

Operating Instructions

ATMOS Record 55

with standard rail

English



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1 Introduction

1.1 Notes on operating instructions



These operating instructions contain important instructions on how to operate your product safely, correctly and effectively.

These operating instructions are designed for training and instructing new operating personnel in the use of the system, and 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 to hand near the device.



Care, period tests, regular cleaning and proper application are essential. They ensure the operational safety and usability of the product.

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



Read chapter "2 Notices for your safety" on page 9 before using the product for the first time. This will help you to avoid potentially dangerous situations.

The product bears CE marking CE 0124 according to the EC Directive of the council for medical products 93/42/EEC and meets the basic requirements of appendix I of this directive.

The product complies with all the applicable requirements of Directive 2011/65/EC on the restriction of the use of certain hazardous substances in electrical and electronic equipment ("RoHS").

The Declaration of Conformity and our general standard terms and conditions can be viewed on our website at www.atmosmed.com.







The quality management system at ATMOS has been certified according to international standard EN ISO 13485.

These operating instructions are valid for the following devices:










ATMOS Record 55 with standard rail 230 V	REF 443.0700.0
ATMOS Record 55 with standard rail 100 V	REF 443.0700.1
ATMOS Record 55 with standard rail 115 V	REF 443.0700.2
ATMOS Record 55 with standard rail 127 V	REF 443.0700.3















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.
ATTENTION	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.
	Useful information on the handling of the device.
1.	Action. Proceed step by step.
»	Result of an action.
	Move, plug in this direction.

On device and type plate

	Follow operating instructions (blue)
	Observe the operating instructions
	Warning; take extra care to observe
	This product complies with the relevant requirements of the EU Directives.
	This product complies with the relevant requirements of the EU Directives.
	Foot switch
	Manufacturer
	Manufacturing date
	GOST Certificate (Russia)

	Eurasian conformity
SN	Serial number
REF	Order number
	European Article Number
IPX1	Protection against the ingress of damaging moisture (dripping water)
	Application part type BF
	Professional disposal
	For single use only (symbol located on consumables)
	Not sterile
	Autoclavable
	Connection suction hose/patient (Serres® canister system)
	Potential equalization
	Protection class II
	Fuse
	Alternating current
	On, connected to the power supply
	Class AP (for use in potentially explosive areas)

1.3 Intended use

Main function: Suction of secretions, blood, serous fluids, rinsing fluids and for the temporary collection of these fluids.

Medical indications / application: For all applications where suction is needed, such as in general surgical procedures (e.g. suction of wound cavities, abscesses), the nasopharyngeal cavity, for endoscopy, for suction of secretion or rinsing fluids, and in neurosurgery. For subcutaneous liposuction.

Specification of the main function:	For the drainage and temporary collection of body fluids. By means of an electrical suction pump a negative pressure is created. An additional secretion canister must be attached to allow temporary collection of the derived body fluids.
User profile:	Doctors, medical auxiliaries without restrictions.
Patient groups:	Patients of all ages with and without restrictions.
Application organ:	Natural orifices and openings which result from a surgical intervention (entire body of humans and animals).
Application time:	For short term use on patients (< 30 days)
Area of application:	The application site is the clinical, outpatient and veterinary field. The device may only be used by persons who have received the relevant training and instruction.
Contraindications:	Not suitable for: <ul style="list-style-type: none"> • Drainage operations in the low vacuum range (e.g. thoracic or wound drainage) • Use outside the medical sector • Suction of flammable, corrosive or explosive substances • Suction in potentially explosive atmospheres • Not suitable for use as a vacuum extraction system
The product is:	Active
Sterility:	No sterile product
Single-use product/ re-sterilisation:	The device and parts of the accessories are reusable. For information on reprocessing, cleaning and disinfection please see the operating instructions.

1.4 Function

The ATMOS Record 55 is a mains-operated surgical suction device, the core of which is a high-performance, maintenance-free diaphragm pump. It generates vacuum in the hose and rinsing canister system which assists in drawing off and collecting the secretions. Via a vacuum regulator with vacuum gauge, the final vacuum and thus the desired suction capacity can be precisely adjusted.

Several secretion canisters of different sizes are available for secretion collection. A mechanical overflow protection on the double hose connector and a bacterial filter in the vacuum hose from the secretion canister to the pump, prevents the suction of secretion into the pump.

1.5 Intended users

May only be used by trained professionals in supervised and medical operations.

1.6 Scope of delivery

Basic device ATMOS Record 55 with standard rail

Name	REF
1x Power cable 5 m	008.0629.0
2x Hydrophobic bacterial and viral filter	443.0738.0
1x Hose holder	443.0003.0
1x Suction hose (silicone), Ø 6 mm, L=2m	000.0361.0
1x Suction hose (silicone), Ø 10 mm, L=2m	000.0243.0
1x Suction hose (silicone), Ø 7 mm, L=0.65m	006.0008.0

1.7 Transport and storage

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

If damage occurs during transport:

1. Document and report the transport damage.
2. Send the device to ATMOS, see Chapter "6.3 Sending in the device" on page 24.

Ambient conditions for transport and storage:

- Temperature: -30...+50°C
- Relative humidity: 5...90% without condensation
- Air pressure: 700...1060 hPa

2 Notices for your safety

2.1 General safety instructions

The product will only meet the safety requirements of users, patients and third parties when it is fully functional. Therefore read the following instructions carefully:

Please read and pay attention to the safety instructions prior to using the product.

