ATMOS
MedizinTechnik

Operating Instructions

ATMOS S 201 Thorax

English

These operating instructions are valid from software version 3.0.54

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CE 0124

Table of contents

1.0 Introduction

1.1 Notes on operating instructions

These operating instructions are valid from software version 3.0.54.

These operating instructions contain important notes on how to operate the ATMOS S 201 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. This document may only be reprinted, either in part or in whole, 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 S 201 Thorax and are therefore a must besides regular cleaning.

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

- The product ATMOS S 201 Thorax bears the CE marking CE 0124 in accordance with EU Council Directive 93/42/EEC concerning medical devices and meets the basic requirements of Annex I to this directive.
- The product ATMOS S 201 Thorax complies with all applicable requirements of the directive 2011/65/EU restricting the use of certain hazardous substances in electrical and electronic equipment ('RoHS').
- The Declarations of Conformity and our General Terms and Conditions can be viewed on our website at www.atmosmed.com.
- The quality management system applied at ATMOS has been certified according to international standard EN ISO 13485.
- Prior to start-up, please peruse chapter '2.0 For your safety' on page 16 in order to be prepared for any possible dangerous situations.

These operating instructions are valid for the following devices:

ATMOS S 201 Thorax	312.1000.0
ATMOS S 201 Thorax	312.1080.0

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 fatal 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 fatal or serious injury.
	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
–	Sub-numeration
	Engage, check correct fit.
	Follow the arrows
	Move, plug in this direction.
	Please press where dot indicates
	Activate the optional foot switch
	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.
	UL Mark MEDICAL EQUIPMENT with respect to electrical shock, fire, and mechanical hazards only in accordance with UL60601-1/ ANSI/AAMI ES60601-1 (2005)/ CAN / CSA – C22.2 No. 60601-1 (2008)
	This device complies with the relevant requirements of the Eurasian Economic Union.
	Manufacturer
	Date of manufacture Country of manufacture
REF	Article number
UDI	Unique Device Identifier of a medical device
MD	Medical device
SN	Serial number
LOT	Batch code
IP X0	Specification of the degree of protection against the ingress of solids and moisture
	Applied part type CF defibrillator protected
	Professional disposal
	Use-by date

	Do not reuse
	Sterilised using ethylene oxide
	Non-sterile
	Single *sterile* barrier system with internal protective packaging
	Single *sterile* barrier system with external protective packaging
	Protection class II device
	Fuse
	Do not use if the packaging is damaged and observe 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

1.3.1 Intended purpose ATMOS S 201 Thorax

Product name:	ATMOS S 201 Thorax
Main functions:	The ATMOS S 201 Thorax is a device for mobile, digital cardiothoracic drainage. The system generates a controlled vacuum close to the patient and has an electronic monitoring system which shows the actual vacuum measured at 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:	Restoration of the (natural) negative pressure in the pleural cavity by draining off air and fluids
Intended users / user profile:	• Trained physicians • Trained healthcare professionals *Prerequisite: Users must not be hard of hearing or deaf and must have adequate visual faculty*
Intended patient target groups:	Patients of all age groups with and without restrictions
Medical conditions to be diagnosed, treated or monitored:	Accumulated air and fluids in the thorax (pleural cavity, mediastinum, pericardium) that must be drained, monitored, and balanced in a controlled manner
Organ(s) applied to:	Thorax (pleural cavity, mediastinum, pericardium)
Duration of application:	For short-term application (< 30 days) on humans
Use environment:	Hospital/clinic environments
Patient selection criteria:	Patients who require cardiothoracic drainage (pleural, mediastinal, pericardial drainage)
Indications:	• After surgical opening of the thorax (especially after cardiac surgical interventions) • Pneumothorax • Pleural effusion • Haemothorax • Pleural empyema • Chylothorax • Other similar conditions
Medical contra-indications:	• Not for cardiothoracic drainage therapy in which no vacuum 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 short- or long-term gravity drainage (more than 60 minutes) • No application in emergency and rescue situations • Not in the homecare area that is not supervised by healthcare professionals • No drainage of flammable, corrosive, or explosive fluids/ gases

Warnings:	The following complications may occur during cardiothoracic 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
The product is:	active
Sterility / specific microbial state:	• The device is used in non-sterile condition. • A sterile secretion canister or a low-germ secretion canister can be used • Hose system is sterile.
Single-use device / reprocessing:	• The device is intended for multiple use. The device and part 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 intended uses.

1.3.2 Intended purpose secretion canister 2 l (REF 312.1150.5) and secretion canister 2 l without water lock (REF 312.1140.0)

Product name:	Secretion canister 2 l – (REF 312.1150.5) Secretion canister 2 l without water lock (REF 312.1140.0)
Main functions:	The secretion canister passes on the controlled vacuum generated by the ATMOS S 201 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. Applies exclusively to the 2 l secretion canister (REF 312.1150.5): An optional water lock visualises the patient's leak in bubbles.
Intended use:	Collection of fluids and air from the thorax. Balancing of the amount of fluid. Applies exclusively to the 2 l secretion canister (REF 312.1150.5): • Optional visualisation of air leak in bubbles • Water lock as one-way valve when using the secretion canister and the hose system (i.e., without the device) for temporary gravity drainage

Intended users / user profile:	• Trained physicians • Trained healthcare professionals *Prerequisite: Users must not be hard of hearing or deaf and must have adequate visual faculty*
Intended patient target groups:	Patients of all age groups with and without restrictions
Medical conditions to be diagnosed, treated or monitored:	Accumulated air and fluids in the thorax (pleural cavity, mediastinum, pericardium) that must be drained, monitored, and balanced in a controlled manner
Organ(s) applied to:	Thorax (pleural cavity, mediastinum, pericardium)
Duration of application:	• Secretion canister with device: For short-term use on the patient (< 30 days) Applies exclusively to the 2 l secretion canister (REF 312.1150.5): • Secretion canister for gravity drainage: For temporary use on the patient (< 60 minutes)
Use environment:	Hospital/clinic environments The secretion canister and the hose system are sterile single-use devices that can be used in the sterile operating theatre environment.
Patient selection criteria:	Patients who require cardiothoracic drainage (pleural, mediastinal, pericardial drainage)
Indications:	• After surgical opening of the thorax • Pneumothorax • Pleural effusion • Haemothorax • Pleural empyema • Chylothorax • Other similar conditions
Medical contra-indications:	• Not for cardiothoracic drainage therapy in which no negative pressure should be applied to the patient
Other contra-indications:	• No application with cardiothoracic drainage systems other than ATMOS S 201 Thorax and ATMOS E 201 Thorax • No application in emergency and rescue situations • Not in the homecare area that is not supervised by healthcare professionals • No drainage of flammable, corrosive or explosive fluids/ gases Applies exclusively to the 2 l secretion canister (REF 312.1150.5): • No separate use of the secretion canister and the hose system (i.e., without the device) for short- or long-term gravity drainage (more than 60 minutes) Applies exclusively to the 2 l secretion canister without water lock (REF 312.1140.0): • No separate use of the secretion canister and the hose system (i.e., without the device) for gravity drainage

Warnings:	The following complications may occur during cardiothoracic 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
The product is:	not active
Sterility / specific microbial state:	Secretion canister is sterile
Single-use device / reprocessing:	Secretion canister is a single-use device

1.3.3 Intended purpose secretion canister 2 l Standard (REF 312.1120.0)

Product name:	Secretion canister 2 l Standard
Main functions:	The secretion canister passes on the controlled vacuum generated by the ATMOS S 201 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. An optional water lock visualises the patient's air leak in bubbles.
Intended use:	• Collection of fluids and air from the thorax • Balancing of the amount of fluid • Optional visualisation of air leak in bubbles • Water lock as one-way valve when using the secretion canister and the hose system (i.e., without the device) for temporary gravity drainage
Intended users / user profile:	• Trained physicians • Trained healthcare professionals *Prerequisite: Users must not be hard of hearing or deaf and must have adequate visual faculty*
Intended patient target groups:	Patients of all age groups with and without restrictions
Medical conditions to be diagnosed, treated or monitored:	Accumulated air and fluids in the thorax (pleural cavity, mediastinum, pericardium) that must be drained, monitored, and balanced in a controlled manner
Organ(s) applied to:	Thorax (pleural cavity, mediastinum, pericardium)
Duration of application:	• Secretion canister with device: For short-term use on the patient (< 30 days) • Secretion canister for gravity drainage: For temporary use on the patient (< 60 minutes)
Use environment:	Hospital/clinic environments
Patient selection criteria:	Patients who require cardiothoracic drainage (pleural, mediastinal, pericardial drainage)

Indications:	• After surgical opening of the thorax • Pneumothorax • Pleural effusion • Haemothorax • Pleural empyema • Chylothorax • Other similar conditions
Medical contra-indications:	• Not for cardiothoracic drainage therapy where no negative pressure should be applied to the patient
Other contra-indications:	• No application with cardiothoracic drainage systems other than ATMOS S 201 Thorax and ATMOS E 201 Thorax • No use if a sterile secretion canister is required for therapeutic reasons • No application in emergency and rescue situations • Not in the homecare area that is not supervised by healthcare professionals • No drainage of flammable, corrosive or explosive fluids/ gases • No separate use of the secretion canister and the hose system (i.e., without the device) for short- or long-term gravity drainage (more than 60 minutes)
Warnings:	The following complications may occur during cardiothoracic 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
The product is:	not active
Sterility / specific microbial state:	Low-germ secretion canister
Single-use device / reprocessing:	Secretion canister is a single-use device

1.3.4 Intended purpose hose system

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 time intervals, a valve opens in order to direct 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 intended for clamping the hose system, i.e., when changing canisters.
Intended use:	• Transport of fluid and air from the thorax • Measurement and regulation of negative pressure on the patient's side
Intended users / user profile:	• Trained physicians • Trained healthcare professionals *Prerequisite: Users must not be hard of hearing or deaf and must have adequate visual faculty*
Intended patient target groups:	Patients of all age groups with and without restrictions.
Medical conditions to be diagnosed, treated or monitored:	Accumulated air and fluids in the thorax (pleural cavity, mediastinum, pericardium) that must be drained, monitored, and balanced in a controlled manner
Organ(s) applied to:	Thorax (pleural cavity, mediastinum, pericardium)
Duration of application:	For short-term application (< 30 days) on humans
Use environment:	Hospital/clinic environments
Patient selection criteria:	Patients who require cardiothoracic drainage (pleural, mediastinal, pericardial drainage)
Indications:	• After surgical opening of the thorax • Pneumothorax • Pleural effusion • Haemothorax • Pleural empyema • Chylothorax • Other similar conditions
Medical contra-indications:	• Not for cardiothoracic drainage therapy in which no negative pressure should be applied to the patient

Other contra-indications:	• No application with cardiothoracic drainage systems other than ATMOS C 051 Thorax, ATMOS S 201 Thorax and ATMOS E 201 Thorax • No application in emergency and rescue situations • Not in the homecare area that is not supervised by healthcare professionals • No drainage of flammable, corrosive or explosive fluids/ gases Applies exclusively in conjunction with the secretion canister 2 l without water lock (REF: 312.1140.0) and with the secretion canister 800 ml (REF: 317.1000.0): • No separate use of the secretion canister and the hose system (i.e., without the device) for gravity drainage
Warnings:	The following complications may occur during cardiothoracic 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
The product is:	not active
Sterility / specific microbial state:	Hose system is sterile
Single-use device / reprocessing:	Hose system is a single-use device

1.4 Function

General description

This product is a device for mobile, digital cardiothoracic 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 electrically 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 after a pneumothorax or a pleural effusion 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 entering into the measuring and rinsing hose or that a syphon effect is created.

