ATMOS MedizinTechnik

Operating Instructions

ATMOS Scope

English

CE

GA1GB.150259.0

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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 they are also intended 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 product.

Care, periodic tests, regular cleaning, and proper application 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 who are familiar with the product. To carry out these measures, the person must have the necessary test devices and original spare parts.

§

Read chapter “2 Notes for your safety” on page 17 before using the product for the first time. This will help you to avoid potentially dangerous situations.

This device bears the CE marking CE in accordance with the European Medical Device Regulation (MDR) 2017/745.

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 Declarations of Conformity and our General 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 Scope 507.7000.0
- ATMOS Scope Pro 507.7050.0
- ATMOS Scope iPrime 507.7060.0

1.2 Explanation of pictures and symbols

In the operating instructions

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

	Notice of potential material damage.
☞	Useful information on the handling of the device.
1.	Action. Proceed step by step.
»	Result of an action.
→	Move, plug in this direction.
	Engage, check correct fit.

On device and type plate

	Follow operating instructions (blue)
CE	This device complies with the relevant requirements of EU regulations.
	UL Recognized Component
	Manufacturer

	Date of manufacture
	Country of manufacture: Germany
	Serial number
	Reference number
	Degree of protection
	Protection class II device
	Professional disposal
	Type BF applied part
	Medical device

	This device complies with the relevant requirements of the Eurasian Economic Union
	Prescription device
	Caution fragile
	Error message of the firmware
	Warning message of the firmware

1.3 Intended purpose

Product name: ATMOS Scope

Main functions: For short-term endoscopic application in natural orifices for the visualization of existing structures

Intended purpose: For endoscopic examination in humans

Intended users / User profile:	Doctors and medical specialists who are specially trained in the handling of endoscopes.
Intended patient target group:	Patients of all age groups without restrictions in whom an endoscopic examination is generally indicated. The use of the device also depends on the patient's general condition and must therefore be critically evaluated by the responsible physician before each use.
Medical conditions to be diagnosed, treated or monitored:	Endoscopy can be performed whenever visual inspection of the internal anatomy of the defined organs is necessary.
Application organ:	Ear, mouth and pharynx, nose
Application period:	Transient (< 60 min)
Application environment:	Outpatient medical facilities, e.g., ENT practices, hospital outpatient departments, medical care centers
Patient selection criteria:	None
Indications:	Need for visual inspection of anatomy in defined organs
Medical contra-indications:	Non-intact mucosa in the area of the application organs

Other contra-indications:	None
Warnings:	None
The product is:	active
Sterility/specific microbial status:	Non-sterile
Single use product / reprocessing:	Not a single-use product. Reprocessing according to instructions for use.

1.4 Function

The flexible ATMOS Scope with integrated camera and LED light source combines all required components in the handle:

- LED light source
- Camera electronics
- Mechanics for controlling the deflection

Thanks to optimized video pre-settings, manual camera setting and white balance are no longer required.

1.5 Scope of delivery

Prior to dispatch, the ATMOS Scope was subjected to an extensive functional test and was carefully packed. Nevertheless, please compare the contents of the shipment on completeness immediately upon receipt (see delivery note).

Description	REF
ATMOS Scope Set includes: • Endoscope • Adapter for leakage test • Attachment for pressure compensation including information tag on pressure compensation • Infection control return bag	507.7000.0

ATMOS Scope Pro Set includes: • Endoscope • Leakage tester • Adapter for leakage test • Attachment for pressure compensation including information tag on pressure compensation • Infection control return bag • ATMOS Capture Suite Basic	507.7050.0
ATMOS Scope iPrime Set includes: • Endoscope • Leakage tester • Adapter for leakage test • Attachment for pressure compensation including information tag on pressure compensation • Infection control return bag • ATMOS Capture Suite HD	507.7060.0

	
ATMOS Scope	Operating Instructions

1.6 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 “6.2 Sending in the device” on page 44).

Ambient conditions for transport, storage and operation:

Please refer to chapter “10 Technical data” on page 54.

- ☞ Please observe the notes on pressure compensation.
- ☞ The attachment for pressure compensation should always be attached when storing and transporting the ATMOS Scope.

