

Operating Instructions

# ATMOS Record 55

DDS

English



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# 1 Introduction

## 1.1 Notes on operating instructions



These operating instructions contain important information 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 be reprinted, either in part or in whole, only 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 be carried out only by persons who have the appropriate technical knowledge and are familiar with the product. The person 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 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 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](http://www.atmosmed.com).







The quality management system applied 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 (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

 <b>DANGER</b>	Warning of a danger that will result in immediate fatal or serious injury. Observe the necessary measures.
 <b>WARNING</b>	Warning of a danger that can cause fatal or serious injury. Observe the necessary measures.
 <b>CAUTION</b>	Warning of a danger that can cause minor injury. Observe the necessary measures.
<b>NOTICE</b>	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)
	Consult operating instructions
	Warning; pay special attention
	This device complies with the relevant requirements of EU directives.
	This device complies with the relevant requirements of EU directives.
	Eurasian conformity
	Manufacturer
	Date of manufacture Country of manufacture
	Foot switch

	Reference number
	Unique Device Identifier of a medical device
	Medical device
	Serial number
IPX1	Protection against the ingress of harmful moisture (dripping water)
	Type BF applied part
	Professional disposal
	For single use only (symbol located on consumables)
	Non-sterile
	Autoclavable
	Connection for suction hose / patient (Serres® canister system)
	Potential equalisation
	Protection class II
	Fuse
	Alternating current
	On, connected to the power supply
	Class AP (for use in potentially explosive areas)
	This side up
	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
(30)	Quantity in pieces

## 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.

<b>Contraindications:</b>	Not suitable for: <ul style="list-style-type: none"> <li>• Drainage operations in the low-vacuum range (e.g., thoracic or wound drainage)</li> <li>• Use outside the medical sector</li> <li>• Suction of flammable, corrosive, or explosive substances</li> <li>• Suction in potentially explosive atmospheres</li> <li>• Not suitable for use as a vacuum extraction system</li> </ul>
<b>The product is:</b>	Active
<b>Sterility:</b>	No sterile product
<b>Single-use product/ re-sterilisation:</b>	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 time.

## 1.5 Intended users

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

## 1.6 Scope of delivery

Basic device ATMOS Record 55 DDS

<b>ATMOS Record 55 DDS (230 V)</b>	<b>REF</b>
1x power cable 5 m	008.0629.0
1x hose support	443.0003.0

<b>ATMOS Record 55 DDS (2 x 3 l secretion canister)</b>	<b>REF</b>
1x power cable 5 m	008.0629.0
1x hose support	443.0003.0
2x DDS-secretion canister, plastic, 3 l, autoclavable	340.0051.0
2x DDS-canister lid with gaskets, 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

<b>ATMOS Record 55 DDS (2 x 5 l secretion canister)</b>	<b>REF</b>
1x power cable 5 m	008.0629.0
1x hose support	443.0003.0
2x DDS-secretion canister, plastic, 5 l, autoclavable	340.0052.0
2x DDS-canister lid with gaskets, 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

Transport the product only in a shipping box that 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.

**Environmental conditions for transport and storage: see chapter '11 Technical data' on page 29**

## 2 Notes for your safety

### 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.

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 carefully 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 in areas that are oxygenated.
- Use only original accessories and original spare parts from ATMOS.

#### **WARNING**

##### **Your patient can be severely injured.**

Avoid improper use.

- The product may be used only by medically trained persons who have been instructed in the handling of the medical suction system.
- The product may be used only by qualified personnel in supervised operation.
- Select the vacuum according to the patient and the application.
- Observe the valid guidelines.
- Always set up the device 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 functional. Replace defective accessories immediately.
- Remove the transport protection on the bottom of the device prior to first start-up.
- 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 can 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 marked with ⊗ more than once. These components are intended for single use only.
- Use sterile-packed parts only if the packaging is undamaged.
- Never operate the device without a bacterial filter.
- A suction catheter, suction attachment, or medical suction instrument must always be connected to the suction 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 before cleaning or disinfecting it.
- You can disconnect the device from the mains power supply only by pulling out the power plug.
- Position the device in such a way that you can easily disconnect it from the mains power supply at any time.
- Connect the device only to a mains power supply with a protective conductor.
- Never touch the plug or power cable with wet hands.
- Use the power cable only in dry surroundings. The surroundings must be non-conductive.
- Ensure that no liquid enters the device. If liquid has entered the device, stop operating the device immediately; it must no longer be used. In this case, clean and disinfect the device and send it to ATMOS for repair.
- Use only proper mains connections and extension cords.
- Never touch the device's interfaces and the patient at the same time!
- Use only original accessories and original spare parts from ATMOS.
- Please pay attention to the information on periodic tests in chapter '6 Maintenance and service' on page 24.
- Assembly, new settings, alterations, extensions, and repairs may be carried out only by authorised persons.
- Do not modify the device without the manufacturer's permission.

