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ATMOS MedizinTechnik

Operating Instructions

ATMOS Record 55

DDS

English

GA1GB.210202.0

2020_06 Index 26

CE 0124

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

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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 available near the device.

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

Maintenance, repairs, and periodic 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 test devices and original spare parts required to carry out these measures.

§

Read chapter 'Notes for your safety' on page 10 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 93/42/EEC of the council for medical products and meets the basic requirements of appendix I of this directive.

The product complies with all applicable requirements of Directive 2011/65/EU 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 products:

ATMOS Record 55 DDS	REF 444.0910.0
ATMOS Record 55 DDS 100 V	REF 444.0910.1
ATMOS Record 55 DDS 115 V	REF 444.0910.2
ATMOS Record 55 DDS 127 V	REF 444.0910.3
ATMOS Record 55 DDS (2 x 3 l secretion canister)	REF 444.0930.0
ATMOS Record 55 DDS (2 x 5 l secretion canister)	REF 444.0940.0

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.
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 in this direction, plug in.

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
EAN	European Article Number
IPX1	Protection against the ingress of damaging moisture (dripping water)
	Applied part type BF
	Professional disposal
	For single use only (symbol located on consumables)
	Not sterile
	Autoclavable
PATIENT	Connection for suction hose/patient
	Potential equalisation
	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 electric suction pump, a negative pressure is created. An additional secretion canister must be attached to allow the temporary collection of drained body fluids.
User profile:	Doctors, medical support staff without restrictions.
Patient groups:	Patients of all ages with and without restrictions.
Application organ:	Natural orifices as well as openings that 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: • 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. Information on reprocessing, cleaning, and disinfection can be found in this document.

1.4 Function

The ATMOS Record 55 DDS 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. The reusable secretion canister can be mounted to the ATMOS Record 55 via the Direct Docking System. The user can connect the suction hose directly. A hydrophobic bacterial filter located in the lid of the canister prevents bacteria and liquids from entering the pump. This filter protects the device against oversuction. The intake located in the hose connection prevents foaming in the secretion canister and therefore ensures a longer filter life.

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 DDS

ATMOS Record 55 DDS (230 V, 100 V, 115 V, 127 V)	**REF**
1x power cable 5 m	008.0629.0
1x hose holder	443.0003.0

ATMOS Record 55 DDS (2 x 3 l secretion canister)	**REF**
1x power cable 5 m	008.0629.0
1x hose holder	443.0003.0
2x DDS secretion canister, plastic 3 l, autoclavable	340.0051.0
2x DDS canister lid with sealings, autoclavable	340.0053.0
2x DDS canister handle, grey, autoclavable	340.0055.0
2x DDS splash protection, silicone, autoclavable	340.0056.0
1x DDS hose adapter set (Ø 6 mm + Ø 10 mm), autoclavable	340.0057.0
12x DDS bacterial filter	340.0054.0
1x suction hose (silicone), Ø 6 mm, L = 2 m	000.0361.0

ATMOS Record 55 DDS (2 x 5 l secretion canister)	**REF**
1x power cable 5 m	008.0629.0
1x hose holder	443.0003.0
2x DDS secretion canister, plastic 5 l, autoclavable	340.0052.0
2x DDS canister lid with sealings, autoclavable	340.0053.0

2x DDS canister handle, grey, autoclavable	340.0055.0
2x DDS splash protection, silicone, autoclavable	340.0056.0
1x DDS hose adapter set (Ø 6 mm + Ø 10 mm), autoclavable	340.0057.0
12x DDS bacterial filter	340.0054.0
1x suction hose (silicone), Ø 6 mm, L = 2 m	000.0361.0

1.7 Transport and storage

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

If damage occurs during transport:

1. Document and report damages in transit.
2. Send the device to ATMOS; see chapter 24‘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 Notes for your safety

2.1 General safety instructions

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

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

2.2 Danger for users, patients, and third parties

⚠ WARNING

Choking hazard for children due to accessories!

Children can strangle themselves or choke on small parts.

- Keep children away from hoses and connection cables.
- Keep children away from swallowable small parts. Examples of such swallowable small parts are the fingertip and sealing ring.