The device is equipped with a rechargeable battery. A charging unit which is located within the suction device guarantees for the secure charging of the battery. Therefore, it is impossible to overcharge the battery.

Bacterial and viral filters in the secretion canister and measuring hose prevent contaminated secretions from entering the device. As accessories a universal connection and a carrying strap can be ordered separately. These enable attachment to the patient's bed, for example, as well as mobilisation.

Essential requirements

- To generate and maintain vacuum

1.5 Transport and storage

Only transport the device in a shipping container which is padded and offers sufficient protection.

After transport of the device at 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 acclimatised, 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 'Delivery complaint/return shipment'.
3. Send the device to ATMOS (see chapter '9.3 Sending in the device' on page 57).

Environmental conditions for transport and storage

- Temperature range: −10...+50 °C
- Relative air humidity: 30...95 %
- Air pressure: 700...1060 hPa

2.0 For your safety

The safety of the ATMOS S 201 Thorax complies with the accepted standards of technology and the guidelines of the German Medical Devices Act.

2.1 General safety instructions

Report all serious incidents that have occurred in connection with this product 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 so that it can always be disconnected from the power supply easily.
- 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 plug or power cable with wet hands.
- Never immerse the device in water or other liquids.
- Do not take a shower or 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 secretion) to enter the device or power cable.
- 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 or an authorised service partner for repair.
- 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 > 10 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.
- Only use original accessories and original spare parts from ATMOS. This applies to the power cable in particular.
- Follow the instructions on periodic tests in chapter ‘9.0 Maintenance and service’ on page 57.

- Assembly, new settings, alterations, extensions, and repairs may only be carried out by authorised 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 ② more than once. These components are intended for single use only.
- Repeated reuse of components which are marked with a ② is forbidden. This product is not re-sterilisable. 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.
- 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 in a vertical position. 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 patient's safety.
- The device should not be carried by 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 34). Leaking connections could lead to a wrong evaluation of the patient's status and could prolong the therapy. Thus, please check all connections for leakages to prevent the intrusion of additional air.
- The leakage test is recommended to check for leakages 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 (see chapter ‘4.9 User settings’ on page 43).
- Minimal leakages can indicate small leaks in the system or irregularities in the course of therapy. This can be excluded by clamping the patient catheter and as a result, the flow value is reduced to zero. If not, check all the connections on the device, the connectors as well as the Luer lock cap for leakage. If there is still only a minimal flow value illustrated, then there is an internal leakage in the system which cannot be rectified by the user. This will be compensated by the system but illustrated as a minimal flow value.
- If the secretion canister tips over during temporary gravity drainage, the functionality of the water lock for gravity drainage is no longer guaranteed. The vacuum at the patient’s end ceases, thus posing a risk of a renewed pneumothorax.
- When using the ATMOS S 201 Thorax with hybrid option, the water lock in the secretion canister must be filled. Gravity drainage is performed with the device switched off.
- The ATMOS S 201 Thorax without hybrid option is not suitable for passive gravity drainage. When the device is switched off, there is a risk of a renewed pneumothorax.
- In the case of larger air leaks and in patients with fistulas, the vacuum and thus the water column in the riser quickly drop to zero. This means that there is no vacuum at the patient’s end, thus posing a risk of a renewed pneumothorax.
- If a high (negative) vacuum occurs (e.g. due to deep inhalation), the water in the water lock can rise through the riser. The vacuum at the patient’s end ceases, thus posing a risk of a renewed pneumothorax.
- The device may not be operated in MRI scanners (magnetic resonance imaging).
- The ATMOS S 201 Thorax is a medical device which is subject to special safety regulations. It must 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.
- The product may only be used by medically trained persons who have been instructed in the handling of the medical suction system.
- 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 same height as the patient’s catheter and check the patient hose for any bends or clogging which could hinder the drainage of liquid and air. Never place the drainage system on the floor.
- Respond immediately to the 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 to 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 patient’s safety.
- Check the hose system at regular intervals. Observe the instructions issued by the attending physician.
- 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 or damaged components must be replaced immediately.
- A vacuum over −50 mbar could cause pain and injury to the patient. A vacuum over −50 mbar may only be adjusted under medical indication.

⚠ WARNING

Explosion and fire hazard.

Burns and injuries are possible.

- Only use 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 (see chapter '11.0 Technical data' on page 61) must be strictly observed.

⚠ CAUTION

Contact may cause allergic 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 allergic reactions. This applies in particular to contact injuries in conjunction with prolonged contact. If this occurs, seek medical attention immediately.

⚠ CAUTION

Tripping hazard due to cables.

Injuries and fractures are possible.

- Lay the power cable properly.

⚠ CAUTION

Avoid improper use.

Your patient can be injured.

- Operation of the secretion canister for temporary gravity drainage is only permitted with REF 312.1150.5 and 312.1120.0. For REF 312.1140.0, the use for temporary gravity drainage is prohibited (see chapter '7.0 Accessories, consumables and spare parts' on page 52).
- Metal parts (e.g., clamps) must be removed before use in MRI.
- Only remove the secretion canister when therapy is stopped.
- It is mandatory to fill the water lock in the secretion canister for temporary gravity drainage.
- Prior to use, the water lock must be filled to the prescribed filling level (2 cm).
- Do not fill the water lock above a level of 2 cm.
- Only use sterile liquid for filling the water lock.
- Every time before using the secretion canister, make sure that the filler of the water lock is sealed with the plug.
- For temporary gravity drainage, place the secretion canister below the patient's chest in an upright position. Make sure that the patient hose has no loops and/or kinks, as this could hinder the drainage of fluids and air.
- The secretion canister must be prevented from tipping or falling over.
- The patient hose and water lock must be checked regularly by trained medical staff.

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 or an authorised service partner for repair.
- 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 that function properly.

2.3.1 General information

- Compliance with proper surgical procedures and techniques is the responsibility of the attending physician. Observe the instructions issued by 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 only be used for temporary gravity drainage when the water lock is filled (filling height 2 cm, H_2O sterile).
- The level in the riser of the water lock corresponds to the vacuum applied to the patient during the temporary gravity drainage. The fluctuations in the patient vacuum, which are synchronous with the patient's breathing, can be observed in the riser.
- The appearance of air bubbles in the water lock indicates the escape of air from the thorax.
- While using the secretion canister for temporary gravity drainage, the warning messages as well as all measuring functions and the hose rinsing function are not active.
- 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 who act in conformity with guidelines.
- A ready-to-use spare device incl. consumables must always be available.
- The device supports the therapy of the patient, but it is not a substitute for the doctor's 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 S 201 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 S 201 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 start-up, check whether the mains voltage specified on the type plate matches 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 a firm, level surface. The device must always be in a vertical position when you use it. Otherwise, secretion may enter the device.

Damage to the device due to low temperatures!

The device may become damaged.

- After transport of the device at 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 acclimatised, 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 power cable and the device must be kept away from hot surfaces.
- The device may only be operated at room temperature and should not be subjected to direct solar irradiation as this could lead to errors.
- Do not close the ventilation slots on the bottom of the device. Otherwise the device could overheat.

Exclusion of liability and warranty

If

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

Advice on disposal

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

3.0 Setting up and starting up

3.1 Scope of delivery

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

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

312.1000.0 ATMOS S 201 Thorax

1x Basic device	
1x Power cable, L = 3 m	507.0859.1
1x Operating instructions	
1x Quick reference guide	

3.2 Device overview

Front side

❶ On / Off sensor

❷ Touchscreen (touch-sensitive display)

❸ Handle

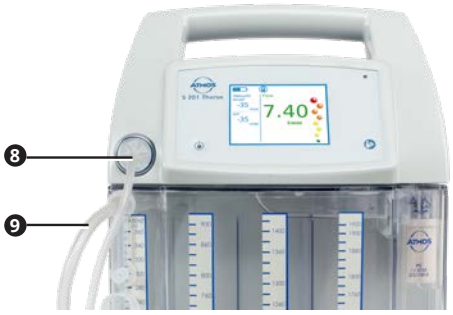
❹ Light sensor

❺ Release button for secretion canister

❻ Connection for secretion canister

❼ Connection for USB flash drive

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



❽ Measuring and rinsing hose connection

❾ Secretion hose connection

Rear side

9 Type plate

10 Charging socket

11 Fixture for device attachment

3.3 Start-up

- Remove the device from the packaging.
- Peruse the safety information in chapter '2.0 For your safety' on page 16 prior to starting up the device for the first time.
- The battery must be fully charged prior to first use. Charging time approx. 2.5 hours.
- Place the device on a safe and even surface.
- After transport of the device at 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 acclimatised, it may not be used, as damage to the diaphragms of the pump 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.

Mains voltage and fuse:

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

3.3.1 Battery charging

Each bar of the symbol represents 20% battery charge.

Attention! Prior to first start-up of the ATMOS S 201 Thorax, the battery must be fully charged.

The battery is recharged by the integrated recharging electronics as soon as you connect the device to the mains supply with the power cable.

Please note the information on how to handle rechargeable batteries in chapter '9.4 Handling of batteries' on page 57.

Correct handling of the rechargeable batteries prolongs the maximum service life.

Batteries are wearing parts and therefore excluded from the general warranty.

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

Attention: If the battery temperature is higher than 50 °C, it can no longer be charged.

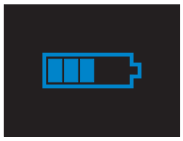
1. Plug the recharger of the power cable into the charging socket of the ATMOS S 201 Thorax.
2. Plug the power plug into the socket.

   ↳The ATMOS S 201 Thorax displays the symbol on the display.
   The bar on the right side flashes. As long as the power plug is connected, the symbol is green.

As soon as the battery is fully charged, the symbol stops blinking.

3. Unplug the power plug from the wall socket.
4. Remove the recharger plug from the charging socket of the ATMOS S 201 Thorax.

As soon as the battery charge level is less than 20%, the cardiothoracic drainage system displays a warning window and triggers an audible warning message (see chapter '5.0 Warning messages' on page 47). Charge the battery in order to continue the therapy without interruption. If the battery is too low for further operation, the ATMOS S 201 Thorax switches off automatically.