## 2.3 Avoiding damage to the device

**NOTICE**

**Storage and operation in an unsuitable environment.**

The product can become damaged.

- Please observe the environmental conditions for transport, storage, and operation.
- After transporting 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 acclimatised, it must not be used as the diaphragms of the pump can 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 is established immediately when the DDS secretion canister is attached!

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

1. Prior to first use, reprocess 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 must not be operated.

### 4.2 Preparing the device

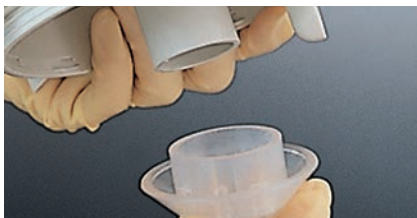
- Check that the voltage and frequency information specified on the device corresponds to the values of the mains power supply and then connect the device to the mains.
- ☞ For surgical procedures, we recommend additionally connecting the device via the connection to the potential equalisation of the examination room.
- » The device is now ready for use.

### 4.3 Assembly of the DDS secretion canister



- ❶ DDS 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 and removing the DDS canister lid

1. **Place** the DDS secretion canister on a firm surface and set the DDS 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 as far as it will go.

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 and removing the DDS bacterial filter / oversuction stop



The DDS bacterial filter / oversuction stop are disposable products.

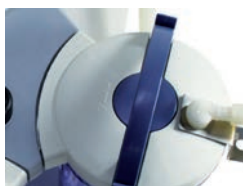
- ☞ Prior to each use, check whether the DDS bacterial filter / oversuction stop are dry and clean. Replace the DDS bacterial filter with a new DDS bacterial filter if it is discoloured or contaminated, or if oversuction has occurred.
1. Push the bacterial filter onto the DDS canister handle.

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



1. To **attach** the DDS canister handle, insert it into the grooves of the canister lid (with the locking latches open).
2. To **close** the DDS 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 and 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 hose holder



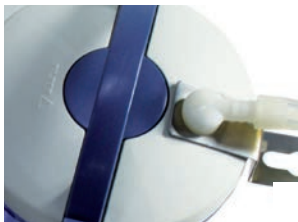
1. If using a DDS hose holder, attach it between the canister lid and the hose adapter.

## 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 suction attachment or suction instrument
    - DDS 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, suction attachment, or suction instrument.
- ☞ 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 switchover station



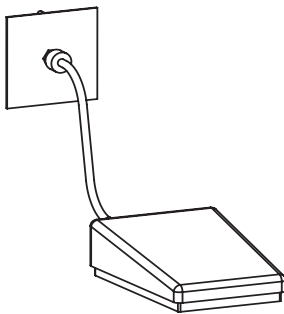
- ☞ The maximum load of the station is 15 kg; higher loads may damage the device!

The DDS switchover station is used if two secretion canisters are required. The switchover 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

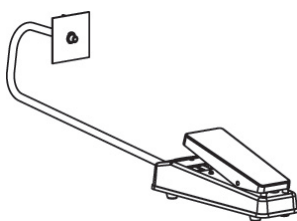
Pneumatically explosion-proof switch for switching the device on and off.



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 control, 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).

6. To increase the vacuum, press the pedal down.
7. 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 required results of cleaning and disinfection are achieved. Generally, validation and routine monitoring of the procedure will be necessary.

Reprocessing may be carried out only 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 medical aids.**

Deadly diseases can be 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 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 can be transmitted.

- Make sure that all areas of the accessories can be easily reached.
- Use only 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 can 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 and completing reprocessing

### Prior to reprocessing

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

### After reprocessing

2. 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

Observe the manufacturer's specifications for the process chemicals.