2.2 Danger for users, patients and third parties

WARNING

Danger of suffocation for children through accessories!

Children can strangle themselves or be suffocated by small parts.

- Keep children away from hoses and connection cables.
- Keep children away from swallowable small parts. Small parts are, e.g. fingertip and sealing ring.

CAUTION

Explosion and fire hazard!

There is a risk of burns and injuries.

- Never suction any explosive, flammable or corrosive gases or liquids. Please observe the intended use in chapter "1.3 Intended use" on page 6.
- Never operate the device in potentially explosive areas or areas which are oxygenated.
- Only use original accessories and original spare parts from ATMOS.

WARNING

Risk of severe injury to your patient.

Avoid misuse.

- The device may only be used by persons who were medically trained, and were instructed in the handling of the medical suction system.
- The product may only be used by qualified personnel in supervised operation.
- Please select the vacuum according to the patient and the application.
- Observe the valid guidelines.
- Always set up the unit in such a way that the operating elements are in clear view and within easy reach of the operator. The device must be set up on a stable, level surface.

⚠ WARNING

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


Your patient could suffocate.

- Before connecting the device it must be checked whether the requested mains voltage on the device matches the mains voltage of the mains power supply.
- Position the unit in an easily accessible location and keep access free.
- Make sure that the power cable is working. Replace defective accessories immediately.
- Prior to first use, the transport protection on the bottom of the device must be removed.
- ATMOS always recommends having an alternative suction device ready to hand thus suction is available even in the event of device failure.

⚠ WARNING

Risk of infection due to pathogens on the product!

Risk of deadly diseases being transmitted.

- In case you come into contact with secretion, disposable gloves should be worn.
- Always wear disposable gloves when using the product.
- Never use components which are marked with  more than once. These components are intended for single use only.
- Sterile packaged parts may only be used when the packaging is undamaged.
- Do not operate the device without a bacterial filter.
- A suction catheter, hose-rinsing aperture, or medical suction set must always be connected to the hose. The suction hose must never come into direct contact with the suction area.
- Clean and disinfect the product after every use.
- Clean and disinfect the product according to the operating instructions.
- The device must not be used following oversuction.

⚠ CAUTION

Tripping hazard by cables.

Injuries are possible.

- Lay connecting cables properly.

⚠ WARNING

Electric shock due to improper mains connection, incorrect handling of the product or damaged product components.

Risk of burns, cardiac arrhythmias and even fatal injury.

- 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.
- Disconnect the device from the mains supply prior to cleaning or disinfection.
- Disconnection of the device is only possible by removing the power plug from the power supply.
- Position the device so that it can be easily disconnected from the mains power supply.
- Never connect the device to a mains power supply without a protective conductor.
- Never touch the plug or power cable with wet hands.
- Only use the power cable in dry surroundings. The surroundings must be non-conductive.
- Ensure that no liquid penetrates the device. If liquid enters the device, operation of the device must cease immediately. In this case, clean and disinfect the device and send it to ATMOS for repair.
- Only use proper power cables and extension cables.
- Never touch the device interface and the patient at the same time!
- Only use original accessories and original spare parts from ATMOS.
- Pay attention to the period tests in chapter 6.0 „Maintenance and service“.
- 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.

2.3 Avoid damage to the device

ATTENTION:

Storage and operation in an unsuitable environment.

Risk of damage to the product.

- Please observe the ambient conditions regarding transport, storage and operation.
- After transportation of the device at low temperatures and prior to first start-up it should be kept at room temperature for at least six hours. If the device is not acclimatized it may not be used as the diaphragm of the pump could be damaged.

3 Setting up and starting up

3.1 Device overview

Front view



- ❶ Vacuum gauge
- ❷ Vacuum regulator
- ❸ On/Off switch
- ❹ Bacterial filter and connection piece
- ❺ Hose holder
- ❻ Connection for foot switch or foot controller (optional)

Rear view



- ❶ Connection for potential equalization
- ❷ Equipment safety fuse
- ❸ Mains supply

⚠ Risk of injury and risk of infection due to production residues.

1. Prior to first use, prepare the product according to the operating instructions.

4 Operation

4.1 Initial start-up

- ☞ Observe the safety instructions prior to initial start-up!
- ☞ Remove the transport protection on the bottom of the device by loosening the two red marked Allen screws.
- ☞ The transport protection screws must be inserted again before a return transport of the device.
- ☞ After transportation of the device at low temperatures and prior to initial start-up it should be kept at room temperature for at least six hours otherwise the device may not be operated.

4.2 Preparing the device

- Check whether the voltage and frequency data listed on the device correspond to the values of the mains power supply and connect it to the mains.
- ☞ For surgical procedures, we recommend additionally connecting the device via the connection to the potential equalization of the examination room.
- » The device is now ready for use.

4.3 Connecting the bacterial filter



- Insert the bacterial filter with the short piece of hose onto the connection piece on the device.
- ☞ Pay attention to the correct flow direction on the bacterial filter. The type label must point towards the front.

4.4 Connecting the vacuum hose



- Connect the vacuum hose to the bacterial filter.