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

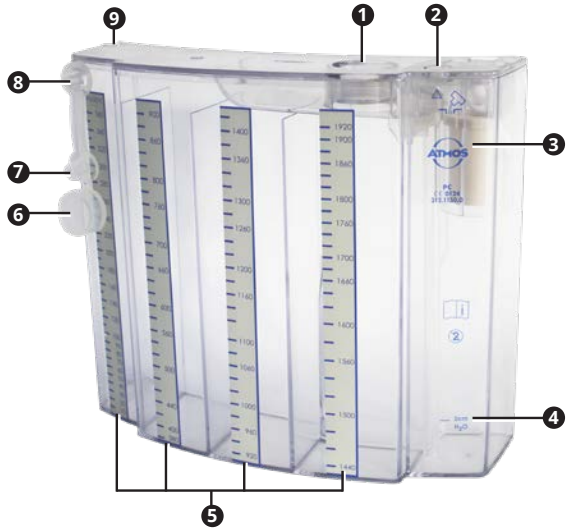
3.3.2 Secretion canister

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!
- Due to hygienic reasons, it is recommended to always change the hose system together with the canister.

3.3.2.1 Secretion canister system overview – versions with a water lock

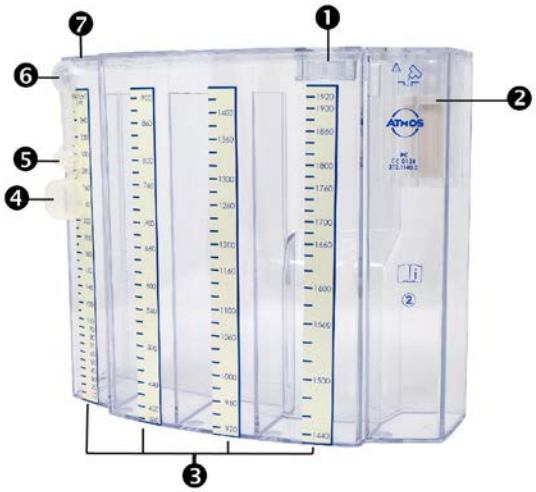
☞ Only applicable for REF 312.1150.5 and 312.1120.0, not for 312.1140.0 (see chapter '7.0 Accessories, consumables and spare parts' on page 52).



1. Pop-off valve (10 mbar overpressure)
2. Filler for water lock
3. Hydrophobic bacterial and viral filter
4. Filling level for water lock function
5. Scaling (in ml)
6. Protection cap for the pop-off valve
7. Protection cap for the secretion hose
8. Patient connection (secretion hose)
9. Secretion canister guide

3.3.2.2 Secretion canister system overview – versions without a water lock

☞ Only applicable for REF 312.1140.0, not for 312.1150.5 and 312.1120.0 (see chapter '7.0 Accessories, consumables and spare parts' on page 52).



1. Pop-off valve (10 mbar overpressure)
2. Hydrophobic bacterial and viral filter
3. Scaling (in ml)
4. Protection cap for the pop-off valve
5. Protection cap for the secretion hose
6. Patient connection (secretion hose)
7. Secretion canister guide

3.3.2.3 Filling the water lock

⚠ Only applicable for REF 312.1150.5 and 312.1120.0, not for 312.1140.0 (see chapter '7.0 Accessories, consumables and spare parts' on page 52).

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

⚠ Prior to use, the water lock must be filled to the prescribed filling level (not above the 2 cm mark) and should be checked regularly to ensure proper operation.

Obligatory: Temporary gravity drainage

Optional: Normal operation, gravity drainage mode

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

1. Use only pre-packaged sterile fluid for filling the water lock.
2. Now insert the filled canister into the device.
3. The canister may only be removed when the pump is switched off.

3.3.2.4 Pop-off valve

The pop-off valve ❶ 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 secretion canister.

3.3.2.5 Inserting the 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.

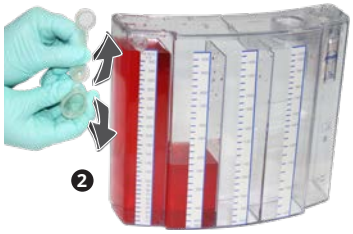
1. Always wear disposable gloves and observe the regulations when handling sterile products.
2. Carefully remove the secretion canister from the packaging.
3. Place the canister guide of the secretion canister into the guide on the bottom left of the device. Hold the secretion canister slightly angled to the device.
4. Press the secretion canister on the right side towards the device until you feel and hear it click into place. The release button returns to its initial position.
5. Pull lightly on the secretion canister to ensure that it is fitted to the device securely.
6. Connect the hose system (see chapter '3.3.3 Connecting the hose system' on page 28).
7. Switch on the device. A leakage test is recommended.
8. Start the therapy.

3.3.2.6 Changing the secretion canister

Prior to exchanging the secretion canister, the chest tube must be clamped so that a continuous vacuum is always available to the patient.

Removing the secretion canister

1. Always wear disposable gloves and observe the regulations when handling sterile products.
2. Have a sterile secretion canister ready at hand.
3. Check whether the target vacuum is reached.
4. Clamp the chest tube close to the straight connector so that a vacuum continues to be applied to the patient.
5. Stop the therapy.
6. Remove the secretion canister by pressing the blue release button ❶ and taking the secretion canister out of the guides on the left side.
7. Place the secretion canister securely on a horizontal surface.



8. Release the 2 Luer lock connections by rotating them counterclockwise to separate the secretion canister and the device from the hose system. Pay attention as secretion could be found in the connection space.
9. Remove the cover cap ❷ from the Luer lock connection of the secretion hose.
10. Separate the cover cap by rotating and pulling it simultaneously.

11. Close the pop-off valve ❸ with the bigger cover cap.
12. Close the Luer lock connection ❹ of the secretion hose with the smaller cover cap. The connection on the rear of the secretion canister must not be sealed.
13. Dispose of the secretion canister properly.

Reinserting the secretion canister

14. Take the new sterile secretion canister and insert the secretion canister guide into the guide on the bottom left of the device. Hold the secretion canister slightly angled to the device.
15. Press the secretion canister on the right side towards the device until you feel and hear it click into place. The release button returns to its initial position.
16. Pull lightly on the secretion canister to ensure that it is fitted to the device securely.
17. Connect the hose system (see chapter ‘3.3.3 Connecting the hose system’ on page 28).
18. Start the therapy.
19. Open the clamp on the chest tube.

3.3.3 Connecting the hose system

❶ Luer lock connection 4 mm with integrated hydrophobic bacterial and viral filter
❷ Measuring and rinsing hose
❸ Luer lock 6 mm
❹ Secretion hose

NOTICE

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

1. Remove the sterile hose system from the sterile wrapping.
2. Connect the Luer lock with the bacterial and viral filter ❶ to the upper canister connection on the secretion canister by rotating it clockwise.
3. Connect the Luer lock connection with the larger diameter to the lower connection of the canister ❸ by rotating it clockwise.
4. A leakage test is recommended (see chapter '3.4.3 Leakage test' on page 29).
5. Use the sterile hose connector, supplied with the sterile straight connector, to connect the hose system to any drainage catheter of your choice. Alternatively, you can also use conventional sterile Y-connectors or straight connectors.

3.4 Hybrid option REF 312.1090.0

⚠ WARNING

Avoid improper use!

The ATMOS S 201 with hybrid option can be used for suction-assisted active drainage or for gravity drainage.

Device switched on = active drainage
Device switched off = gravity drainage
(The water lock must be filled!)

⚠ WARNING

Avoid improper use!

The ATMOS S 201 Thorax without hybrid option is not suitable for passive gravity drainage. When the device is switched off, there is a risk of a renewed pneumothorax.

3.4.1 Prerequisites for operating the secretion canister for temporary gravity drainage with the device switched off

- Device ATMOS S 201 Thorax with hybrid option (REF 312.1000.0 and 312.1090.0 – see display for markings)
- Secretion canister with water lock (REF 312.1150.5 or 312.1120.0)
- Filled water lock (50 ml)
- It is mandatory to perform a leakage test upon device start-up (see chapter '3.4.3 Leakage test' on page 29)

The hybrid option is only valid in conjunction with a secretion canister with water lock (REF 312.1150.5 and 312.1120.0) and the ATMOS S 201 Thorax with hybrid option.

The device can be identified by the following markings:

3.4.2 Filling the water lock

Only applicable for REF 312.1150.5 and 312.1120.0, but not for REF 312.1140.0 (see chapter '7.0 Accessories, consumables and spare parts' on page 52).

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

⚠ Prior to use, the water lock must be filled to the prescribed filling level (not above the 2 cm mark) and should be checked regularly to ensure proper operation.

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

1. Use only pre-packaged sterile fluid for filling the water lock.
2. Now insert the filled canister into the device.

3.4.3 Leakage test

The leakage test checks the tightness of the entire system.

⚠ In order to use the ATMOS S 201 Thorax with hybrid option for gravity drainage, a leakage test must be passed before use! The leakage test must not be deactivated.

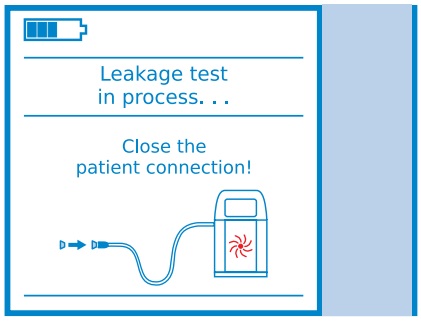
1. Connect the secretion hose of the hose system to the secretion canister.
2. Connect the measuring and rinsing hose of the hose system to the device.

⚠ Do not overtighten the Luer lock connections!

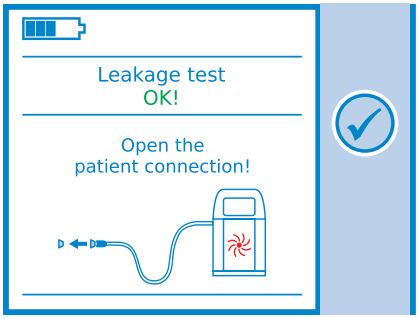
3. Attach the connector of the hose system to the hose end at the patient's side.

⚠ Check the Luer lock cap of the connector for leak tightness!

4. Close the connector.
5. Switch on the device.



Leakage test starts automatically!



Only proceed shortly before connecting the patient!

6. Only proceed if the leakage test has been passed!

3.4.4 Switching from active drainage to passive gravity drainage

Stop therapy by touching the ⏸ button. Switch off the device.

The measuring and rinsing hose can remain on the device. From a technical point of view, it is not necessary to clamp the measuring and rinsing hose.

For temporary gravity drainage, place the device (still switched off) with the installed secretion canister and its filled water lock below the patient's chest in an upright position.

⚠ Make sure that the patient hose has no loops and/or kinks, as this could hinder the drainage of fluids and air.

⚠ The secretion hose and water lock must be inspected regularly by trained medical staff to ensure correct operation.