⚠ CAUTION

Explosion and fire hazard!

Burns and injuries are possible.

- Never suction any explosive, flammable, or corrosive gases or liquids. Please observe the intended use in chapter '1.3 Intended use'.
- Never operate the product in potentially explosive areas or areas that are oxygenated.
- Only use original accessories and original spare parts from ATMOS.

⚠ WARNING

Your patient can be severely injured.

Avoid misuse.

- The product may only be used by medically trained persons who have been instructed in the handling of the medical suction system.
- The product may only be used by qualified personnel in supervised operation.
- 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, check whether the required mains voltage on the device matches the mains voltage of the mains power supply.
- Position the device in an easily accessible location and keep access free.
- Make sure that the power cable is working. Replace defective accessories immediately.
- Remove the transport protection on the bottom of the device prior to first use.
- ATMOS recommends always having another suction device ready at hand. That way you can also perform suctioning if a device should fail.

⚠ WARNING

Risk of infection due to pathogens on the product!

Deadly diseases may be transmitted.

- Always wear disposable gloves if you might come into contact with secretion.
- Always wear disposable gloves when using the product.
- Never use components that are marked with ⊘ more than once. These components are intended for single use only.
- Sterile-packed parts may only be used if 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 product must not be used following oversuction.

⚠ WARNING

Tripping hazard due to cables.

Injuries are possible.

- Lay connecting cables properly.

⚠ WARNING

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

Burns, cardiac arrhythmias, and even fatal injury are possible.

- 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 power supply prior to cleaning or disinfection.
- You an only disconnect the device by removing the power plug from the mains power supply.
- Position the device in such a way that you can easily disconnect it from the mains power supply at any time.
- Only connect the device to a mains power supply with 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 has entered 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 cords.
- Never touch the device's interfaces and the patient at the same time!
- Only use original accessories and original spare parts from ATMOS.
- Pay attention to the periodic tests in chapter ‘6 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 Avoiding damage to the device

ATTENTION

Storage and operation in an unsuitable environment.

The product may become damaged.

- Please observe the ambient conditions regarding transport, storage, and operation.
- After transporting the device at low temperatures, keep it at room temperature for at least six hours before initial start-up. If the device is not acclimatised, it may not be used, as the diaphragm of the pump could become damaged.

3 Setting up and starting up

3.1 Device overview

Front view

❶ Vacuum gauge
❷ Vacuum regulator
❸ On/off switch
❹ DDS canister handle
❺ DDS canister lid
❻ DDS secretion canister
❼ Connection for the foot controller or foot switch (optional)

Rear view

❶ Connection for potential equalisation
❷ Equipment safety fuse
❸ Mains supply

Vacuum connection: Direct Docking System

☞ The vacuum connection between the pump and secretion canister system is immediately established when the DDS canister is attached!

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 Allen screws marked in red.

☞ The transport protection screws must be inserted again before returning the device.

☞ After transporting the device at low temperatures, it should be kept at room temperature for at least six hours before initial start-up; 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 then connect it to the mains.

☞ For surgical procedures, we recommend additionally connecting the device via the connection to the potential equalisation of the examination room.

» The device is now ready for use.

4.3 Assembly of the DDS secretion canister

❶ DDS secretion canister handle

❷ DDS bacterial filter

❸ DDS hose adapter

❹ DDS canister lid

❺ DDS splash protection

❻ DDS secretion canister

4.4 Using the DDS splash protection

1. Attach the splash protection to the pipe connection in the DDS canister lid.

☞ The splash protection protects the DDS bacterial filter from becoming wetted prematurely by liquids and/or foam formation.

4.5 Attaching/removing the DDS canister lid

1. **Place** the DDS secretion canister on a firm surface and **set** the DDS secretion canister lid horizontally on it (the lid cannot be turned incorrectly).
2. Gently **press** the DDS canister lid with both hands onto the secretion canister.

3. To **open** the DDS canister lid, hold it on the reinforcement bars of the mounting fixture and then pull the DDS canister lid up and off by reaching into the opening for the filter.

4.6 Inserting/removing the DDS bacterial filter / oversuction stop

The DDS bacterial filter / oversuction stop are disposable products.