4.5 Attaching the secretion canister

1. Attach the secretion canister to the standard rail.
2. Connect the canister lid or double hose connector to the bacterial filter using a hose.
3. First make sure that the secretion canisters are attached in the front area. If additional secretion canisters are required, they can be attached laterally.

4.6 Connecting the suction hose

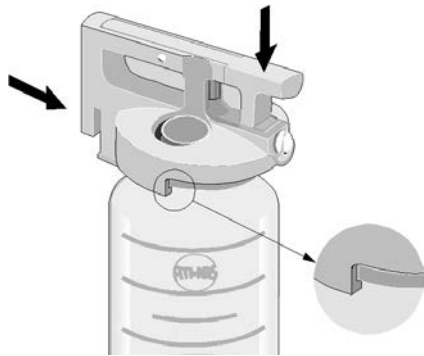


- Attach the suction hose to the angled connection.

4.7 Serres®, Medi-Vac® secretion canister system, other canister systems

- ☞ Observe the operating instructions by the manufacturer of the corresponding canister system.
- ☞ Do not operate the device without a bacterial filter.

4.8 Secretion canister system



- Slide the canister lid over the secretion canister (make sure the lid edge is over the edge of the canister) and press the locking handle downwards until it engages.
- The canister lid must tightly seal the secretion canister so that the desired vacuum can build up inside the secretion canister.

4.9 Double hose connector



Before inserting the double hose connector, check whether the float ball for the overflow safety can be easily moved. Then insert the double hose connector into the canister lid. Make sure that it fits tightly.

- ❶ Connection for vacuum hose
- ❷ Connection for suction hose
- ❸ Float ball for the overflow safety

4.10 Using an overflow canister



If the bacterial filter becomes blocked too frequently, ATMOS recommends integrating an additional overflow canister (REF 444.0646.0) between the secretion canister and the bacterial filter. This absorbs moisture and foam bubbles occurring.

An additional DDS bacterial filter can be used in the overflow canister. Replace the bacterial filter (REF 340.0054.0) with a new filter if it is discoloured, contaminated or oversucked. When the filter is used regularly, a filter change is recommended after 14 days at the latest.

4.11 Using a smoke evacuation filter

According to the intended use, the device is used to suction liquids and pieces of tissue. In conjunction with the use of laser, HF or radiosurgical devices, surgical smoke is generated and does not remain in the secretion canister, but is drawn with the air flow in the direction of the pump and can quickly block the bacterial filter for microbiological protection as well as the overflow protection. To increase the service life of the bacterial filter, an activated charcoal filter (REF 008.0758.0) or a specific smoke evacuation filter (HM 57524928) can be placed in front of it. This filters the aerosols / ultra-fine particles out of the air stream and protects the bacterial filter.

ATTENTION! THE SMOKE EVACUATION FILTER DOES NOT REPLACE THE BACTERIAL FILTER!

The smoke filter, however, prevents a premature decrease in suction performance by blocking the bacterial filter.

4.12 Suction

1. Please ensure that the following parts have been reprocessed before treating a new patient:
 - Suction hose including hose-rinsing aperture or suction instruments
 - Secretion canister including canister lid and double hose connector
 - Vacuum hose
2. Prior to each use check whether the bacterial filter must be replaced.
3. Replace the bacterial filter with a new filter if it is discoloured, contaminated or oversucked.
4. Switch on the device.
5. Close the suction hose and set the desired vacuum.
6. Connect the suction catheter, hose-rinsing aperture or suction instruments.
 - ☞ Observe the liquid level in the secretion canister during suction. The mechanical overflow protection and the bacterial filter prevent liquid from being sucked into the pump. Nevertheless, the secretion canister should be emptied or replaced when it is 2/3 full (including foam crown).
 - ☞ If liquid has been sucked into the pump despite the overflow protection and bacterial filter, the device may not be operated again until it has been checked by a authorized service partner

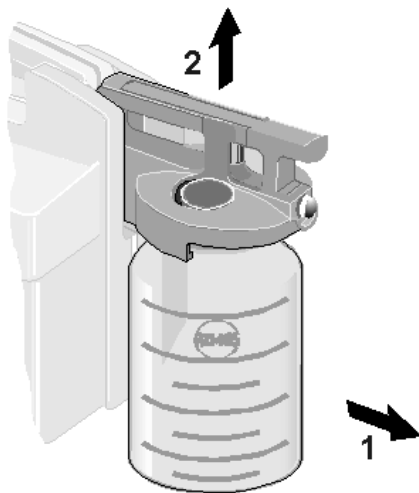
4.13 Checking the bacterial filter

ATTENTION

The bacterial filter is a disposable product and cannot be autoclaved or disinfected.

- Set the vacuum regulator to "max".
 - As soon as the vacuum gauge shows a vacuum value > -0.3 bar, while the suction hose is open, the filter must be replaced.
 - To do this, remove the suction connections on the bacterial filter and insert the new bacterial filter. Pay attention to the correct flow direction.
 - Dispose of the used bacterial filter immediately.
- ☞ Always have some spare filters ready to hand!