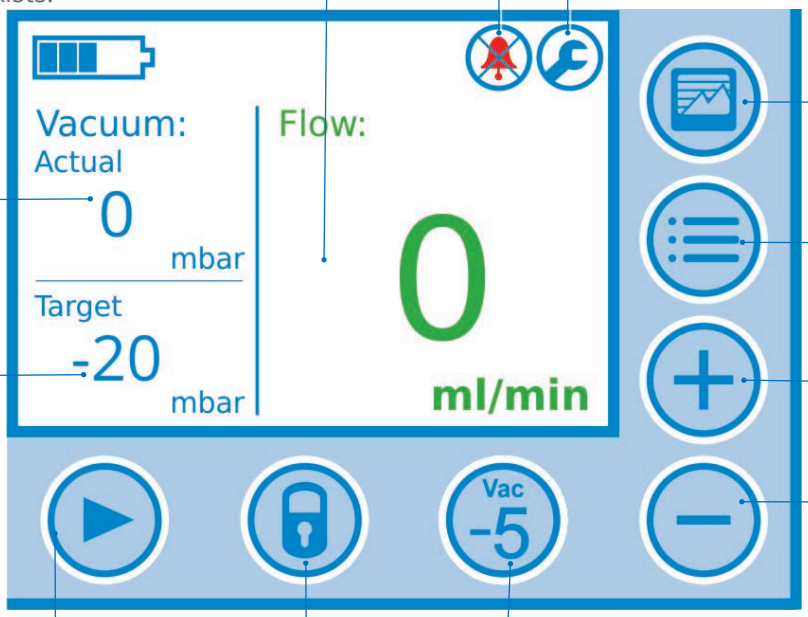
⚠ When the device is switched off, no therapy data is recorded by the device. The passive drainage is to be monitored by trained medical staff. The device cannot detect any error conditions and thus cannot display any warning messages when it is switched off.

4.0 Operation

Ambient conditions for operation

- Temperature range: +10...+35 °C
- Relative air humidity: 30...95 %
- Air pressure: 700...1060 hPa

4.1 Explanation of the display



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

System information

Actual vacuum
Display of the actual vacuum value.

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

Therapy process
Changeover to the graphic diagram

User settings

Setting button
Increase of the target vacuum

Setting button
Decrease of the target vacuum

Gravity drainage mode
Quick setting of the target vacuum to −5 mbar

Start/stop therapy

Key lock manual

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 the therapy
	Stop the 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

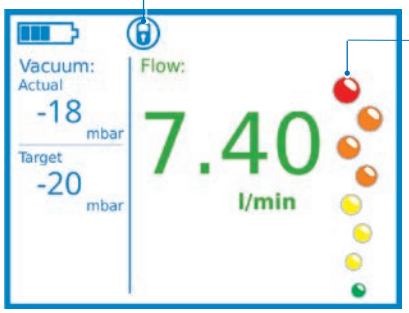
Figure	Function
	Battery status indicator / charging indicator
	Key lock activated
	Hose rinsing activated
	Upcoming warning message suppressed
	Annual inspection is required

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.

Key lock activated



Flow displayed as bubbles

Each additional coloured bubble represents an additional flow.

None: 0 to < 50 ml/min

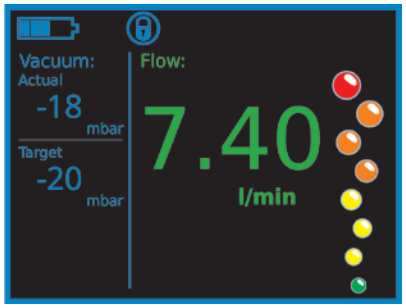
Green: 50 to < 100 ml/min

Yellow: 100 to < 630 ml/min

Orange: 630 ml to 5.51 l/min

Red: >5.51 l/min to maximum.

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



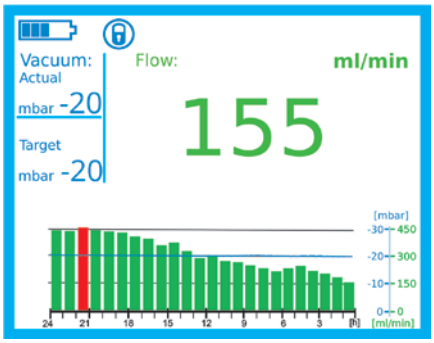
Day/night mode

The ATMOS S 201 Thorax has a day/night mode, i.e. the device adjusts automatically to the light conditions in a room.

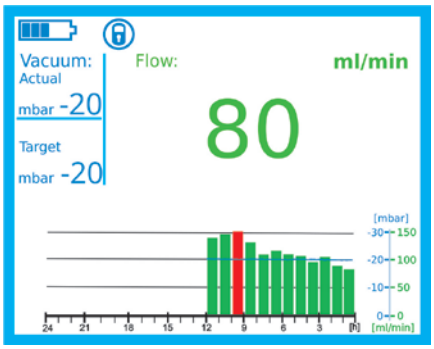
Under low ambient light conditions, the display has dark background illumination.

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.



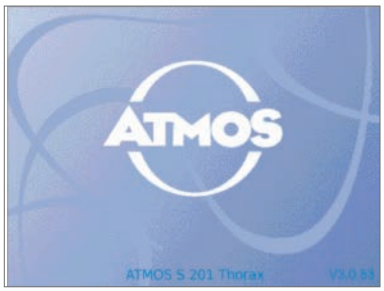
The bar chart appears with a max. flow scaling of 150 ml/min if the average flow value is less than 150 ml/min for at least one hour.

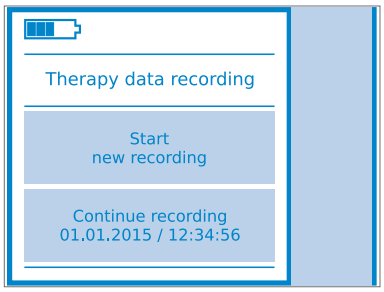
A change of the bar chart with flow scaling from 450 ml/min to 150 ml/min takes place automatically as soon as the hourly average value is less than 150 ml/min. The recording is restarted in the process.

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 S 201 Thorax, touch the sensor above the symbol for 2 seconds.
2. The ATMOS logo appears with the software version number in the bottom right corner.
3. Depending on the user settings, the leakage test starts automatically after a short time (see next chapter).
4. Subsequently, ‘Therapy data recording’ will appear in the display.
   By touching the buttons, you can start a new therapy recording or continue recording.

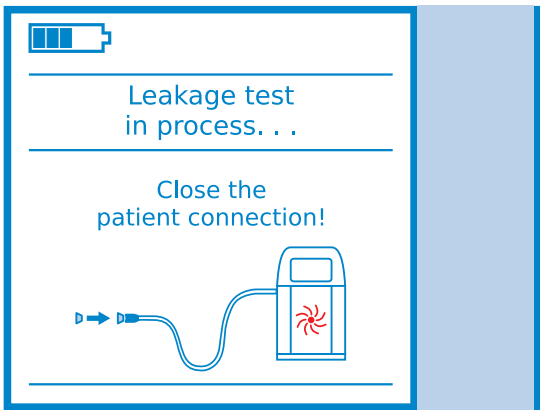
☞ During initial start-up, only one new therapy can be started.

5. The main display appears.
6. The device is now ready for use.

4.5 Leakage test

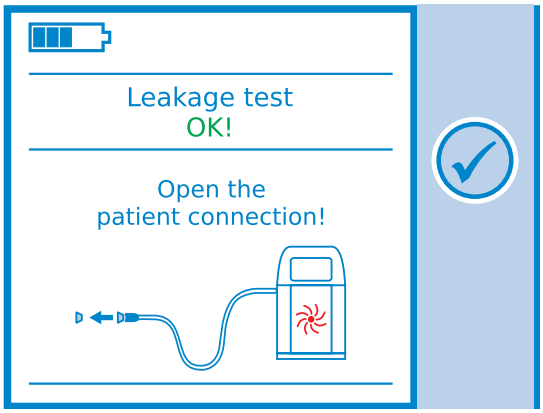
The leakage test checks the tightness of the entire system. The leakage test function is activated in the factory settings. The leakage test can be deactivated (see chapter ‘4.9 User settings’ on page 43).

Generally, it is recommended that the leakage test be performed prior to each application to check for leakages.

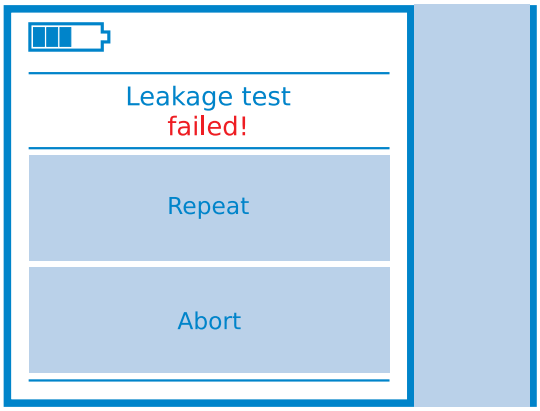


If the leakage test is activated, it will start automatically once the device is switched on.

The hose attachment towards the drainage catheter 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. By touching the corresponding buttons, you now have the option to:

a) repeat the test

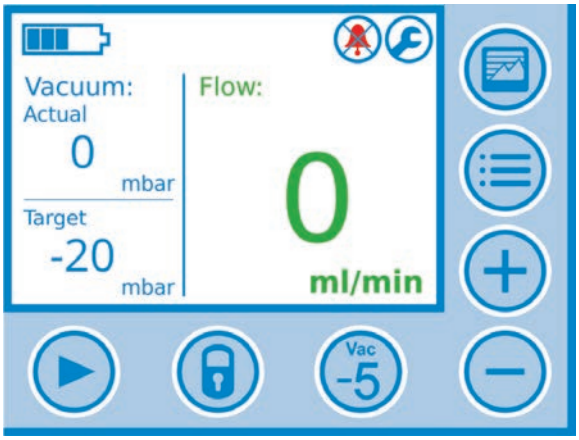
b) or abort the test and continue by pressing the respective buttons on the screen.

ATTENTION: If the leakage test is carried out properly, the leakage must not be ignored. If the device has been dropped, it must no longer be operated. Send the device in for repair. Treatment using a defective device can cause fatal injuries to the patient.

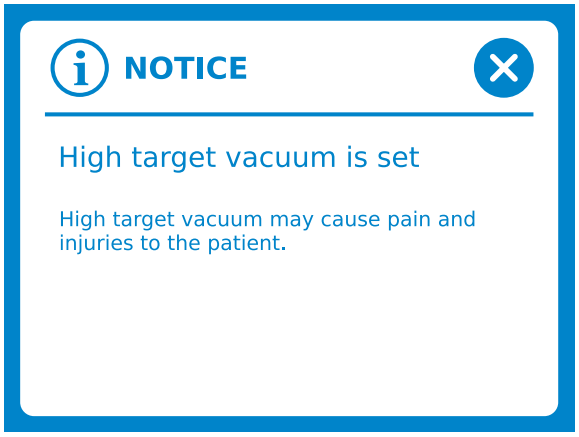
The intention of the option ‘Abort leakage test’ is to skip the leakage test if a proper test cannot be carried out under the given conditions.