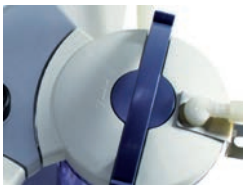
☞ Before each use, check whether the DDS bacterial filter / oversuction stop is dry and clean. Replace the DDS bacterial filter with a new DDS bacterial filter if it is discoloured or contaminated or if oversuction has occurred.

1. Insert the bacterial filter into the DDS secretion canister handle.

4.7 Attaching, closing, and opening the DDS secretion canister handle

1. To **attach** the DDS secretion canister handle, insert it into the grooves of the canister lid (with the locking latches open).
2. To **close** the DDS secretion canister handle, clip the locking latches under the canister rim. Then press the clips towards the secretion canister until they click into place.
3. To **open**, pull the clips outwards and remove the locking latches from under the canister rim.

4.8 Attaching/removing the DDS secretion canister



1. To attach the DDS secretion canister, allow it to slide vertically downwards into the mounting fixture.
2. To remove the DDS secretion canister, lift it straight up.

4.9 DDS secretion canister hose holder

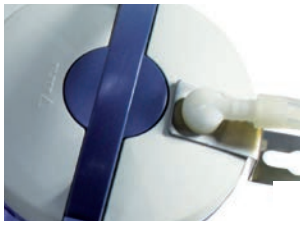
1. If using a DDS secretion canister hose holder, attach it between the canister lid and the hose adapter.

4.10 Inserting the DDS hose adapter

1. Insert the DDS hose adapter (Ø 6 or 10 mm) into the ‘Patient’ opening on the DDS canister lid.
2. Turn it slightly and press it down.

☞ The adapter can be removed again by turning it slightly.

4.11 Connecting the suction hose



☞ Connect the suction hose to the already inserted hose adapter.

4.12 Suctioning

1. Please ensure that the following parts have been reprocessed prior to treating a new patient:
   - Suction hose including hose-rinsing aperture or suction instruments
   - DDS secretion canister system including DDS canister lid and DDS hose adapter
2. Prior to each use, check whether the DDS bacterial filter was inserted during cleaning and disinfection.
3. Replace the bacterial filter with a new bacterial filter if it is discoloured or contaminated, or if oversuction has occurred.
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 DDS bacterial filter prevents 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 bacterial filter, the device may not be operated again until it has been checked by an authorised service partner.

4.13 DDS changeover docking station

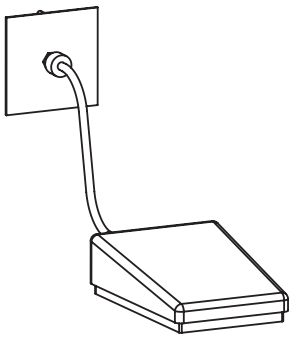
☞ The maximum load of the station is 15 kg; higher loads may damage the device!

The DDS changeover docking station is used if two secretion canisters are required. The changeover lever serves to switch the vacuum to the secretion canister being used. When removing or attaching a secretion canister, switch the lever towards the second secretion canister.

4.14 Options

Foot switch REF 443.0755.0

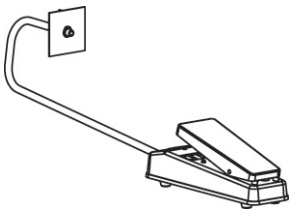
Pneumatically explosion-proof switch for switching the device on and off.



1. Connect the foot switch.
2. Set the main switch in the control panel to foot switch operation (OFF).
3. Pressing the foot switch turns the device on.
4. Pressing the foot switch again turns the device off.
5. 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

For regulating the vacuum.



Connect the foot controller (remove the protection cap and tighten the nut on the foot controller hose).

1. To increase the vacuum, press the pedal down.
2. When you lift off your foot, the controller locks in that position.

5 Reprocessing

5.1 Safety instructions for reprocessing

5.1.1 General safety instructions

We recommend that you 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. Generally, validation and routine monitoring of the procedure will be necessary.

Reprocessing may only be carried out by persons who have the necessary expertise. The person in question must have the necessary equipment to carry out these measures.