1.7 Attaching the attachment for pressure compensation

Attach the attachment for pressure compensation onto the valve and turn it by 90° in a clockwise direction. The attachment is then firmly attached to the endoscope and cannot be removed. Please observe the following chapter “3.2 Leakage tester and hose” on page 23.

Attach before:

- Low temperature sterilization
- Ventilation
- Shipping

1.8 Removing the attachment for pressure compensation

Turn the attachment for pressure compensation counterclockwise by 90°. The attachment for pressure compensation can then be removed from the valve of the endoscope.

Remove before:

- Immersion in liquids
- Using on patients

2 Notes for your safety

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

2.1 General safety instructions

Only use accessories and options that are specifically suited for combination with the product and that meet the performance and safety requirements.

The PC used must comply with the standard IEC 60950-1 or IEC 62368-1, respectively.

If you wish to connect more than one device or applied part, you must always observe their safety instructions.

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

2.2 Danger for users, patients, and third parties

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

Minor injuries are possible.

- Prior to each use, check the device and cable for damage. Do not operate the device if you notice any damage. Check the device for leak tightness (see chapter “3.6.3 Performing a leakage test” on page 28). Do not operate the device if the leakage test is failed. In this case, clean and disinfect the device and send it to ATMOS for repair.

- You can only disconnect the device from the power supply by pulling out the power cable.
- Position the device in such a way that you can easily disconnect it from the PC/ laptop at any time.
- Never touch the power plug or power cable with wet hands.
- Use only original accessories and original spare parts from ATMOS.
- Follow the instructions regarding periodic tests (see chapter “6.1 Periodic tests” on page 44).
- Assembly, new settings, modifications, extensions, and repairs may only be carried out by authorized persons.
- Do not modify the device without the manufacturer’s permission.
- During prolonged use of the ATMOS Scope, the distal endoscope tip can heat up to 53.5 °C.
- Never leave the patient unattended near the device.

⚠ CAUTION

Risk for patients

Risk for patients due to the use of products with sharp edges or otherwise dangerous surface damage.

Do not use these products any longer.

Keep the device fully functional at all times.

Malfunctions could cause injury to you and your patients.

- Please observe the notes on the electromagnetic compatibility (EMC) of the device.

Risk of infection due to pathogens on the product!

Diseases can be transmitted.

- Always wear disposable gloves when using the product.
- Reprocess the ATMOS Scope before using it on a patient and observe the chapter “5 Reprocessing” on page 31.
- Clean and disinfect the device according to the operating instructions, see chapter “5 Reprocessing” on page 31.

2.3 Avoiding damage to the device

Handle the system with utmost care as it contains sensitive optical, mechanical, and electronic components.

2.3.1 Unsuitable mechanical stress

Do not knock or drop the ATMOS Scope, and protect it from blows and impacts. Damage to the USB cable and the distal tube of the ATMOS Scope is possible.

- Do not bend, kink, pull, or squeeze the insertion and distal tube. The outer sheath and inner components could become damaged.
- Do not knock the distal end against hard surfaces.
- Never move the tip of the distal tube or the tip cover glass against resistance. The tip contains components that may scratch or break when used incorrectly.
- Make sure that both the USB cable and the distal tube are not pinched, squeezed, knotted, or clamped off.
- Avoid excessive pressure and tension on the flexible endoscope components. Do not pull on the USB cable or distal tube of the ATMOS Scope.

The pressure compensation valve may only be used with ATMOS accessories and can be fixed without tools.