4.6 Function

4.6.1 Target vacuum



- Please note that 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 touching the ⊕, ⊖, or Vac -5 button.
- 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 ⊕ or ⊖ button is touched and held, the increase or decrease is 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 chapter '4.6.2 Gravity drainage mode' on page 36.



If the target vacuum is adjusted over −50 mbar, the notice 'High target vacuum is set' appears.

4.6.2 Gravity drainage mode

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

ATTENTION

☞ 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 ⊕ button.

4.6.3 Suction

- When the device is switched on, the pump is not activated. The pump or therapy is started by touching the ▶ button. This is visually illustrated by a symbol change from ▶ to ⏸ in the lower left of the display.
- By touching the ⏸ button, the pump is stopped.
- The ATMOS S 201 Thorax has a vacuum regulator. On the one hand, this means that the integrated pump only starts if the actual vacuum does not correspond to the target vacuum. On the other hand, the pump performance depends on the difference between the actual vacuum and the target vacuum.
- The vacuum is measured at the patient-side of the hose system.

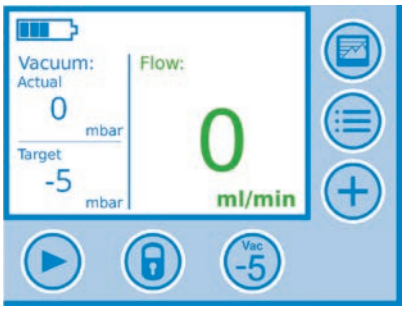
4.7 Key lock

The ATMOS S 201 Thorax has an automatic key lock.

1. Automatic activation of the key lock

If the settings on the display 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 activating the key lock

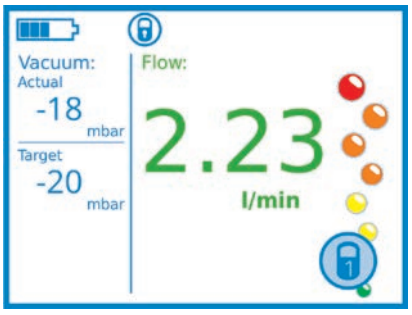


The key lock can be manually activated after all the therapy values are set and the therapy is started.

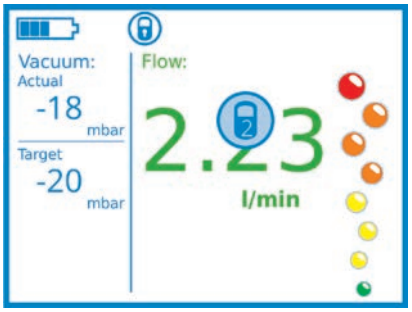
Touch the button to activate the key lock.

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

3. Deactivating the key lock



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

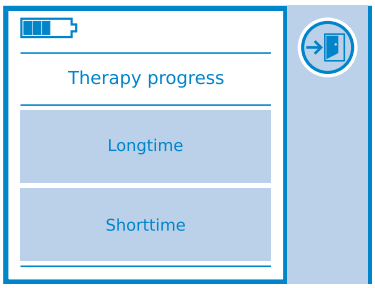


By touching the contact point, the second contact point appears.

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

If you do not touch both the symbols and within 6 seconds, the key lock remains activated. The deactivation process can be started by touching the display again.

4.8 Therapy process

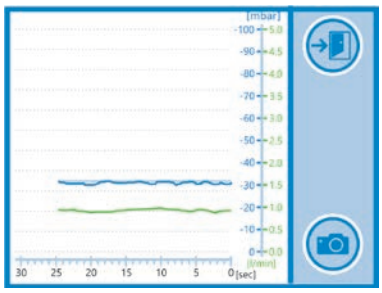


The ATMOS S 201 Thorax offers 2 graphs that make it easier to analyse the course of the flow and actual vacuum.

Selection menu

By touching the button, you enter the menu for graphical diagram modus. By touching the respective buttons, you can select the modus of your choice, e.g. long time display / short time display.

4.8.1 Short time display



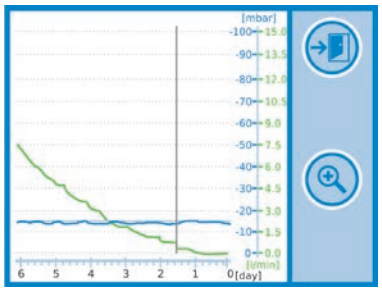
The graphical diagram starts when you call up the menu. In this mode, the real measurements (flow, vacuum) from the last 30 seconds can be shown. Therefore, you can visualise cough tests and other procedures.

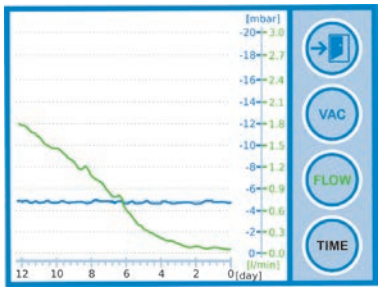
By touching the button, the diagram can be frozen to enable a graphical interpretation. When you touch the button again, the short time display is restarted.

By touching the button, you will return to the main menu.

☞ Set the cycle duration for 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 catheters, 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 touching the VAC, FLOW, or TIME buttons.
- In the scaling display, the scale can be increased or decreased by touching the or buttons.

Time scaling:

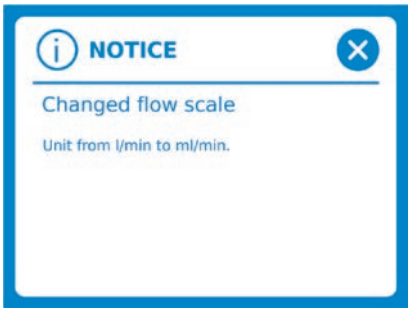
- The endpoint on the right side of the graphic is always the actual point of time.
- The scaling can be selected in 7 steps, between the display of the past 60 minutes and the last 12 days.
- A vertical line shows when the therapy was interrupted.

Flow scaling:

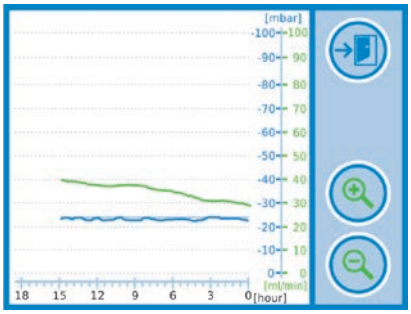
- The scaling can be selected between 0–100 ml/min and 0–15 l/min in 4 steps.

Vacuum scaling:

- The scaling can be selected between 0–100 mbar (= cmH_2O) and 0–20 mbar (= cmH_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, the data is 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 an Excel file.

If you continue the therapy after the data transfer, the data will still be recorded. The transmitted data will not be deleted.

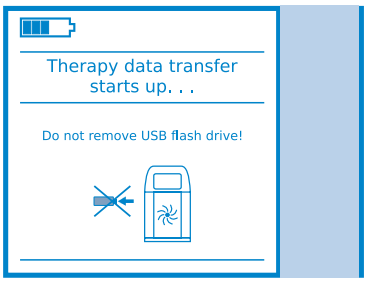
If you are starting a new therapy, the previous data will be overwritten.

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

Suitable USB flash drives for therapy data transfer

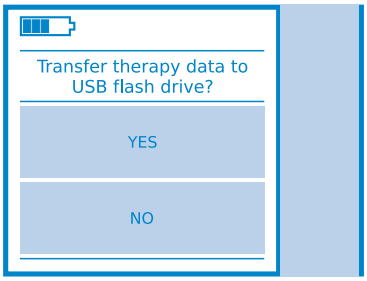
- Manufacturer: SanDisk, Kingston, ATMOS flashdrive
- System: USB 2.0, 3.0, 3.1
- Capacity: ≤ 32 GB
- Formatting: FAT 32
- No stored encryption

ATMOS recommends: Use a USB flashdrive with no contents. Other USB flashdrives may not be recognised; thus, the therapy data read-out does not start.

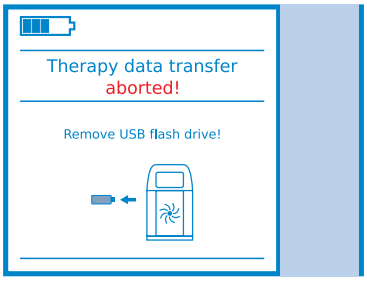


Start the therapy data transfer

- Press the release button. The secretion canister swivels forward to the right.
- Connect the USB flashdrive; see '3.2 Device overview' on page 22.
- The device prepares the therapy data transfer.

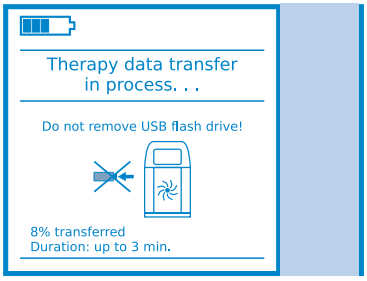


- In order to start the transfer, confirm the query on the device with 'YES'.
- To abort the transfer, confirm the query on the device with 'NO'.



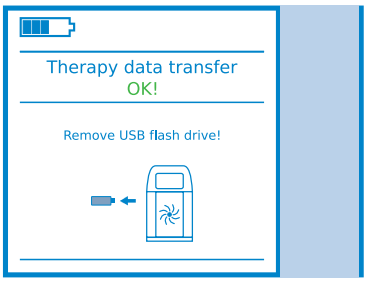
Termination

- Remove the USB flashdrive. Now you return to the main screen.



Therapy data transfer

- The USB flashdrive 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 flashdrive may be removed. Now you return to the main screen.

If the therapy data should be transferred during a patient's therapy, follow the steps below:

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

Perform the therapy data transfer as described.