Cleaning agent (manufacturer)	Active ingredients in 100 g	Type	Housing
<b>Disinfection</b>			
Green&Clean SK (Metasys)	<1 g dialkyldimethylammonium chloride, <1 g alkyl dimethylethylbenzylammonium chloride, <1 g alkyl dimethylbenzylammonium chloride	Foam Ready to use	x

Cleaning agent (manufacturer)	Active ingredients in 100 g	Type	Housing
Dismozon® plus (Bode Chemie)	95.8 g magnesium monoperoxyphthalate hexahydrate	Granulate	x
Kohrsolin® FF (Bode Chemie)	5 g glutaral, 3 g benzyl-C12-C18 alkyldimethylammonium chlorides, 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
Bacillo® 30 Foam (Bode Chemie)	14 g ethanol, 10 g propan-2-ol, 6 g propan-1-ol, 0.5 g N-alkyl-aminopropylglycine	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

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-treatment	Pre-cleaning	Manual cleaning and disinfection	Mechanical cleaning and disinfection	Sterilisation
<b>Secretion canister system</b>													
• DDS secretion canister <sup>2</sup>		60	x						x	x		x	x
• DDS canister lid <sup>2</sup>		60	x						x	x		x	x
☞ DDS canister handle													
☞ DDS splash protection													
☞ DDS hose adapter													
• DDS bacterial filter <sup>1</sup>	x <sup>3</sup>												

Accessories	Disposable product	Max. reprocessing cycles	After each application	After each patient	Daily	Weekly	Every 14 days	Monthly	Pre-treatment	Pre-cleaning	Manual cleaning and disinfection	Mechanical cleaning and disinfection	Sterilisation
<b>Hoses</b>													
• Suction hose		60	x						x	x		x	x

<sup>1</sup>Replace the DDS bacterial filter if it is discoloured or soiled, or if oversuction has occurred; see chapter 4.6.

<sup>2</sup>If an accessory shows any visible damage, please replace it.

<sup>3</sup>Replace the DDS bacterial filter at every cleaning or when disinfecting the DDS 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
<b>Cleaning agents - Mechanical reprocessing</b>				
neodisher® Medi-Clean forte (Dr. Weigert)	<5% nonionic and anionic surfactants, enzymes	Liquid concentrate		x
neodisher® An (Dr. Weigert)	<5% nonionic surfactants, >30% phosphates, enzymes	Powder	x	
<b>Neutraliser</b>				
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 hard-to-reach areas:

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

Take particular care when reprocessing hard-to-reach areas.

<b>Pre-treating at the site of use</b> <ul style="list-style-type: none"> <li>• Flushing: 60 s</li> <li>• Rinsing: 60 s</li> </ul>	<ul style="list-style-type: none"> <li>• Empty the secretion canister</li> <li>• Clean the accessories under cold, running water.</li> <li>• Thoroughly rinse out the hollow spaces and lumens of the accessories with running water.</li> </ul> <p>No more residue is visible.</p>
<b>Collecting and transporting</b>	<ul style="list-style-type: none"> <li>• Label any damaged accessories.</li> <li>• Place the accessories in a secretion canister.</li> <li>• Transport the secretion canister to the reprocessing site.</li> </ul>

<p><b>Disassembly</b></p>	<ul style="list-style-type: none"> <li>• See chapter '5.2 Preparing and completing reprocessing'</li> <li>• Dispose of disposable products</li> </ul>
<p><b>Pre-cleaning</b></p> <ul style="list-style-type: none"> <li>• Flushing: 1x / 30 s</li> <li>• Rinsing: 60 s</li> </ul> <p>Brush: Round brush Size: 7 mm, material: nylon</p> <p>Brush: Round brush Size: 11 mm, material: nylon</p> <p>Brush: Round brush Size: 15 mm, material: nylon</p> <p>Brush: Square Size: 40 x 10 mm, material: nylon, special features: with angled head</p>	<ul style="list-style-type: none"> <li>• Make the following hollow spaces accessible: <ul style="list-style-type: none"> <li>– double hose connector</li> <li>– canister lid</li> </ul> </li> <li>• Make the following lumens accessible: <ul style="list-style-type: none"> <li>– double hose connector</li> </ul> </li> <li>• Thoroughly clean the accessories evenly with a suitable brush under running water</li> <li>• Thoroughly rinse out the hollow spaces and lumens of the accessories with running water.</li> </ul>
<p><b>Mechanical cleaning and disinfection</b></p> <p>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 Drying: 12 min, 110 °C / 230 °F</p>	<ul style="list-style-type: none"> <li>• Secure the accessories on a suitable load carrier.</li> <li>• Clean and disinfect using a suitable programme: <ul style="list-style-type: none"> <li>– rinse with cold water</li> <li>– clean with cleaning agents</li> <li>– neutralise with neutralising agents</li> <li>– intermediate rinse with softened, cold water</li> <li>– disinfect with demineralised water</li> <li>– dry</li> </ul> </li> <li>• Washer-disinfector: according to EN ISO 15883-1</li> <li>• Programme: Miele Vario TD</li> </ul>
<p><b>Checking and maintaining</b></p>	<ul style="list-style-type: none"> <li>• Check whether reprocessing was successful using a suitable light magnifier. The accessories must be free of particles and organic material.</li> <li>• If reprocessing was unsuccessful, reprocess the accessories again.</li> <li>• Dispose of damaged accessories or have them repaired.</li> </ul>
<p><b>Assembly</b></p>	<ul style="list-style-type: none"> <li>• Not necessary.</li> </ul>
<p><b>Function check</b></p>	<ul style="list-style-type: none"> <li>• Not necessary.</li> </ul>
<p><b>Packing</b></p>	<ul style="list-style-type: none"> <li>• Label the accessories.</li> <li>• Pack the accessories using a packaging system according to DIN EN ISO 11607.</li> </ul>
<p><b>Sterilisation</b></p> <p>Pre-fractionated vacuum: 3x Temperature: 134 °C / 273 °F Time: 5 min Drying: 10 min</p>	<ul style="list-style-type: none"> <li>• Sterilise the accessories using a suitable procedure: <ul style="list-style-type: none"> <li>– steam sterilisation / autoclaving</li> </ul> </li> <li>• Steriliser: according to EN 285</li> </ul>
<p><b>Storage</b></p>	<ul style="list-style-type: none"> <li>• Observe the environmental conditions; see chapter '11 Technical data' on page 29'.</li> </ul>