4.14 Exchanging the secretion canister

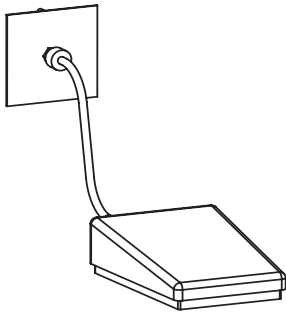


1. Stop the suction process and switch off the pump.
2. Remove the double hose connector from the full secretion canister. If you have attached a second canister, insert it and continue the suction process.
3. To remove the secretion canister, first tip it slightly away from the device (1) and then pull it upwards (2).
4. Now either empty it or replace it with a new secretion canister. To open the clamping bracket, put the secretion canister down and press the release button. Dispose the suction material properly.
5. After use, switch off the device and clean the device and accessories as described in the operating instructions.

4.15 Changing Serres®, Medi-Vac® secretion canister system and other secretion canister systems

- ☞ Observe the operating instructions by the manufacturer of the corresponding canister systems.

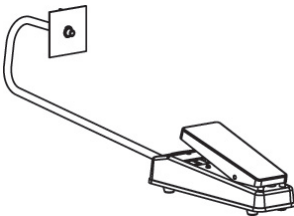
4.16 Options



Foot switch REF 443.0755.0

Pneumatically explosion-proof switch for switching the device on and off.

1. Connect the foot switch.
2. Set the main switch in the control panel to foot switch operation (OFF).
3. When you press the foot switch the device is switched on.
4. When you press the foot switch again the device is switched off.
 - If the main switch in the control panel is set to continuous operation (ON), the foot switch produces **no** effect.



Foot controller REF 443.0770.0

Foot controller for regulating the vacuum.

1. Connect the foot controller (remove the protection cap and tighten the nut of the foot controller hose).
2. To increase the vacuum press down the pedal.
 - When you lift up your foot, the controller locks in that position.

5 Reprocessing

5.1 Safety instructions for reprocessing

5.1.1 General safety instructions

We recommend you to always document all maintenance work and part replacements in writing.

It is the responsibility of the user to ensure that the demands for cleaning and disinfection are adhered to. Validation and routine monitoring of the procedure will generally be necessary.

The reprocessing treatment may only be carried out by persons who have the necessary expertise. To carry out these measures the person must have the necessary devices.

5.1.2 Danger for users, patients and third parties

Risk of infection due to unsuitable accessories.

Risk of deadly diseases being transmitted.

- Always wear your own personal protective equipment. The protective equipment consists of protective gloves, protective clothing, goggles and mouth and nose protection for all steps where the product components are still contaminated.
- Only use accessories which can be easily reprocessed or are disposable products.

Risk of infection due to unsuitable reprocessing.

Risk of deadly diseases being transmitted.

- Make sure that all areas of the accessories can be easily reached.
- Only use suitable load carriers for mechanical reprocessing. This especially applies to accessories with difficult to access cavities and lumens.
- Make sure that air bubbles do not form in the cavities and lumens when placed in the processing solution.

5.1.3 Avoiding damage to the device

Equipment damage due to fixed cleaning.

Residues cannot be permanently removed.

- Do not use aldehydes before and during cleaning.
- Do not expose the product to temperatures > 40°C / 104°F before and during cleaning.

Unsuitable accessories.

- ☞ Observe the respective operating instructions of all the accessories and devices used.

Unsuitable cleaning agents and disinfectants.

Risk of damage to the product.

- Do not use any process chemicals which contain the following ingredients **on plastic parts**
 - Chloramide or phenol derivatives
- Do not use any process chemicals which contain the following ingredients **on stainless steel**
 - Organic or inorganic bases
 - Alkaline solutions

Incorrect mechanical cleaning and disinfection.

Corrosion due to moisture.

- When the program is finished remove the products immediately.

5.2 Preparing/completing reprocessing

Prior to reprocessing

1. Disassemble the product for reprocessing into the following items:
 - Device
 - Hoses
 - Secretion canister system

After reprocessing

1. Perform a function check.

5.3 Prepare surfaces

5.3.1 Overview

Surface	After each application	After each patient	Daily	Weekly	Every 14 days	Monthly	Pre-cleaning	Wipe cleaning	Wipe-disinfection	Spray disinfectant	Remarks
Housing	X						X		X		

5.3.2 Select process chemicals

Always observe the manufacturer's specifications for the process chemicals.

Cleaning agent (manufacturer)	Active ingredients in 100 g	Type	Housing
Disinfection			
Green & Clean SK (Metasys)	<1 g of dialkyldimethylammonium chloride, <1 g of alkyldimethylethylbenzylammonium chloride, <1 g of alkyldimethylbenzylammonium chloride	Foam Ready for use	x
Dismozon® plus (Bode Chemie)	95.8 g of magnesium peroxyphthalate hexahydrate	Granulate	x
Kohrsolin® FF (Bode Chemie)	5 g of glutaral, 3 g of benzyl C 12 -C 18 -alkyldimethylammonium chlorides, 3 g of didecyldimethylammonium chloride	Liquid concentrate	x
Kohrsolin® extra (Bode Chemie)	14.1 g (ethylenedioxy) dimethanol, 5 g glutaral, 8 g didecyldimethylammonium chloride	Liquid concentrate	x
Perform® (Schülke & Mayr)	45 g of pentapotassium bis (peroxymonosulfate) bis (sulfate)	Powder	x
Mikrobac® forte (Bode Chemie)	19.9 g of benzyl C12-18-alkyldimethylammonium chloride, 5 g of N-(3-aminopropyl) -N-dodecylpropane-1,3-diamine	Liquid concentrate	x
Bacillo® 30 Foam (Bode Chemie)	14 g of ethanol, 10 g of propan-2-ol, 6 g of propan-1-ol, 0.5 g of N-alkyl-aminopropylglycine	Foam ready to use	x
Incidin® Active (Ecolab)	Peracetic acid	Powder	x
Mikrozid® Sensitive Wipes (Schülke & Mayr)	0.26 g of alkyl (C12-16) dimethylnezylammonium chloride, 0.26 g of didecyldimethylammonium chloride, 0.26 g of alkyl (C12-14) ethylbenzylammonium chloride	Wipes	x