2.3.2 Storage and operation in an unsuitable environment

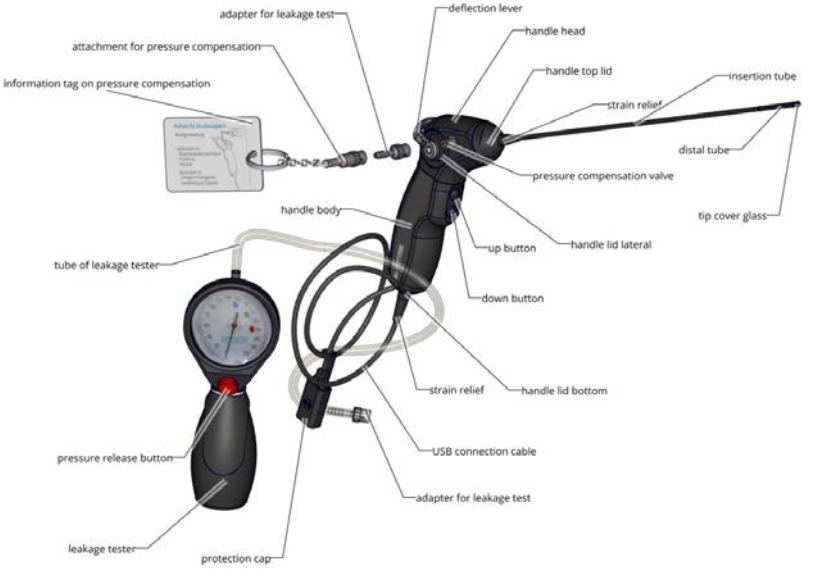
The product may become damaged.

- Please observe the ambient conditions for transport, storage, and operation. Please observe the following chapter “10 Technical data” on page 54.

☞ Please also observe the following chapter “5.1.3 Avoiding damage to the device” on page 32.

3 Setting up and starting up

3.1 Device overview



3.2 Leakage tester and hose

Set for leakage tester REF 507.7031.0 (leakage tester REF 507.7030.0 and adapter for leakage tester to hose REF 507.7024.0)

Adapter for leakage tester to hose REF 507.7024.0 (must be pushed on as far as it will go!)

3.3 Combination with other devices

Only qualified personnel are authorized to install electrical systems. The manufacturer of an electrical medical system is responsible for ensuring that the performance, safety, technical data, and intended use of the ATMOS Scope are not impaired.

Observe the following information when connecting the device in the required combination:

- Refer to the specifications of IEC 60601-1 on medical electrical systems.
- Pay particular attention to the information on the patient environment and leakage currents.

3.4 Assembly and initial installation

Risk of injury due to production residue

- Please observe the following chapter “2 Notes for your safety” on page 17.
- ⚠ Reprocess the ATMOS Scope before using it on the patient. Please observe the following chapter “5 Reprocessing” on page 31.

3.5 System requirements

3.5.1 Hardware system requirements

The system requirements for the ATMOS Scope are the standard USB 3.0 and the system requirements of the ATMOS Capture Suite HD software. The new ATMOS Scope can be used on PCs that meet these system requirements. Please use a PC or an equivalent system (in accordance with IEC 60950-1 or IEC 62368-1, respectively). The color reproduction of the ATMOS Scope has been adjusted to the ATMOS hardware and may differ on third-party hardware. ATMOS assumes no liability or service for third-party hardware.

3.5.2 Software system requirements

The ATMOS Scope is recognized by compatible computers as an external video source.

Despite usability with a variety of third party software, ATMOS strongly recommends using the ATMOS Scope exclusively with the video software ATMOS Capture Suite Basic or ATMOS Capture Suite HD.

ATMOS assumes no liability or service for using the ATMOS Scope with third-party software.

3.5.3 Installation of ATMOS Capture Suite Basic

1. Insert the supplied USB flashdrive into the designated jack.
2. Launch “Install.exe”.
3. Click on “Capture Suite Basic“.
4. Restart your computer.
5. Installation is complete.

3.5.4 Installation of the ATMOS Scope using ATMOS Capture Suite Basic

1. Launch the software.
2. Open the settings.
3. Select the ATMOS Scope as source.

4. Close the software.
5. Restart your computer.
6. Installation is complete.

3.6 Checks and tests

3.6.1 Carrying out the function check

1. Carry out a visual inspection of the entire ATMOS Scope for visible damage and inspect the glass surfaces (see chapter “3.6.2 Checking the glass surfaces” on page 27).
2. Remove the attachment for pressure compensation and the protection cap on the USB connector. Before use, check that there is no moisture on the USB connector.
3. Check the deflection mechanism (see chapter “3.6.4 Testing the deflection mechanism” on page 29).
4. Check the ATMOS Scope for leak tightness using the manual leakage tester (see chapter “3.6.3 Performing a leakage test” on page 28).
5. Check whether an image is displayed and the LED lamp is turned on. Depending on the working distance, the endoscopic image must be crisp, clear, and bright.