### 5.4.3 Hoses

☞ Take particular care when reprocessing hard-to-reach areas.

<b>Pre-treating at the site of use</b>	<ul style="list-style-type: none"> <li>• Clean the accessories under cold, running water.</li> <li>• Thoroughly rinse out the hollow spaces of the accessories with running water.</li> </ul> <p>No more residue is visible.</p>
<b>Collecting and transporting</b>	<ul style="list-style-type: none"> <li>• Label any damaged accessories.</li> <li>• Place the accessories in a secretion canister.</li> <li>• Close the secretion canister.</li> <li>• Transport the secretion canister to the reprocessing site.</li> </ul>
<b>Pre-cleaning</b>	<ul style="list-style-type: none"> <li>• Clean the accessories evenly under running water.</li> <li>• Thoroughly rinse out the lumens of the accessories with running water.</li> </ul>
<b>Disassembly</b>	Not necessary.
<b>Mechanical cleaning and disinfection</b> 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 Drying: 12 min, 110 °C / 230 °F	<ul style="list-style-type: none"> <li>• Secure the accessories on a suitable load carrier.</li> <li>• Clean and disinfect using a suitable programme:               <ul style="list-style-type: none"> <li>– rinse with cold water</li> <li>– clean with cleaning agents</li> <li>– neutralise with cold water</li> <li>– intermediate rinse with softened, cold water</li> <li>– disinfect with demineralised water</li> <li>– dry</li> </ul> </li> <li>• Washer-disinfector: according to EN ISO 15883-1</li> <li>• Adapter: Miele E366/E446</li> <li>• Programme: Miele Vario TD</li> </ul>
<b>Checking and maintaining</b>	<ul style="list-style-type: none"> <li>• Check whether reprocessing was successful using a suitable light magnifier.</li> <li>• If reprocessing was unsuccessful, reprocess the accessories again.</li> <li>• Dispose of damaged accessories or have them repaired.</li> </ul>
<b>Assembly</b>	Not necessary.
<b>Function check</b>	Not necessary.
<b>Packing</b>	<ul style="list-style-type: none"> <li>• Label the accessories.</li> <li>• Pack the accessories using a packaging system according to DIN EN ISO 11607.</li> </ul>
<b>Sterilisation</b> Pre-fractionated vacuum: 3x Temperature: 134 °C / 273 °F Time: 5 min Drying: 10 min	<ul style="list-style-type: none"> <li>• Sterilise the accessories using a suitable procedure:               <ul style="list-style-type: none"> <li>– steam sterilisation / autoclaving</li> </ul> </li> </ul> <p>Steriliser: according to EN 285.</p>
<b>Storage</b>	<ul style="list-style-type: none"> <li>• Observe the environmental conditions; see chapter '10 Technical data'.</li> </ul>