5.3.3 Pre-cleaning

1. Disconnect the device from the mains power supply.
2. Clean the surface evenly with a suitable cloth and clear water. Pay particular attention to hard to reach areas.
 - » There is no more residue visible.

5.3.4 Wipe disinfection

Always observe the manufacturer's specifications for the process chemicals.

5.4 Reprocessing the accessories

5.4.1 Overview

	Disposable product	Max. reprocessing cycles	After each application	After each patient	Daily	Weekly	Every 14 days	Monthly	Pretreat	Pre-cleaning	Manual cleaning and disinfection	Mechanical cleaning and disinfection	Sterilize
Accessories													
Secretion canister system													
• Secretion canister ²		-	X						X	X		X	X
• Canister lid ²		-	X						X	X		X	X
• Twin hose nozzle ²		--	X						X	X		X	X
• DDS-Bacterial filter ¹	X						X						
Hoses													
• Suction hose		60	X						X	X		X	X
• Vacuum hose		60	X						X	X		X	X
• Vacuum hose		60	X						X	X		X	X

¹ Replace the DDS bacterial filter if it is discolored, soiled or oversucked, see Chapter 4.3.

² If there are visible defects/damage, accessories must be replaced.

5.4.2 Select process chemicals

Always observe the manufacturer's specifications for the process chemicals.

Cleaning agent (manufacturer)	Active ingredients in 100 g	Type	Secretion canister system	Hoses
Cleaning agents - Mechanical reprocessing				
neodisher® MediClean forte (Dr. Weigert)	<5% nonionic and anionic surfactants, enzymes	Liquid concentrate		X
neodisher® An (Dr. Weigert)	<5% nonionic surfactants, >30% phosphates, enzymes	Powder	X	
Neutralizer				
neodisher® Z (Dr. Weigert)	<5% nonionic and anionic surfactants, enzymes	Liquid concentrate	X	

5.4.3 Secretion canister system

Characteristics

The accessories have the following areas which are difficult to access:

- Double hose connector (lumens)

Carefully prepare areas which are difficult to access.

<p>Pretreatment at the site of use</p> <ul style="list-style-type: none"> • Flushing: 60 s • Rinsing: 60 s 	<ul style="list-style-type: none"> • Empty the rinsing canister • Clean the accessories under cold, running water. • Thoroughly rinse the cavities and lumens of the accessories with running water. <p>There is no more residue visible.</p>
<p>Collect and transport</p>	<ul style="list-style-type: none"> • Label any damaged accessories. • Place the accessories in a rinsing canister. • Transport the rinsing canister to the treatment site.
<p>Dismantle</p>	<ul style="list-style-type: none"> • See chapter "5.2 Preparing / completing reprocessing" • Dispose of disposable products
<p>Pre-cleaning</p> <ul style="list-style-type: none"> • Flushing: 1x / 30s • Rinsing: 60 s <p><u>Brush: Round brush</u> Size: 7 mm, Material: Nylon</p> <p><u>Brush: Round brush</u> Size: 11 mm, Material: Nylon</p> <p><u>Brush: Round brush</u> Size: 15 mm, Material: Nylon</p> <p><u>Brush: Square</u> Size: 40 x 10 mm, Material: Nylon, Special features: with angled head</p>	<ul style="list-style-type: none"> • Make the following cavities accessible: <ul style="list-style-type: none"> – Double hose connector – Canister lid • Make the following lumens accessible: <ul style="list-style-type: none"> – Double hose connector • Thoroughly clean the accessories evenly with a suitable brush under running water • Thoroughly rinse the cavities and lumens of the accessories with running water.
<p>Mechanical cleaning and disinfection</p> <p>Pre-wash 1 min Cleaning: 5 min, 50°C / 122°F Neutralize 2 min Intermediate rinse 1 min Disinfect 5 min, 93°C / 199°F Dry: 12 min, 110°C / 230°F</p>	<ul style="list-style-type: none"> • Secure the accessories on a suitable load carrier. • Clean and disinfect using a suitable program: <ul style="list-style-type: none"> – Pre-rinse with cold water – Cleaning with cleaning agent – Neutralize with neutralizing agent – Intermediate rinse with softened, cold water – Disinfection with demineralized water – Drying • Cleaning and disinfection device: according to EN ISO 15883-1 • Program: Miele Vario TD
<p>Check and maintain</p>	<ul style="list-style-type: none"> • Check the success of the reprocessing with a suitable light magnifier. They must be free of particles and organic material. • If reprocessing was unsuccessful, the procedure must be repeated. • Dispose of damaged accessories or have them repaired.
<p>Assembly</p>	<ul style="list-style-type: none"> • Not necessary.
<p>Function check</p>	<ul style="list-style-type: none"> • Not necessary.
<p>Packaging</p>	<ul style="list-style-type: none"> • Label damaged accessories. • Pack the accessories with a packing system according to DIN EN ISO 11607.
<p>Sterilize</p> <p>Prefractionated vacuum: 3x Temperature: 134°C / 273°F Time: 5 min Dry: 10 min</p>	<ul style="list-style-type: none"> • Sterilize the accessories using a suitable procedure: <ul style="list-style-type: none"> – Steam sterilization / autoclaving • Sterilizer: According to DIN EN 285
<p>Storage</p>	<ul style="list-style-type: none"> • Observe the ambient conditions, see Chapter "11 Technical data".