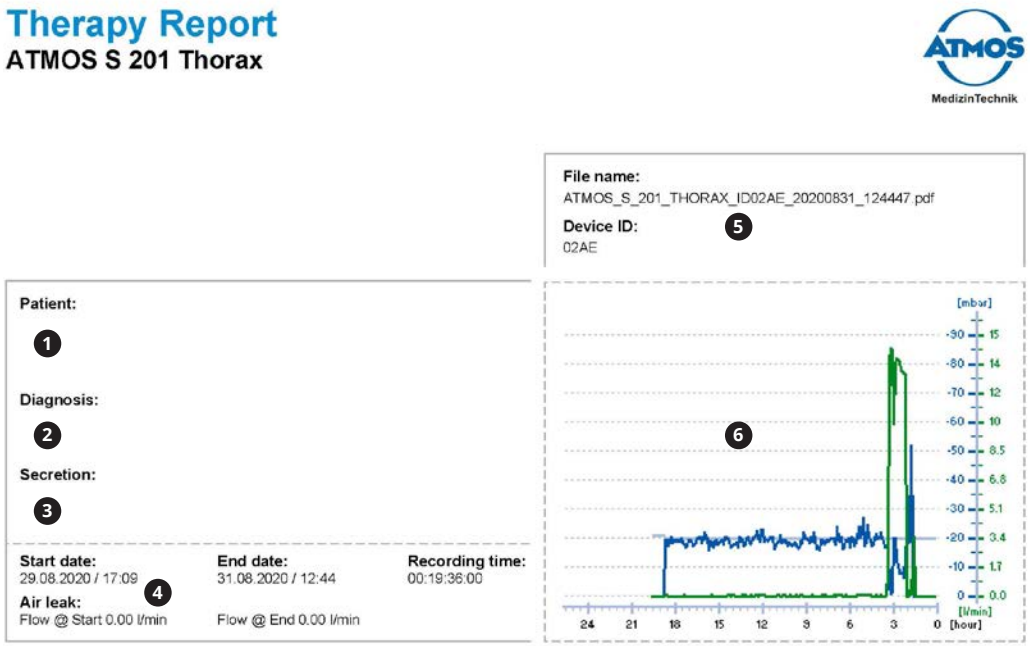
- Install the secretion canister
- Continue the therapy
- Open the clamp on the chest tube

4.8.4 Reading out the therapy data

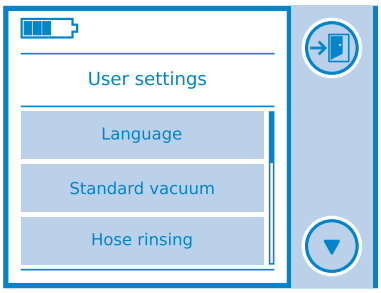
- Connect the USB flashdrive to a PC.
- Open the folder on the USB flashdrive. This folder contains a PDF file and an Excel file:
- Open the PDF file.
- Enter the desired information:
  - ❶ Patient data
  - ❷ Diagnosis
  - ❸ Description of the secretion

The 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



Touch the button to access user settings.

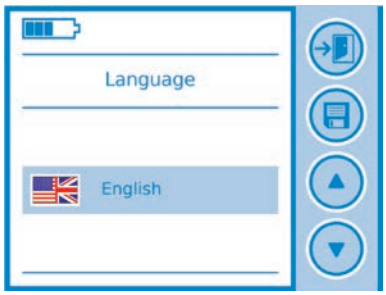
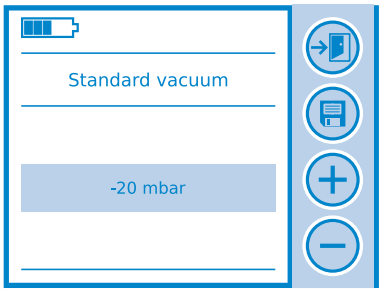
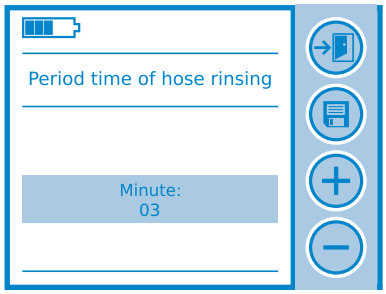
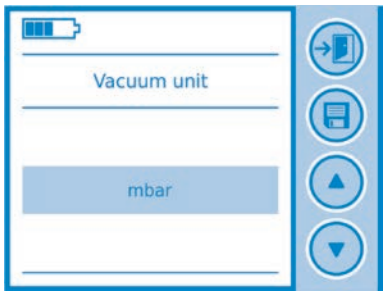
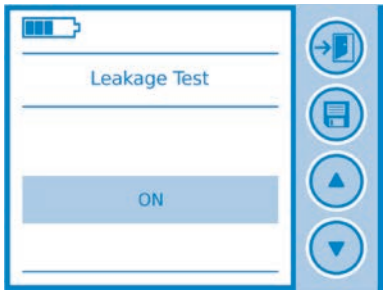
Touch the and buttons to move up and down in the menu selection.

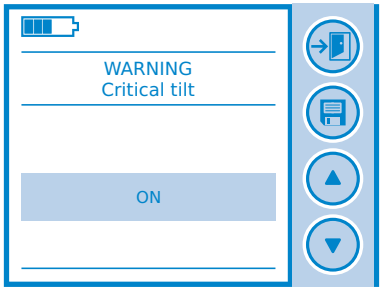
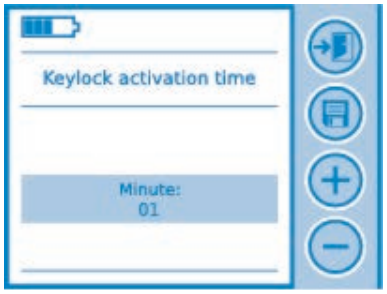
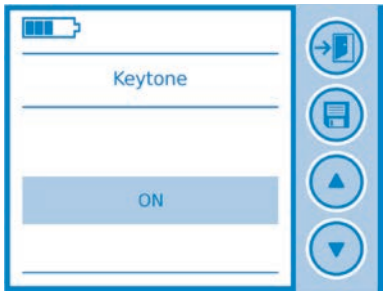
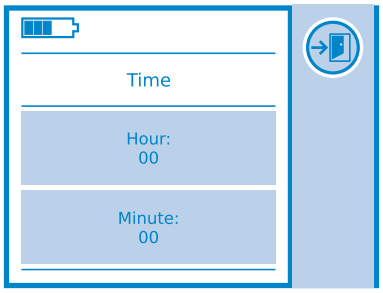
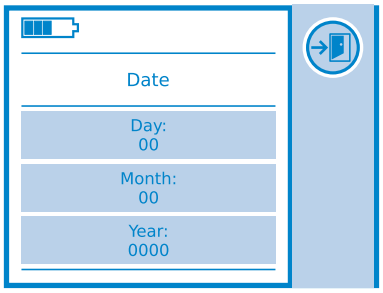
To select a settings menu, touch the text box.

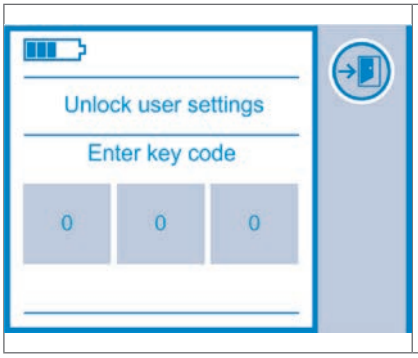
These buttons can be found in every settings menu:

- By touching the button, you will return to the user menu.
- ⚠ The selected data are only saved if you touch the save entry button.

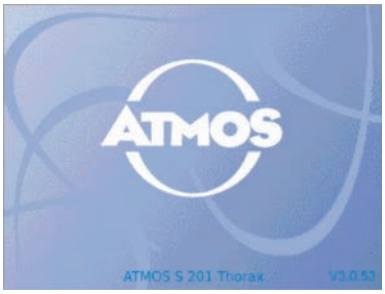
In the user settings, the following positions can be selected:

	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 −.
	Cycle duration for 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 using ▲ and ▼.
	Time	By touching one of the two buttons (hour or minute), you can access the individual settings. Now you can change the time with ⊕ and ⊖.
	Date	By touching 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 Switching off the device

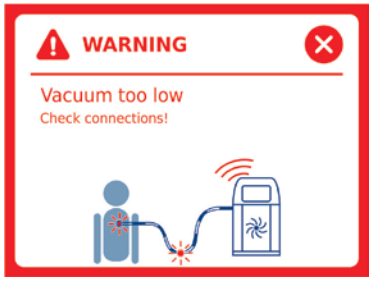
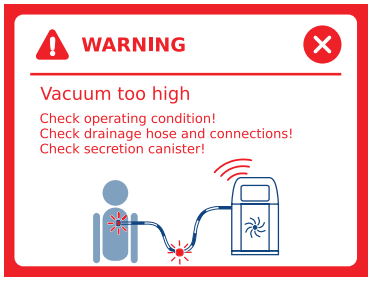
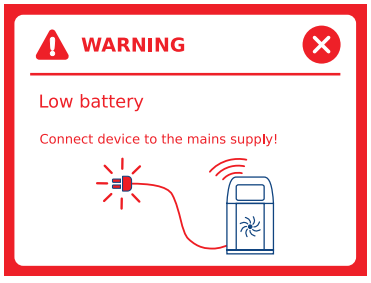


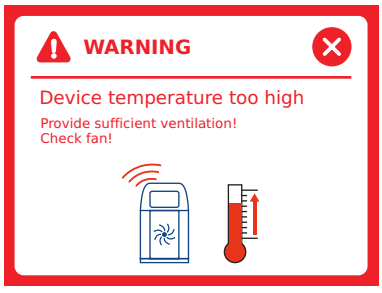
- To switch off the ATMOS S 201 Thorax, stop the therapy and touch the sensor for 2 seconds.
- The ATMOS logo appears on the screen and the device shuts down.

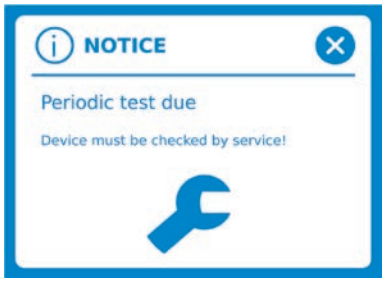
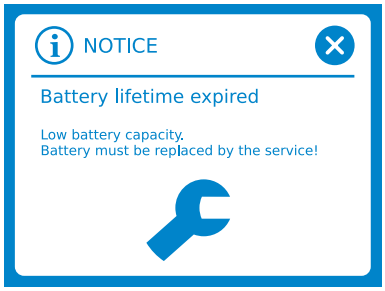
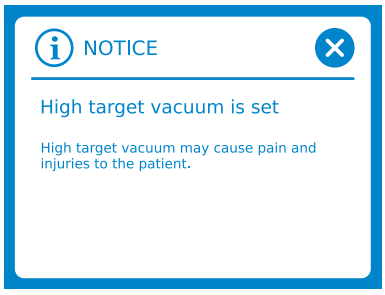
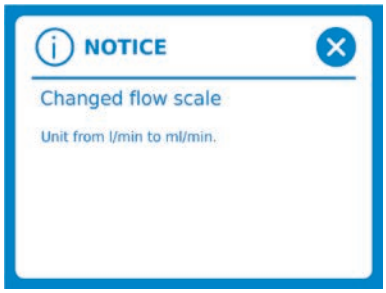
5.0 Warning messages

⚠ 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. A warning message is displayed. This contains advice for the elimination 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 reached, the alternating warning message 'Vacuum too low' and 'Secretion canister full or hose blocked' is activated. Possible reasons for this warning message are: Leakages	• Check for leakage: - Connection from the hose system to the patient catheter - Connection from the hose system to the secretion canister - Secretion canister connection • Contact ATMOS Service
	If the target vacuum is not reached, the alternating warning message 'Vacuum too low' and 'Secretion canister full or hose blocked' is activated. Possible reasons for this warning message are: • Blockages	• Check for blockages: - Secretion canister - Hose - Filter in the secretion canister - Filter in the measuring hose • Contact ATMOS Service
	The measurement of an excessively high vacuum results in the display showing the warning message 'Vacuum too high'. Possible reasons for this warning message are: • Ventilation valve is defective. • There are further vacuum sources in the drainage area.	• Remove vacuum sources • Contact ATMOS Service
	If the voltage of the battery falls below a specific value, the warning message for 'Battery low' is displayed.	Connect device to the supply network. The battery is charged and the state of charge is indicated in the display.