5.1.2 Danger for users, patients, and third parties

Risk of infection due to unsuitable accessories.

Deadly diseases may be transmitted.

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

Risk of infection due to unsuitable reprocessing.

Deadly diseases may be 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 hollow spaces and lumens that are hard to reach.
- Make sure that air bubbles do not form in the hollow spaces and lumens of accessories when placing them in processing solutions.

5.1.3 Avoiding damage to the device

Damage to the device due to cleaning with fixatives.

Stains cannot be removed permanently.

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

Unsuitable aids.

☞ Follow the corresponding operating instructions of all aids and devices used.

Unsuitable cleaning agents and disinfectants.

The product may become damaged.

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

Incorrect mechanical cleaning and disinfection.

Corrosion due to moisture.

- Remove the products immediately after the programme is finished.

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 Preparing 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 disinfection	Remarks
Housing	x						x		x		

5.3.2 Selecting process chemicals

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

Cleaning agent (manufacturer)	Active ingredients in 100 g	Type	Housing
Disinfection			

Cleaning agent (manufacturer)	Active ingredients in 100 g	Type	Housing
Green & Clean SK (Metasys)	<1 g dialkyldimethylammonium chloride, <1 g alkyldimethylethylbenzylammonium chloride, <1 g alkyldimethylbenzylammonium chloride	Foam Ready to use	x
Dismozon® plus (Bode Chemie)	95.8 g magnesium monoperoxyphthalate hexahydrate	Granulate	x
Kohrsolin® FF (Bode Chemie)	5 g glutaral, 3 g benzyl-C12-18-alkyldimethylammonium chloride, 3 g 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 pentapotassium bis(peroxymonosulphate) bis(sulphate)	Powder	x
Mikrobac® forte (Bode Chemie)	19.9 g benzyl-C12-18-alkyldimethylammonium chloride, 5 g N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine	Liquid concentrate	x
Bacillol® 30 Foam (Bode Chemie)	14 g ethanol, 10 g propan-2-ol, 6 g propan-1-ol, 0.5 g n-alkyl-aminopropyl-glycine	Foam, ready to use	x
Incidin® Active (Ecolab)	Peracetic acid	Powder	x
mikrozid® sensitive wipes (Schülke & Mayr)	0.26 g alkyl(C12-16)dimethylbenzylammonium chloride, 0.26 g didecyldimethylammonium chloride, 0.26 g 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.

» No more residue is 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

Accessories	Disposable product	Max. reprocessing cycles	After each application	After each patient	Daily	Weekly	Every 14 days	Monthly	Pre-treat	Pre-cleaning	Manual cleaning and disinfection	Mechanical cleaning and disinfection	Sterilisation
Secretion canister system													
• DDS secretion canister[2]		60	x						x	x		x	x
• DDS canister lid[2] ☞ DDS secretion canister handle ☞ DDS splash protection ☞ DDS hose adapter		60	x						x	x		x	x

Accessories	Disposable product	Max. reprocessing cycles	After each application	After each patient	Daily	Weekly	Every 14 days	Monthly	Pre-treat	Pre-cleaning	Manual cleaning and disinfection	Mechanical cleaning and disinfection	Sterilisation
• DDS bacterial filter[1]	x[3]												
Hoses													
• Suction hose		60	x						x	x		x	x

[1] Replace the DDS bacterial filter if it is discoloured or soiled, or if oversuction has occurred; see chapter 15‘4.6 Inserting/removing the DDS bacterial filter / oversuction stop’ on page 15.

[2] If an accessory shows any visible damage, please replace it.

[3] Replace the DDS bacterial filter at every cleaning or when disinfecting the DDS secretion canister system.

Selecting process chemicals

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	
Neutraliser				
neodisher® Z (Dr. Weigert)	<5% nonionic and anionic surfactants, enzymes	Liquid concentrate	x	

5.4.2 Secretion canister system

Characteristics

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

- DDS hose adapter (lumens)
- Canister lid (hollow spaces)

Carefully prepare areas which are difficult to access.

Pre-treating at the site of use • Flushing: 60 s • Rinsing: 60 s	• Empty the secretion canister. • Clean the accessories under cold, running water. • Thoroughly rinse the hollow spaces and lumens of the accessories with running water. No more residue is visible.