5.4.4 Hoses

Pretreatment at the site of use	<ul style="list-style-type: none"> • Clean the accessories under cold, running water. • Thoroughly rinse the cavities of the accessories with running water. <p>There is no more residue visible.</p>
Collect and transport	<ul style="list-style-type: none"> • Label any damaged accessories. • Place the accessories in a rinsing canister. • Close the rinsing canister. • Transport the rinsing canister to the treatment site.
Pre-cleaning	<ul style="list-style-type: none"> • Clean the accessories under running water. • Thoroughly rinse the lumen of the accessories with running water.
Dismantle	Not necessary.
Mechanical cleaning and disinfection Pre-wash 1 min Cleaning: 5 min, 55°C / 131°F Neutralize 2 min Intermediate rinse 1 min Disinfect 5 min, 93°C / 199°F Dry: 12 min, 110°C / 230°F	<ul style="list-style-type: none"> • Secure the accessories on a suitable load carrier. • Clean and disinfect using a suitable program: <ul style="list-style-type: none"> – Pre-rinse with cold water – Cleaning with cleaning agent – Neutralize with cold water – Intermediate rinse with softened, cold water – Disinfection with demineralized water – Drying • Cleaning and disinfection device: according to EN ISO 15883-1 • Adapter: Miele E366/E446 • Program: Miele Vario TD
Check and maintain	<ul style="list-style-type: none"> • Check the success of the reprocessing with a suitable light magnifier. • If reprocessing was unsuccessful, the procedure must be repeated. • Dispose of damaged accessories or have them repaired.
Assembly	Not necessary.
Function check	Not necessary.
Packaging	<ul style="list-style-type: none"> • Label damaged accessories. • Pack the accessories with a packing system according to DIN EN ISO 11607.
Sterilize Prefractionated vacuum: 3x Temperature: 134°C / 273°F Time: 5 min Dry: 10 min	<ul style="list-style-type: none"> • Sterilize the accessories using a suitable procedure: <ul style="list-style-type: none"> – Steam sterilization / autoclaving • Sterilisator: according to EN 285.
Storage	<ul style="list-style-type: none"> • Observe the ambient conditions, see Chapter "11 Technical data".

6 Maintenance and service

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

ATMOS recommends: Work should be carried out by an authorised ATMOS service partner. This ensures that repairs and tests are carried out professionally, original spare parts are used and warranty claims are maintained. Maintenance, repairs and period tests must **not** be performed, while the product is being used on the patient.

6.1 Period tests

At least every 12 months a repeat test of the electrical safety should be performed according to IEC 62353.

ATMOS recommends conducting this inspection in accordance with the manufacturer's specifications.

6.2 Function check

- Prior to every use a visual inspection of the device, hoses, secretion canister and device connecting cables must be performed.
- Replace any damaged parts immediately.

6.3 Sending in the device

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 the QD 434 "Delivery complaint/return shipment" form and the corresponding **decontamination certificate**.
- ☞ This form is enclosed with each delivery and can be found at www.atmosmed.com.
5. Affix the transport protection to the bottom of the device.
6. The device must be well padded and packed in suitable packaging.
7. Place the QD 434 "Delivery complaint/return shipment" form and the corresponding **decontamination certificate** in an envelope.
8. Affix the envelope to the outside of the package.
9. Send the product in to ATMOS or your dealer.

6.4 Reprocessing by the manufacturer

If you pass on the device to a new owner, the device must be professionally reprocessed. The device may only be passed on in a hygienically and technically safe condition. Observe country specific regulations.

In Germany, only ATMOS or authorized professionals may reprocess the device for distribution.

7 Troubleshooting

7.1 Troubleshooting

The product has been subjected to a thorough quality control in the factory. However if a fault should occur, you may be able to resolve it yourself.

Error symptom	Possible cause	Remedy
<ul style="list-style-type: none"> • Device does not start 	<ul style="list-style-type: none"> • Power plug is fitted badly • No mains voltage • Defective fuse 	<ul style="list-style-type: none"> • Check the connection to the socket and the device • Check main fuse • Exchange the fuse
<ul style="list-style-type: none"> • Not enough power 	<ul style="list-style-type: none"> • Leakage in the hose or in the secretion canister system 	<ul style="list-style-type: none"> • Check the canister lid and hoses for tightness, replace sealing ring on the canister lid if necessary
<ul style="list-style-type: none"> • No suction capacity 	<ul style="list-style-type: none"> • Bacterial filter is blocked (vacuum gauge indicates vacuum) • The float of the overflow protection seals the double hose connector • Secretion or blood was sucked in and the valve plates of the aggregate are stuck together 	<ul style="list-style-type: none"> • Replace the bacterial filter • Check fluid level in the secretion canister, If necessary it must be emptied. Clean overflow protection and check float for free movement • In this case, the device must be sent in for repair