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 warning message function is activated in the factory settings. If the warning message 'Device in critical tilt' is not desired, it can be deactivated (see chapter '4.9 User settings' on page 43). Generally, it is recommended to activate the warning message function 'Device in critical tilt' to avoid malfunction caused by the device tipping over.		
	If the device is in a tilted position, the warning message 'Device in critical tilt' appears.	Place the device in an upright position. The warning message is automatically deactivated.
	If the therapy has not been started after new installation/ start-up of the device, the warning message 'Inactive therapy' appears without tone.	Touch 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.	Touch 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 ATMOS Service.
	Device temperature too high. • Device is in the sun or near a heater. • Ventilation slots are covered. • Fan is defective.	• Place the device in a cooler location. • Please ensure sufficient air ventilation. • Please contact ATMOS Service.

Display	Cause	Recommended actions
	Carry out an inspection according to the manufacturer's specifications every 12 months. This will be displayed on the device.	Contact ATMOS Service.
	A dwindling battery capacity is indicated to you on the device.	Battery must be replaced by ATMOS Service.
	If the set target vacuum is greater than −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 appears indicating that the scaling unit has changed from l/min to ml/min.	

6.0 Function

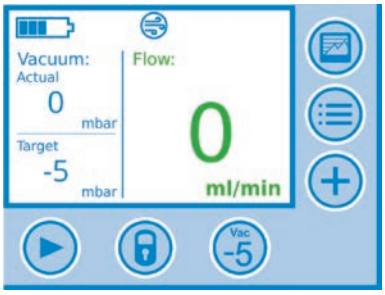
6.1 Hose rinsing

- The ATMOS S 201 Thorax has an automatic hose rinsing function that 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 manufacturer's default setting for the period between 2 rinsing cycles is 3 minutes.

ⓘ If the water lock function is being used, air bubbles are likely to appear during the hose rinsing period. These air bubbles occur at regular intervals according to the set cycle duration of the hose rinsing process and have nothing to do with the patient's condition (e.g. fistula).

The automatic hose rinsing process is indicated by the symbol in the display.

6.2 Gravity drainage mode while using the drainage system



During normal operation, the filling of the water lock in the secretion canister is optional.

A physiological vacuum can be generated by setting the target vacuum to −5 mbar (touch the Vac -5 button):
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 safety features.

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

6.3 Operation of the secretion canister for temporary gravity drainage

⚠ Operation of the secretion canister for temporary gravity drainage is only permitted with REF 312.1150.5 and 312.1120.0. For REF 312.1140.0, the use for temporary gravity drainage is prohibited (see chapter '7.0 Accessories, consumables and spare parts' on page 52).

⚠ It is mandatory to fill the water lock in the secretion canister for temporary gravity drainage.

1. Set the desired target vacuum (max. −18 mbar) on the activated device and wait until the target vacuum is reached. The target vacuum is thus set at the beginning for temporary gravity drainage in the secretion canister.
2. Afterwards, stop therapy by touching the ⏸ button.
3. Clamp the measuring and rinsing hose and remove it from the drainage system.
4. The bacterial and viral filter of the measuring and rinsing hose (see chapter '3.3.3 Connecting the hose system' on page 28) can also be inserted into the cover cap to seal the secretion hose (see chapter '3.3.2.1 Secretion canister system overview – versions with a water lock' on page 25).
5. Then press the release button to remove the secretion canister from the drainage system (see chapter '3.2 Device overview' on page 22).

6. Place the secretion canister below the thorax in an upright position for temporary gravity drainage.

⚠ Make sure that the patient hose has no loops and/or kinks, as this could hinder the drainage of fluids and air.

7. The vacuum applied at the patient's end corresponds to the water level in the riser of the water lock.
8. The secretion hose and water lock must be inspected regularly by trained medical staff to ensure correct operation.

7.0 Accessories, consumables, and spare parts

Accessories	REF
Universal bracket for ATMOS S 201 Thorax	312.1160.0
Carrying strap for ATMOS S 201 Thorax	312.0850.0
Hose clamp	061.0079.0

Consumables	REF
OT set for ATMOS E/S 201 Thorax Included in the OT set: Secretion canister 2 l, 10 pcs. (sterile) Hose system, 10 St. (sterile)	312.1031.0
Secretion canister 2 l, 5 pcs.	312.1150.5
Secretion canister 2 l without water lock, 5 pcs.	312.1140.0
Secretion canister 2 l – Standard, 10 pcs.	312.1120.0
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
Y-connector, 50 pcs.	312.1101.0
Pediatrics connector, with different ends, 1 pc.	312.1102.0
Straight connector (without Luer-Lock), 1 pc.	312.1103.0
Connection set for thoracic catheters, 50 pcs.	312.1104.0

Spare parts	REF
3-pole power cable, L = 3 m	507.0859.1
3-pole power cable, L = 5 m	008.0629.0

7.1 Attachment of the universal bracket (accessories)

The universal bracket can be mounted to infusion tripods, wheelchairs, to crossrods and longitudinal bars of the bed, or to a standard rail.

Align the fastening clamp ❶:

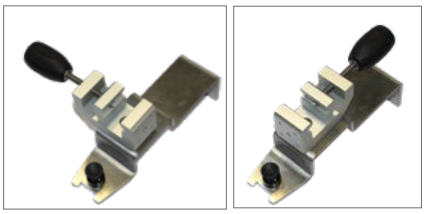
1. Pull the stop bolt ❸.
2. Rotate the fastening clamp 90°.
3. Allow the stop bolt to snap into position.

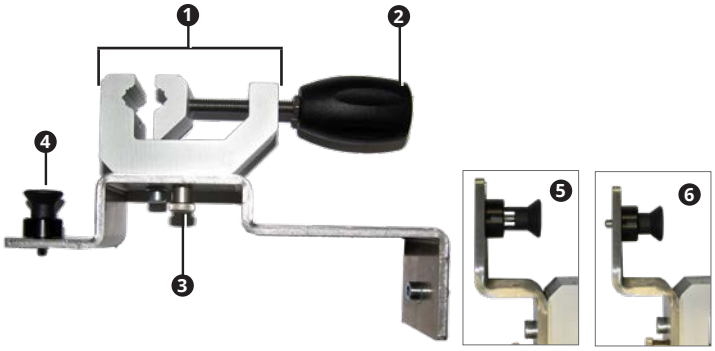
Attach the universal bracket:

4. Hold the universal bracket on the desired rail.
5. Turn the knob ❷ until the universal bracket is fixated.

Attach the device to the universal bracket:

6. Pull the locking system ❹ and rotate it by 90° so that the stop bolt is drawn in ❺.
7. Place the device on the universal bracket.
8. Pull the locking system and rotate it by 90° so that the stop bolt fixates the device ❻.





7.2 Attaching the carrying strap

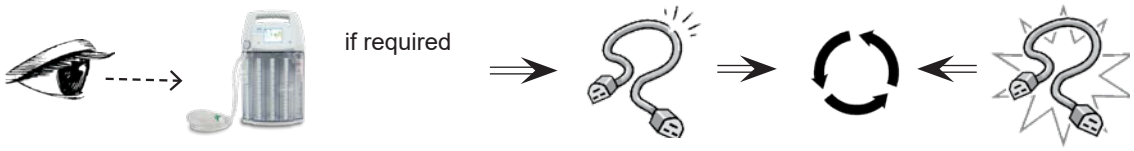
Attach the carrying strap to the handle using the Velcro fastener, adjust the strap to the desired length, and put the device over your shoulder.

8.0 Cleaning and care

8.1 General information on cleaning and disinfection

Prior to cleaning:

Medical devices such as the ATMOS S 201 Thorax must operate safely and reliably at all times. Therefore, we recommend prior to every use:



⚠ Handling of the cardiothoracic drainage system determines to a large extent its reliability and safety. These hygiene measures are necessary measures for the protection of patients and users, and for maintaining the functional reliability of the cardiothoracic drainage system.

⚠Prior to cleaning the device, please remove all disposable parts such as the secretion canister and hoses. Please also remove the power cable.

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

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

⚠ Prevent liquids from entering the cardiothoracic 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 containing organic or inorganic acids or bases, as they could cause corrosion damage.
- Disinfectants containing chloramides or phenol derivatives, as they could cause stress cracks in the plastic material used.

Disposable gloves must be worn for all work.

For disinfection, you may use all surface disinfectants listed in chapter ‘8.4 Recommended disinfectants’ on page 55.

When the device is used on another patient, all parts which come into contact with the patient or 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 agents and disinfectants on the surface have dried completely.

We recommend that you always document all maintenance work and part replacements 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 one of the following surface disinfectants.

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 disinfected with one of the following surface disinfectants.

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

8.3 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 one of the following surface disinfectants. 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 disinfected with one of the following surface disinfectants.

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

8.4 Recommended disinfectants

Disinfectant	Contents	in 100 g	Manufacturer
ATMOS Green & Clean SK	Di alkyl dimethyl ammonium chloride Alkyldimethylethylbenzylammoniumchloride Alkyldimethylbenzylammoniumchloride	< 1 g < 1 g < 1 g	Metasys, Rum (Austria)
Dismozon® pur (granule) End of product 12/2014	Magnesium peroxyphthalate Hexahydrate	80 g	Bode Chemie, Hamburg
Dismozon® plus (granule)	Magnesium peroxyphthalate Hexahydrate	95.8 g	Bode Chemie, Hamburg
Kohrsolin® FF (Application concentrate)	Glutaral Benzyl-C12-18-alkyldimethyl-ammonium chlorides Didecyldimethylammoniumchloride	5 g 3 g 3 g	Bode Chemie, Hamburg
Kohrsolin® extra (Application concentrate)	(ethylenedioxy)dimethanol Glutaral Didecyldimethylammoniumchloride	14.1 g 5 g 8 g	Bode Chemie, Hamburg
perform®	Pentapotassium-bis(peroxymonosulphate)-bis(sulphate)	45 g	Schülke & Mayr, Norderstedt
Bacillol® 30 Foam ⓘ Do not use for touch screen!	Ethanol Propane-2-ol Propane-1-ol n-alkyl-aminopropylglycine	14 g 10 g 6 g < 1 g	Bode Chemie, Hamburg
SaniCloth® Active	Didecyldimethylammonium chloride	< 1 g	Ecolab, Düsseldorf
Incidin® Active	Peracetic acid	< 1 g	Ecolab, Düsseldorf
mikrozid® sensitive wipes	Benzyl-C12-16 alkyldimethyl-, chloride Didecyldimethylammoniumchloride Benzyl-C12-14-alkyl [(ethylphenyl)methyl]dimethyl-, chlorides	0.26 g 0.26 g 0.26 g	Schülke & Mayr, Norderstedt

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

When using disinfectants containing aldehyde and amine on the same object, discolouring may occur.