Collecting and transporting	• Label any damaged accessories. • Place the accessories in a secretion canister. • Transport the secretion canister to the reprocessing location.
Dismantling	• See chapter '5.2 Preparing / completing reprocessing'. • Dispose of disposable products.
Pre-cleaning • Flushing: 1x / 30 s • Rinsing: 60 s Brush: Round brush Size: 7 mm; material: nylon Brush: Round brush Size: 11 mm; material: nylon Brush: Round brush Size: 15 mm; material: nylon Brush: Square Size: 40 x 10 mm; material: nylon; special features: with angled head	• Make the following cavities accessible: – double hose connector – canister lid • Make the following lumens accessible: – double hose connector • Thoroughly clean the accessories evenly with a suitable brush under running water. • Thoroughly rinse the hollow spaces and lumens of the accessories with running water.
Mechanical cleaning and disinfection Pre-rinse: 1 min Clean: 5 min, 50 °C / 122 °F Neutralise: 2 min Intermediate rinse 1 min Disinfect: 5 min, 93 °C / 199 °F Dry: 12 min, 110 °C / 230 °F	• Secure the accessories on a suitable load carrier. • Clean and disinfect using a suitable programme: – rinse with cold water – clean with cleaning agents – neutralise with neutralising agents – intermediate rinse with softened, cold water – disinfect with demineralised water – dry • Cleaning and disinfection device: according to EN ISO 15883-1 • Programme: Miele Vario TD
Checking and maintaining	• Check the success of reprocessing with a suitable light magnifier. The accessories 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.
Assembly	• Not necessary.
Function check	• Not necessary.
Packaging	• Label the accessories. • Pack the accessories with a packing system according to DIN EN ISO 11607.
Sterilising Prefractionated vacuum: 3x Temperature: 134 °C / 273 °F Time: 5 min Dry: 10 min	• Sterilise the accessories using a suitable procedure: – steam sterilisation / autoclaving • Steriliser: according to DIN EN 285
Storage	• Observe the ambient conditions; see chapter '11 Technical data'.

5.4.3 Hoses

☞ Carefully prepare areas which are difficult to access.

Pretreatment at the site of use	• Clean the accessories under cold, running water. • Thoroughly rinse the hollow spaces of the accessories with running water. No more residue is visible.
Collecting and transporting	• Label any damaged accessories. • Place the accessories in a secretion canister. • Close the secretion canister. • Transport the secretion canister to the reprocessing location.
Pre-cleaning	• Clean the accessories under running water. • Thoroughly rinse the lumens of the accessories with running water.
Dismantling	Not necessary.
Mechanical cleaning and disinfection Pre-rinse: 1 min Clean: 5 min, 55 °C / 131 °F Neutralise: 2 min Intermediate rinse: 1 min Disinfect: 5 min, 93 °C / 199 °F Dry: 12 min, 110 °C / 230 °F	• Secure the accessories on a suitable load carrier. • Clean and disinfect using a suitable programme: – rinse with cold water – clean with cleaning agents – neutralise with cold water – intermediate rinse with softened, cold water – disinfect with demineralised water – dry • Cleaning and disinfection device: according to EN ISO 15883-1 • Adapter: Miele E366/E446 • Programme: Miele Vario TD

Checking and maintaining	• Check the success of reprocessing with a suitable light magnifier. • If reprocessing was unsuccessful, reprocess the accessories again. • Dispose of damaged accessories or have them repaired.
Assembly	Not necessary.
Function check	Not necessary.
Packaging	• Label the accessories. • Pack the accessories with a packing system according to DIN EN ISO 11607.
Sterilising Prefractionated vacuum: 3x Temperature: 134 °C / 273 °F Time: 5 min Dry: 10 min	• Sterilise the accessories using a suitable procedure: – steam sterilisation / autoclaving Steriliser: according to EN 285.
Storage	• Observe the ambient conditions, see chapter '11 Technical data'.

6 Maintenance and service

Maintenance, repairs, and periodic 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 periodic tests must **not** be performed while the product is being used on a patient.