8 Accessories

Accessories	REF
Foot switch	443.0755.0
Foot controller ATMOS Record 55	443.0770.0
Potential equalization cable	008.0596.0
Secretion canister 1.5 l (PC)	444.0100.0
Secretion canister 3 l (PC)	444.0099.0
Secretion glass, with graduation, 1.5 l	444.0032.0
Secretion glass, with graduation, 3 l	444.0033.0
Secretion glass, with graduation, 5 l	444.0034.0
Canister lid	444.0650.0
Canister lid incl. standard rail holder	444.0015.0
Nippel set	444.0640.0
Nippel set with overflow electrode	444.0012.0
Serres® outer canister 1 l	312.0465.0
Serres® outer canister 2 l	310.0402.0
Serres® outer canister 3 l	310.0403.0
Standard rail holder Serres® complete	444.0484.0
Receptal® outer canister 1.5 l	310.0221.0
Receptal® outer canister 2 l	443.0256.0
Receptal® outer canister 3 l	444.0157.0
Receptal® holder complete for standard rail 1 x 2 l	444.0160.0
Receptal® holder complete for standard rail 1 x 3 l	444.0170.0
Receptal®-holder complete for standard rail (single)	444.0150.0
Receptal®-holder complete for standard rail (2 times)	444.0156.0
Holder for Receptal® canister, with equipment mount	HM57525661
Receptal®-Package 1 x 2 l for mounting on a standard rail	444.0030.0
Receptal®-Package 1 x 3 l for mounting on a standard rail	444.0031.0
Receptal®-Package 2 x 1,5 l for mounting on a standard rail	444.0027.0
Receptal®-Package 2 x 2 l for mounting on a standard rail	444.0028.0
Receptal®-Package 2 x 3 l for mounting on a standard rail	444.0029.0
Receptal®-adapter for tissue collector	444.0148.0
Medi-Vac® outer canister 1 l	312.0473.0
Standard rail Medi-Vac®	444.0451.0
Vacuum shift	HM57522049
Rail clamp for equipment mount, plastic	HM57522540
Rail clamp for equipment mount, metal	HM57522048
Overflow canister 250 ml (without hydrophobic DDS bacterial filter)	444.0646.0
Overflow canister 250 ml (with hydrophobic DDS bacterial filter)	444.0646.1
Hose holder, for attachment to a standard rail	444.0450.0
Hose holder, stainless steel	320.0611.0
Holder for activated charcoal filter, not autoclavable	444.0660.0

Accessories	REF
Storage tray, stainless steel	443.0790.0
Tray, diameter 20 cm	HM57524538
Storage basket, dimensions 170 x 130 x 85 mm	HM57508012
Catheter holder for trolley, dimensions 150 x 100 x 480 mm	HM57508002
Catheter holder, dimensions 90 x 90 x 350 mm	HM57505157
Catheter quiver	HM57525150
Cover for catheter quiver	HM57525151

9 Consumables

Spare part	REF
Bacterial filter for ATMOS DDS secretion canister, pack of 10 pcs.	340.0054.0
Hydrophobic bacterial and viral filter, Ø 11 mm	443.0738.0
Hydrophobic bacterial and viral filter, Ø 8 mm	444.0628.0
Smoke evacuation filter	HM57524928
Suction hose, PVC, disposable, Ø 8 mm, L = 2,10 m, 50 pcs.	006.0059.0
Suction hose, silicone, Ø 6 mm, L = 1.30 m, 1 pcs.	000.0013.0
Suction hose, silicone, Ø 6 mm, L = 2 m, 1 pcs.	000.0361.0
Suction hose, silicone, Ø 6 mm, 1 m (minimum order 5 m)	006.0009.0
Suction hose, silicone, Ø 10 mm, L = 1.30 m, 1 pcs.	318.1012.0
Suction hose, silicone, Ø 10 mm, L = 2 m, 1 pcs.	000.0243.0
Suction hose, silicone, Ø 10 mm, 1 m (minimum order 5 m)	006.0026.0
Serres® disposable suction liner 1 l without gelling agent, 36 pcs.	312.0466.0
Serres® disposable suction liner 1 l, with gelling agent, 32 pcs.	312.0467.0
Serres® disposable suction liner 2 l without gelling agent, 24 pcs.	310.0410.0
Serres® disposable suction liner 2 l, with gelling agent, 22 pcs.	310.0400.0
Serres® disposable suction liner 3 l without gelling agent, 24 pcs.	310.0411.0
Serres® disposable suction liner 3 l with gelling agent, 20 pcs.	310.0401.0
Hose 287 mm with joint blue	HM57522085
Vacuum-regular hose silicone, 175 mm	HM57522084
Receptal® disposable suction liner 1,5 l, without overflow valve filter, 50 pcs.	310.0222.1
Receptal® disposable suction liner 1.5 l with overflow valve filter, 50 pcs.	310.0222.2
Receptal® disposable suction liner 2 l, without overflow valve filter, 50 pcs.	443.0257.0
Receptal® disposable suction liner 2 l with overflow valve filter, 50 pcs.	443.0257.2
Receptal® disposable suction liner 3 l without overflow valve filter, 50 pcs.	444.0153.0
Receptal® disposable suction liner 3 l with overflow valve filter, 50 pcs.	444.0154.0
Medi-Vac® disposable suction liner 1 l, 50 pcs.	312.0474.0
Tissue collector 50 ml, disposable	401.0555.0
Tissue collector 300 ml, disposable	340.0061.0
Activated charcoal filter	008.0758.0
Hose connector for reducing from Ø 10 mm to Ø 6 mm	000.0239.0
Sealing for canister lid	055.0070.0