## 6 Maintenance and service

Maintenance, repairs, and periodic tests may be carried out only by persons who have the appropriate technical knowledge and are familiar with the product. The person must possess the 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 canisters, 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 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](http://www.atmosmed.com).
5. Attach the transport protection.
6. The product must be well padded and packed in suitable packaging.
7. Place the form QD 434 'Delivery complaint / return shipment' 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, it must be reprocessed professionally. The device may be passed on only 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
<ul style="list-style-type: none"> <li>• Device does not start</li> </ul>	<ul style="list-style-type: none"> <li>• Power plug fits poorly</li> <li>• No mains voltage</li> <li>• Defective fuse</li> </ul>	<ul style="list-style-type: none"> <li>• Check the connection at the wall socket and on the device</li> <li>• Check main fuse</li> <li>• Exchange the fuse</li> </ul>
<ul style="list-style-type: none"> <li>• Not enough power</li> </ul>	<ul style="list-style-type: none"> <li>• Leakage in the hoses or the secretion canister system</li> </ul>	<ul style="list-style-type: none"> <li>• Check the canister lid, hose adapter, and suction hose for tight fit</li> </ul>
<ul style="list-style-type: none"> <li>• No suction capacity</li> </ul>	<ul style="list-style-type: none"> <li>• Bacterial filter is blocked (vacuum gauge indicates vacuum)</li> <li>• Secretion or blood was sucked in and the valve plates of the aggregate are stuck together</li> </ul>	<ul style="list-style-type: none"> <li>• Replace the bacterial filter</li> <li>• Check the fluid level in the secretion canister; if necessary, it must be emptied</li> <li>• In this case, the device must be sent in for repair</li> </ul>

## 8 Accessories

Accessories	REF
Foot switch	443.0755.0
Foot control for 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 gaskets, autoclavable	340.0053.0
DDS-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 300 ml, disposable	340.0061.0

## 10 Disposal

### Packaging

1. Please recycle the product packaging.

### Secretion and blood

2. 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.

3. Clean and disinfect the reusable products of the secretion canister system.
4. 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.

5. Clean and disinfect the product.
6. Dispose of the product properly and in accordance with country-specific laws and regulations.


The housing is fully recyclable. However, please observe country-specific laws and regulations.



### 10.1 Expected service life

When used according to the operating instructions, the device (ATMOS Record 55 DDS) has an expected service life of 8 years. Regular thorough cleaning and disinfection of the suction device and its applied parts as well as operation of the device according to the operating instructions are assumed.

## 11 Technical data

Input voltage	230 V~, 50/60 Hz
Current consumption	approx. 0,45 A (230 V~)
Power consumption	100 VA (230 V~)
Fuses	T 630 mA/H (230 V~)
Vacuum regulator	Mechanical valve
Noise level	Free flow: 49 dB (A) @ 1m (acc. to ISO 3774) End vacuum: 39 dB (A) @ 1m (acc. to ISO 3774)
Max. vacuum at NN	-98 kPa* (-980 mbar) * 1 bar $\cong$ 750.06 mmHg $\cong$ 1000 hPa / dependent on daily air pressure
Vacuum display	-1...0 bar ( $\pm$ 2,5 % of the final value)
Suction capacity of pump	55 $\pm$ 3 l/min
Secretion canister	1.5 l / 3 l / 5 l Polysulphone canister
Suction tubing	$\varnothing$ 6 mm, 2 m long
Power cable	Length: 5 m
Operating time	> 8 h continuous
Operating time	Continuous operation
Protective earth conductor resistance	max. 0,1 $\Omega$
Earth leakage current	N.C. < 0,5 mA
Touch current	N.C. < 0,1 mA
Patient leakage current	----
Environmental conditions: Transport/storage	
• Temperature range	-30...+50° C
• Air humidity without condensation	5...90 %
• Air pressure	700..1060 hPa
Environmental conditions: Operation	
• Temperature range	+10...+32° C
• Air humidity without condensation	20...80 %
• Air pressure	700...1060 hPa
Maximum operating altitude	3000 m
Contamination level	2
Overvoltage category	II
Dimensions (H x W x D)	940 x 500 x 390 mm (without secretion canister)
Weight	24 kg (without secretion canister)
Periodic tests	Repeat test of the electrical safety every 12 months. Recommended: Inspection according to the manufacturer's specifications.
Classification of applied parts	Type BF applied parts 

Degree of protection	IPX 1
CE marking	<b>CE</b> 0124
Reference number (REF)	443.0700.0 444.0930.0 444.0940.0

### Hydrophobic DDS bacterial and viral filter

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

\*External test report (test laboratory)

## 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, hospitals/clinics, first-aid facilities, and 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.
- 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 the device is used in such an environment.

### Guidance and manufacturer's declaration – key features

- ☞ Please note the Technical Data in these operating instructions. 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 (e.g., radios, antenna cables) should be used no closer than 30 cm\* to any parts of the ATMOS Record 55, including cables, specified by the manufacturer. Otherwise, this can lead to a reduction in the device's performance.

- ☞ \* 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.



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