⚠ Do not use disinfectants containing alcohol (exception: Bacillol 30 foam).

8.5 Hygiene plan

WHAT	HOW				WHEN					NOTES
	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
Canister ⊗	X								X	Disposable product – not suitable for reprocessing, change after use
Hose system ⊗	X								X	Disposable product – not suitable for reprocessing, change after use
Carrying strap	X								X	A new carrying strap should be used for each patient.
Connectors ⊗	X								X	Disposable product – not suitable for reprocessing, change after use
Universal bracket		X					X		X	Manual wipe cleaning
			X				X		X	Manual wipe disinfection

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

9.0 Maintenance and service

9.1 Basic instructions

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

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

Carry out an inspection according to the manufacturer's specifications every 12 months. The device does not require any further maintenance.

Regular, thorough cleaning and disinfection of the device and the applied parts as well as the operation of the device in line with the operating instructions are assumed.

Please observe any national and international regulations applicable for your institution.

9.2 Repairs

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

- Liquid has penetrated the cardiothoracic 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 chapter '10.0 Troubleshooting' on page 59.

9.3 Sending in the device

If the cardiothoracic 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 all consumables and dispose of them properly.
2. Clean and disinfect the product and accessories in accordance with the operating instructions.
3. Place any used accessories with the product.
4. Fill in form QD 434 'Delivery complaint / return shipment' and the corresponding **Decontamination certificate**.

☞ This form is enclosed with 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 your dealer.

9.4 Handling of batteries

Rechargeable batteries are wear parts with a limited lifetime. Under optimal conditions of use, lithium-ion batteries are usually worn after approx. 500 charge cycles and should then be replaced. Handling of the device and the batteries significantly affects lifetime of the batteries.

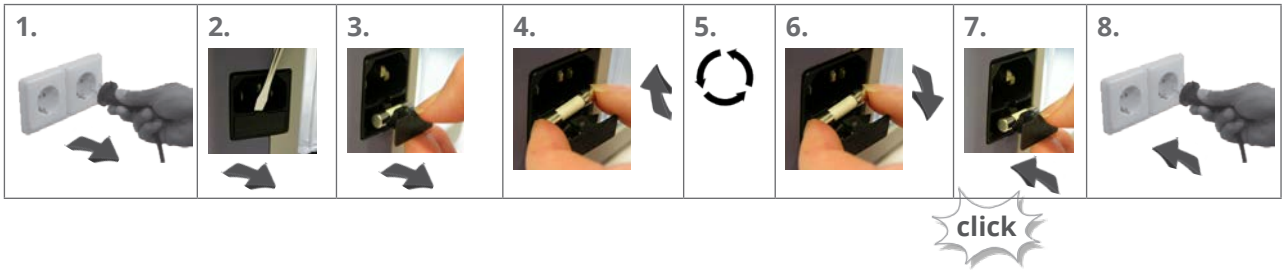
Non-observance of the following recommendations may significantly decrease lifetime.

- ☞ Always store device with batteries in a cool and dry place (room temperature 18–25 °C).
- ☞ Always store device with batteries at a charge status of 20–40%.
- ☞ Avoid deep discharge: Devices with permanently installed batteries should be recharged every 4–5 months.
- ☞ Never cover the device, never expose the device to direct sunlight, and never charge, operate, or store the device in close vicinity of heaters.
- ☞ Always charge the batteries using the respective charging accessories. Overcharging will destroy the batteries.
- ☞ The lifetime of lithium-ion 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!

9.5 Changing the fuse



10.0 Troubleshooting

Description	Possible causes	Measures
Device cannot be switched on.	Battery is completely empty.	Connect the power cable and thereby charge the battery. Observe the display of battery status.
Battery does not recharge; charging symbol does not light up even though power cable is plugged in.	Fuses are defective.	Check the building and device fuses.
	Power cable defective or not connected properly.	Check the power cable.
	Recharging unit, charging electronics, or battery are internally defective.	Contact 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 patient catheter, connection of the hose system to the secretion canister/device, and connection of the secretion canister.
'Secretion canister full or hose blocked'	Secretion canister full.	Exchange secretion canister. See chapter '3.3.2.6 Changing the secretion canister' on page 27.
	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 in the 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 defective.	Contact ATMOS Service or a certified service partner. The device must be checked.
'Battery low'	Battery almost empty.	Connect device to the supply network. The battery is charged and the state of charge is indicated in the display.

System shut down.	Battery empty.	Connect device to the supply network. The battery is charged and the state of charge is indicated in the display.
High temperature of the device.	Ventilation slots are covered.	Please ensure sufficient air ventilation. Contact ATMOS Service or a certified service partner. The device must be checked.
Leakage test failed.	Hose system is not completely closed.	Check the hose system and secretion canister for correct fit. See chapter '3.3.2.6 Changing the secretion canister' on page 27.
	Secretion canister is leaking.	
	Internal error.	Contact ATMOS Service or a certified service partner. The device must be checked.
Flow readout is always 0 l/min.	Component error.	1) Check whether the flow is also 0 l/min when the system is open. 2) Contact ATMOS Service or a certified service partner. The device must be checked.
	Secretion has entered the device.	
'Device cannot be operated'	Internal error.	Contact ATMOS Service or a certified service partner. The device must be checked.

11.0 Technical data

11.1 ATMOS S 201 Thorax

Input voltage	100 – 240 V~; 50/60 Hz
Power consumption	max. 70 VA
Rechargeable battery, built-in	Li-Ion, 14.4 V nominal, 3350 mAh nominal
Fuses	1 x T 1.25 A/H, 250 V
Other safety lugs	Pressure control valve „pop-off" in the canister. Vacuum limitation in the device to approx. 150 mbar. Acoustic and optical error warnings.
Pump performance	Freeflow 18 ± 2 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. Up to 12 days recording possible.
Mode of operation	Continuous operating, at ambient temperatures. Simultaneous battery recharging and operation possible.
Battery operation time at maximum continuous suction	1 h
Battery operation time at standard operation (without fistula)	12 h
Battery recharging time	Fully recharged (at least 95 %) in approx. 2.5 h
Earth leakage current	max. 0.5 mA
Patient leakage current	max. 0.01 mA
Environmental conditions Transport/storage	
• Temperature range	−10...+50 °C
• Air humidity without condensation	30...95 %
• Air pressure	700...1060 hPa
Environmental conditions Operation	
• Temperature range	+10...+35 °C
• Air humidity without condensation	30...95 %
• Air pressure	700...1060 hPa
Maximum operating altitude	3000 m (NN)
Contamination level	Class 2
Overvoltage category	II
Dimensions (H x W x D)	approx. 365 x 250 x 168 mm
Weight	3.7 kg (device with canister)
Housing material	ABS/PC UL 94 V0, grey-white and pigeon blue

Noise level	max. 31 dB(A) @ 1 m
Periodic tests	Inspection according to manufacturer's specifications every 12 months. *(Germany: Safety inspection according to MPBetreibV)
Protection class against electric shock (acc. to EN 60601-1)	II, protective earth conductor only for EMC protection
Classification of applied parts	Type CF applied parts  Recovery time: 10 sec.
Degree of protection	IPX0
CE marking	CE 0124
Reference number (REF)	312.1000.0 ATMOS S 201 Thorax 312.1080.0 ATMOS S 201 Thorax

11.2 Secretion canister 2 l

Capacity	Max. 2000 ml
Characteristics	• ATMOS disposable canister • Transparent • Adaption to device by "Plug'n Play system"
Material	PC Lexan 144R Resin
Components	• Over pressure valve (pop-off valve) • Hydrophobic viral and bacterial filter • With and without integrated water lock • Covering caps for closing the pop-off valve & inlet of secretion hose • Graduation on all chambers of the canister
Environmental conditions Transport/storage	
• Temperature range	−20...+40 °C
• Air humidity without condensation	30...95 %
• Air pressure	700...1060 hPa
Environmental conditions Operation	
• Temperature range	+10...+35 °C
• Air humidity without condensation	30...95 %
• Air pressure	700...1060 hPa
Dimensions (W x H x D)	214 x 280 x 96 mm
Weight	430 g
Packaging	Canister with protection caps for sterile packaging on top and on the bottom. Sterile packaging: PET/PE centre strip pouch (a foil pouch with a Tyvek paper strip).
Packaging unit	5 separately packed canisters in a brown packaging.
Sterilisation	EO (ethylene oxide)

CE marking	CE 0124
Reference number (REF)	312.1150.5 Secretion canister 2 l 312.1140.0 Secretion canister 2 l without water lock

Bacterial and viral filter

Bacterial filtration efficiency (BFE)	99.999778%*
Viral filtration efficiency (VFE)	99.73 %*
Overall filtration efficiency	>99.95%*
Filter class	H13 (High-Efficiency Particulate Air/Arrestance)*

*External test report (test laboratory)

11.3 Hose system

Length	1.80 m
Characteristics	• 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 plug • Connectors (with or without Luer lock) • Luer lock cap • Hose clamp
Environmental conditions Transport/storage	
• Temperature range	−20...+40 °C
• Air humidity without condensation	30...95 %
• Air pressure	700...1060 hPa
Environmental conditions Operation	
• Temperature range	+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 packaging: foil 100 µm (Tyvek)
Packaging unit	10 separately packed hose systems in a brown packaging.

Sterilisation	EO (ethylene oxide)
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

Bacterial filtration efficiency (BFE)	99.999778%*
Viral filtration efficiency (VFE)	99.73 %*
Overall filtration efficiency	>99.95%*
Filter class	H13 (High-Efficiency Particulate Air/Arrestance)*

*External test report (test laboratory)

12.0 Disposal/recycling

Packaging

1. Recycle any device packaging you no longer need.

Hose and secretion canister system

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

ATMOS S 201 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 recycle the device professionally.
3. In other countries: Recycle the device professionally 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 S 201 Thorax) has an expected service life of 8 years. A regular thorough cleaning and disinfection of the suction device and its applied parts as well as operation in line with the operating instructions are assumed.

13.0 Notes on EMC (Electromagnetic compatibility)

- ℹ 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 60601-1-2:2016-05.

13.1 Guidance and manufacturer's declaration – ambient conditions

The ATMOS S 201 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, hospitals/clinics, or first-aid facilities as well as operating theatres/rooms.

It is not suitable for use in the vicinity of HF surgical devices and in settings outside of an HF-shielded room of a magnetic resonance imaging system.

☞ The customer or user of the ATMOS S 201 Thorax must ensure that it is used in such an environment.

13.2 Guidance and manufacturer's declaration – key features

The ATMOS S 201 Thorax has the following electrical components:

Type	REF	Max. cable length
3-pole power cable, L = 3 m	507.0859.1	3 m
3-pole power cable, L = 5 m	008.0629.0	5 m

13.3 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 S 201 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 S 201 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.

ATMOS
MedizinTechnik

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