10 Disposal

Packaging

1. Please recycle the packing.

Secretion and blood

1. Please dispose of secretion, blood and contaminated parts in line with country-specific regulations.

In the Federal Republic of Germany the „Requirements on the implementation aid for disposal of waste from healthcare institutions“ are valid, a statement of the Federal / State Working Group on Waste.

Secretion canister system

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

The following notes are only applicable for reusable products.

1. Clean and disinfect the reusable products of the canister system.
2. Recycle the disinfected reusable products.

ATMOS Record 55

Do not dispose of the product together with household waste.

The product does not contain any hazardous materials.


1. Clean and disinfect the device.
2. In Germany: Send the product back to ATMOS or your specialist dealer. They will dispose of the device professionally.
3. In other countries: Dispose of the product professionally and according to the country-specific laws and regulations.

In Germany, the device is excluded from the Electrical and Electronic Equipment Act (ElektroG) in accordance with the National Register for waste electric equipment because it may be contaminated. Do not dispose of the device in the electrical waste.

The housing is fully recyclable. Observe the country-specific laws and regulations.



11 Technical data

Unit suction capacity	55 ± 3 l/min
Max. vacuum	-98 kPa (-980 mbar or -735 mmHg)
Vacuum display	-1...0 bar ± 25 mbar
Vacuum regulator	Mechanical regulation valve
Suction hose	Ø 6 mm, 2 m long Ø 10 mm, 2 m long
Nominal voltage	230 V~, 50/60 Hz
Nominal current	ca. 0.45 A bei 230 V~
Power consumption	Approx. 100 W
Power cable	5 m
Operating time	>8 h continuous operation (depending on ambient conditions)
Fuse	630 mA/H für 230 V~
Protective earth conductor resistance	< 0.1 Ω
Earth leakage current	N.C. < 0.5 mA
Housing leakage current	N.C. < 0.1 mA
Patient leakage current	---
Heat output	100 J/s
Noise level	Free flow: 46 dB (A) @ 1m (as per ISO 7779) Final vacuum: 39 dB (A) @ 1m (as per ISO 7779)
Ambient conditions	-30 ... +50°C
Transport/storage	5 ... 90% humidity without condensation at air pressure 700 ... 1060 hPa
Ambient conditions for operation	+10 ... +32°C 20 ... 80% humidity without condensation at air pressure 700 ... 1060 hPa
Dimensions	H 940 x W 500 x D 390 (without secretion canister)
Weight	24 kg (without secretion canister)
Period tests	Repeat test of the electrical safety every 12 months. Recommended: inspection according to the manufacturer's specifications.
Protection class	I
Degree of protection	Type BF 
Type of protection	IPX 1
Classification according to Annex IX, EC Directive 93/42/EEC	Ila
CE marking	CE 0124
	Subject to technical changes (as of January 2017)!

** 1 bar ≅ 750.06 mm Hg ≅ 1000 hPa / dependent on daily air pressure

12 Notices on EMC

- ☞ Medical electrical equipment is subject to special precautions with regard to EMC and must be installed acc. to following EMC notes.

Guidance and manufacturer's declaration - ambient conditions

The ATMOS Record 55 is suitable for use in the following environments:

- In professional health care facilities, such as: Medical practices, clinics, first aid facilities and operating theaters. Not suitable is the environment of HF surgical devices and outside of an RF-shielded room of a magnetic resonance imaging system.
- Special environments such as factory or military facilities and medical areas near HF surgical devices, short wave therapy equipment or within a RF shielded room of a magnetic resonance imaging system.

The customer or user of the ATMOS Record 55 must ensure that it is used in such an environment.

Guidance and manufacturer's declaration - key features

- ☞ Please note the technical data in this manual. The essential features are fully usable even in the presence of electromagnetic disturbances.

Guidance and manufacturer's declaration - for accessories, transducers and cables

The ATMOS Record 55 has the following electrical components:

Type	REF	Max. cable length
Power cable	008.0629.0	5 m

Guidance and manufacturer's declaration - Warnings

⚠ WARNING

The use of third-party accessories, transducers and cables as specified or provided by the manufacturer may result in increased electromagnetic emissions or reduced immunity to electromagnetic interference and result in erroneous operation.

⚠ WARNING

Portable RF communications equipment (for example, radios, antenna cables) should not be used within 30 cm of * the manufacturer's designated parts or lines of the ATMOS Record 55. Failure to do so may result in a reduction in the performance of the device.

- ☞ * At higher immunity test levels the distance may be reduced.

⚠ WARNING

Placement on or next to another device should be avoided. This could result in incorrect operation. If this is unavoidable, the proper functioning of the device must be monitored regularly. Please switch off any nearby devices which are not in use, if possible.



MedizinTechnik

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