⚠ CAUTION

Risk for patients

Risk for patients due to the use of products with sharp edges or otherwise dangerous surface damage.

☞ Do not use these products any longer.

⚠ CAUTION

Damaged products

Do not use products with a damaged camera chip (e.g. recognizable by image interferences), damaged glass surfaces, or stubborn deposits that cannot be removed by cleaning.

Send damaged products to the manufacturer or a repair center authorized by them for inspection. Names of authorized repair centers can be requested from the manufacturer.

3.6.2 Checking the glass surfaces

Visual inspection of the glass surfaces: the surfaces must be clean and smooth.

☞ If impairments are found during inspection, observe the notes on the cause and how to remedy it in the chapter “7 Troubleshooting” on page 47.

3.6.3 Performing a leakage test

- Check whether the tube of the leakage tester is correctly attached to the leakage tester.
- Attach the adapter for the leakage test onto the valve and turn it by 90° in a clockwise direction. The tester is then firmly attached to the endoscope and cannot be removed.
- Generate a test pressure of maximum 160 mmHg by pumping on the leakage tester.
- Wait 30 s and observe the pressure If the value on the manometer display drops continuously, do not place the endoscope in liquid as the device has a leak.
- Vent the system by pressing the red button on the leakage tester.
- Remove the adapter for the leakage test from the valve after the leakage test. Unlock and remove the adapter for the leakage test by pressing and turning it by 90°.

☞ The leakage test is mandatory before each use, cleaning, disinfection, and sterilization or any other immersion process.

☞ A leaky device must not be applied on patients.

☞ A leaky device will become damaged by penetrating liquids and can no longer be reprocessed. In this case, please send in the device for repair.

☞ Never connect or disconnect the leakage tester from the endoscope under water.

☞ Never immerse the endoscope in liquid if there is a pressure drop.

☞ The leakage tester must not be immersed in water and may only be cleaned by wipe disinfection.

3.6.4 Testing the deflection mechanism

1. Slowly operate the deflection lever to check the function.
2. Move the deflection lever several times and check that it moves easily and that the distal end moves properly

⚠ CAUTION

Limitations in deflection can indicate an endoscope defect. In order to avoid major damage to the endoscope, only use the endoscope if the deflection works smoothly and without limitation.

4 Operation

4.1 Use/operation

Please also observe the chapter “2 Notes for your safety” on page 17.

4.1.1 Switching on and adjusting the system

1. Take the flexible ATMOS Scope in your hand.

☞ The system turns on automatically.

4.1.2 Functions of the buttons with the ATMOS Capture Suite

When using the ATMOS Capture Suite Basic software, the upper button is "Trigger snapshot" and the lower button is "Video Start/Stop".

The two buttons on the handle body can be set in the software ATMOS Capture Suite HD. In the photo mode of the programs, “Trigger snapshot” is stored by default on the upper button and “Switch to video function” on the lower button. In the video mode of the programs, the upper button is “Video start/stop” and the lower button is “Switch to snapshot function"

5 Reprocessing

5.1 Safety instructions for reprocessing

5.1.1 General safety instructions

Reprocess the ATMOS Scope before using it on the patient.

It is the responsibility of the user to ensure that the required results of cleaning and disinfection are achieved. Validation and routine monitoring of the procedure will usually be necessary.

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

5.1.2 Danger for users, patients, and third parties

Risk of infection due to unsuitable aids and tools

Deadly diseases can be transmitted.

- Always wear your own personal protective equipment. The protective equipment consists of protective gloves, protective clothing, safety goggles, and mouth and nose protection for all steps in which the product components are contaminated.
- Only use aids and tools 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 device can be reached easily.

5.1.3 Avoiding damage to the device

Do not expose the product to temperatures above 65 °C / 149 °F before and during cleaning.

Use only suitable load carriers with silicone pads for mechanical reprocessing.

Damage to the device due to cleaning with fixatives

- · Do not use aldehydes before and during cleaning.

Unsuitable aids and tools

The product may become damaged.

- Use only lint-free, soft cloths.
- Use only brushes with soft bristles.
- Never clean and/or disinfect the product in an ultrasonic bath.
- Follow the corresponding operating instructions of all aids, tools, and devices used.

