Capacity	max. 800 ml
Properties	• ATMOS disposable canister • Transparent • Connection to the device with "plug and play system"
Material	SAN LURAN® CC 358 N
Components	• Over pressure (Pop-off valve) • Hydrophobic viral and bacterial filter • Covering caps for closing the pop-off valve & inlet of secretion hose • Graduation on all chambers of the canister
Ambient conditions: transport/storage • Temperature • Air humidity without condensation • Air pressure	 −20... +40 °C 30...95 % 700...1060 hPa
Ambient conditions: operation • Temperature • Air humidity without condensation • Air pressure	 +10... +35 °C 30...95 % 700...1060 hPa
Dimensions (W x H x D)	160 x 210 x 80 mm
Weight	280 g ± 5 g

Packaging	Sterile packaging: Sengewald flap bag Flexopeel 16000, with tyvek paper strip (Tyvek 1073B)
Packaging unit	10 separately packed canisters in a brown packaging.
Sterilization	EO (Ethylenoxid)
CE marking	CE 0124
Reference number (REF)	317.1000.0 Secretion canister 800 ml

Bacterial and viral filter

Protection against bacteria (BFE)	Filtration efficiency: 99.89667 %*
Protection against viruses (VFE)	Filtration efficiency: 99.0 %*
Filter class	H13 (High-Efficiency Particulate Air/Arrestance)*

*External test report (test laboratory)

11.3 Hose system

Length	1.80 m
Properties	• ATMOS disposable hose • Transparent • Adaption to canister/device by Luer lock
Material	PVC (tube and connectors) PP (adapter) ABS (plug)
Components	• Double lumen hose system: - Suction hose with Luer-Lock adapter - Measuring- and rinsing hose with Luer-Lock viral and bacterial filter • Hose nozzle • Sealing plugs • Connector (with or without Luer-Lock) • Luer-Lock cap • Hose clamp
Ambient conditions: transport/storage	
• Temperature	−20... +40 °C
• Air humidity without condensation	30...95 %
• Air pressure	700...1060 hPa
Ambient conditions: operation	
• Temperature	+10... +35 °C
• Air humidity without condensation	30...95 %
• Air pressure	700...1060 hPa
Dimensions D_i x D_a (mm)	5.15 x 8.15 mm/ 3.65 x 5.15 mm
Weight	119 g
Packaging	Sterile packing: foil 100 µm (Tyvec)

Packaging unit	10 separately packed hose systems in a brown packaging.
Sterilization	EO (Ethyleneoxid)
CE marking	CE 0124
Reference number (REF)	312.1170.0 Hose system 312.1201.0 Hose system with connector small 312.1202.0 Hose system with connector medium 312.1203.0 Hose system with connector large 312.1204.0 Hose system with Y-connector medium 312.1205.0 Hose system with Y-connector large

Bacterial and viral filter

Protection against bacteria (BFE)	Filtration efficiency: 99.89667 %*
Protection against viruses (VFE)	Filtration efficiency: 99.0 %*
Filter class	H13 (High-Efficiency Particulate Air/Arrestance)*

*External test report (test laboratory)

11.4 Software Bill of Materials

The device software contains the following third-party components:

- emWin, version 4.08a, manufacturer Segger
- OT-USB, version 3.20, manufacturer Micrium / OnChip

12.0 Disposal/recycling

Packaging

1. Recycle any device packaging you no longer need.

Hose system and secretion canister

Disposable products may not be reprocessed and may not be reused! Please dispose of disposable products properly.

ATMOS C 051 Thorax

Do not dispose of the device with household waste.

1. Clean and disinfect the device.
2. In Germany: Send in the device to ATMOS or your specialised dealer. They will dispose of the device professionally.
3. In other countries: dispose of the device properly and in accordance with country-specific laws and regulations.

12.1 Expected service life

When the device is operated according to the operating instructions the device (ATMOS C 051 Thorax) has an expected service life of 8 years. Regular thorough cleaning and disinfection of the device and the application parts, and operation of the device in line with the operating instructions, respectively, are assumed.

13.0 Notes on EMC (Electromagnetic compatibility)

ⓘ Medical electrical equipment is subject to special precautions with regard to EMC and must be installed according to the following EMC notes, which correspond to the requirements from DIN EN 60601-1-2:2022-01.

13.1 Guidance and manufacturer's declaration – ambient conditions

The ATMOS C 051 Thorax is suitable for use in the following environments:

In fields of home health care in any buildings, outdoor areas and means of transport

and/or

in professional healthcare facilities such as doctor's practices, clinics, or first-aid facilities as well as operating rooms and outside of the HF-shielded room of a magnetic resonance imaging system

☞ The customer or user of the ATMOS C 051 Thorax should ensure that it is used in such an environment.

13.2 Guidance and manufacturer's declaration – essential features

The product ATMOS C 051 Thorax has the following essential features:

- Build-up and maintenance of a defined target vacuum. Loss of vacuum to 0 mbar is not acceptable.

The essential features are fully usable even in the presence of electromagnetic disturbances.

13.3 Guidance and manufacturer's declaration – electrical components

The ATMOS C 051 Thorax has the following electrical components:

Type	REF	Max. cable length
Battery recharging unit	313.0089.0	1.8 m
Power cable	008.1014.0	4 m

13.4 Guidance and manufacturer's declaration – compliance level for each emissions and immunity test

A. Emissions tests

- Mains terminal interference voltage according to DIN EN 55011: 2018: Residential area - Class B in Frequency range 0.15 MHz – 30 MHz
- Radiated electromagnetic field according to DIN EN 55011: 2018: Residential area - Class B in the Frequency range 30 MHz – 1000 MHz
- Harmonic interference according to DIN EN 61000-3-2: 2015
- Flicker according to DIN EN 61000-3-3: 2014

B. Immunity tests

- Electrostatic discharge (ESD) according to DIN EN 61000-4-2: 2009
- High-frequency electromagnetic fields according to DIN EN 61000-4-3: 2011
- Electrical fast transients (Burst) according to DIN EN 61000-4-4: 2013
- Surge according to DIN EN 61000-4-5: 2015
- Conducted disturbances, inducted by radio frequency field according to DIN EN 61000-4-6: 2014
- Power frequency magnetic field according to DIN EN 61000-4-8: 2010
- Voltage dips, short interruptions and voltage variations according to DIN EN 61000-4-11: 2005

13.5 Guidance and manufacturer's declaration – warnings

⚠ WARNING

The use of accessories, transducers, and cables other than those specified or provided by the manufacturer may cause increased electromagnetic emissions or reduced immunity to electromagnetic interference and result in faulty operation.

⚠ WARNING

Portable HF communications equipment (radios, antenna cables) should not be used within 30 cm* of any parts as specified by the manufacturer or of the ATMOS C 051 Thorax cables. Otherwise, degradation of the performance of this device could result.

*The distance may be reduced at higher immunity test levels.

⚠ WARNING

Avoid using the ATMOS C 051 Thorax in close proximity to other devices or with other devices in a stack, as this may cause interference. If this cannot be avoided, the device must be monitored regularly for proper functioning and if possible please switch off any nearby devices that are not in use.

14.0 Notes

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