6.1 Periodic tests

Perform a repeat test of the electrical safety according to IEC 62353 at least every 12 months.

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

6.2 Function check

- Prior to each use, perform a visual inspection of the device, hoses, secretion canister, and connecting cables.
- 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 according to the operating instructions.
3. Enclose 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. Attach the transport protection.
6. The product 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 reprocessed professionally. The device may only be passed on in a hygienically and technically safe condition. Observe country-specific regulations.

In Germany, only ATMOS or authorised 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
• Device does not start	• Power plug is fitted badly • No mains voltage • Defective fuse	• Check the connection to the socket and the device • Check main fuse • Exchange the fuse
• Not enough power	• Leakage in the hose or in the secretion canister system	• Check the canister lid, hose adapter, and suction hose for tight fit
• No suction capacity	• Bacterial filter is blocked (vacuum gauge indicates vacuum) • Secretion or blood was sucked in and the valve plates of the aggregate are stuck together	• Replace the bacterial filter • Check fluid level in the secretion canister; if necessary, it must be emptied • 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 equalisation cable	008.0596.0
Practice package 1.5 l	340.0002.0
Practice package 3 l	340.0003.0
DDS secretion canister, plastic 1.5 l, autoclavable	340.0050.0
DDS secretion canister, plastic 3 l, autoclavable	340.0051.0
DDS secretion canister, plastic 5 l, autoclavable	340.0052.0
DDS secretion canister set 2 x 3 l, autoclavable	444.0901.0
DDS secretion canister set 2 x 5 l, autoclavable	444.0902.0
DDS canister lid, complete set	340.0040.0
DDS canister lid with sealings, autoclavable	340.0053.0
DDS secretion canister handle, grey, autoclavable	340.0055.0
DDS secretion canister handle, blue, autoclavable	340.0326.0
DDS splash protection, silicone, autoclavable	340.0056.0
DDS hose adapter set (Ø 6 mm + Ø 10 mm), autoclavable	340.0057.0
DDS secretion canister hose holder, autoclavable	340.0066.0
DDS adapter for tissue collector	340.0062.0
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
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 pc.	000.0013.0
Suction hose, silicone, Ø 6 mm, L = 2 m, 1 pc.	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 pc.	318.1012.0
Suction hose, silicone, Ø 10 mm, L = 2 m, 1 pc.	000.0243.0
Suction hose, Ø 10 mm, 1 m (minimum order 5 m)	006.0026.0
Tissue collector 50 ml, disposable	401.0555.0
Tissue collector 300 ml, disposable	340.0061.0

10 Disposal

Packaging

1. Please recycle the product packaging.

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 of the 'Implementation Aid for Disposal of Waste from Healthcare Institutions' apply, a statement issued by 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 properly.

The following notes only apply to reusable products.

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

ATMOS Record 55 DDS

Do not dispose of the product together with household waste.

The product does not contain any hazardous materials.

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

In Germany, the product 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 product in electronic waste.

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

11 Technical data

Pump 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 regulating valve
Suction hose	Ø 6 mm, 2.1 m long
Nominal voltage	230 V~, 50/60 Hz
Nominal current	Approx. 0.45 A at 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 for 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 Transport/storage	−30 ... +50 °C 5 ... 90% humidity without condensation at air pressure 700 ... 1060 hPa
Ambient conditions 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)
Periodic tests	Repeat test of 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 in accordance with Annex IX of EC Directive 93/42/EEC	IIa
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 Notes on EMC

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

Guidance and manufacturer's declaration – ambient conditions

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

- In professional healthcare facilities, such as: medical practices, clinics, first aid facilities, and operating theatres.
  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.
- Special environments such as factory or military facilities and medical areas near HF surgical devices, short-wave therapy equipment, or within an HF-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 accessories, transducers, and cables other than those specified or provided by the manufacturer may result in increased electromagnetic emissions or decreased immunity to electromagnetic interference and result in improper operation.

⚠ WARNING

Portable RF communications equipment (for example, radios, antenna cables) should be used no closer than 30 cm* to the manufacturer's designated parts or cables 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 that are not in use, if possible.

13 Notes

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