Unsuitable cleaning agents and disinfectants

The product may become damaged.

Do not use any process chemicals containing the following ingredients on the **ATMOS Scope as well as for all accessories:**

- Chloramines
- Phenol derivatives

Incorrect cleaning and disinfection

Corrosion due to moisture.

- Remove the products immediately after the program is finished.
- Only place the device in suitable load carriers with silicone pads in order to avoid damage to the device. Please clean carefully, as the tube and bendable end can be damaged by kinking, twisting, pushing, or pulling. Gross contamination should be removed carefully with a soft cloth or a soft brush.
- The insertion tube must not bend less than a minimum bending radius of

40 mm during reprocessing.

5.1.4 Further cleaning instructions

Image quality can be reduced even by the slightest contamination such as fingerprints on the tip cover glass.

After use, you can protect the ATMOS Scope from dust by storing it on a soft cloth and covering it.

5.2 Preparing and completing reprocessing

Prior to reprocessing

1. Prior to cleaning, put the protection cap onto the USB connector.
2. Make sure that the protection cap is fitted securely on the USB connector.
3. Carry out the leakage test before immersing the device in liquids (see chapter “3.6.3 Performing a leakage test” on page 28).

After reprocessing

Perform a function check. Please observe the chapter “3.6.1 Carrying out the function check” on page 26.

5.3 Preparing surfaces

5.3.1 Overview

Surface	After each patient	Pre-treatment	Pre-cleaning	Manual cleaning and immersion disinfection	Mechanical cleaning and disinfection	Sterilization	Drying with cloth	Remarks
ATMOS Scope with USB cable and USB protection cap	X	X	X	X	X		X	

5.3.2 Selecting process chemicals

Material compatibility tests using the following cleaning agents and disinfectants were carried out for the ATMOS Scope. Please follow the instructions specified by the manufacturer of the cleaning agents and disinfectants, particularly with regard to

concentrations, temperature, duration of use, and contact times as well as protective measures.

Cleaning agent (manufacturer)	Active ingredients in 100 g (if published or released by the manufacturer)	Type
Cleaning agents – manual reprocessing		
MetriSponge, Metrex	Water and nonhazardous ingredients 30–60 % Propylene glycol 10–30 % Nonionic surfactants 10–20 % Fragrance oil 5–10 % Proteinase subtilisin 0.1–1 % Octamethylcyclotetrasiloxane <0.2 %	Ready-to-use
Prolystica, Steris	Alcohols, C9–11, ethoxylated surfactant 5 % Glycerin 5 % Citric acid 5 % N,N-Dimethyloctadecylamine oxide 2 % Proteolytic enzymes 1 %	Liquid concentrate
Gigazyme, Schülke & Mayr	Nonionic surfactants, enzymes, fragrances 5–15 %	Liquid concentrate
Helizyme, BBraun	Surfactants, enzymes, complexing agents, corrosion inhibitors, additives	Liquid concentrate
mikrozid® sensitive wipes, Schülke & Mayr	0.25 g Alkyl (C12–16) dimethylbenzylammonium chloride 0.25 g Didecyldimethylammonium chloride 0.25 g Alkyl (C12–14) ethylbenzylammonium chloride	Wipes Ready-to-use

Disinfectants – manual reprocessing		
Metricide 28, Metrix	Water and nonhazardous ingredients Glutaraldehyde	Liquid concentrate
Revital OX Resert, Steris	2-Furancarboxylic acid 2–3 % Hydrogen peroxide 1–2 % Potassium hydroxide 0.405 % Phosphoric acid 0.4 % 1-Hydroxyethane-1, 1-diphosphonic acid 0.3 %	Liquid concentrate
Cidex OPA, ASP	Phthalaldehyde	Ready-to-use
Gigasept FF, Schülke & Mayr	93.9 g reaction product of DMO-THF, ethanol and water	Liquid concentrate
mikrozid® sensitive wipes, Schülke & Mayr	0.25 g Alkyl (C12–16) dimethylbenzylammonium chloride 0.25 g Didecyldimethylammonium chloride 0.25 g Alkyl (C12–14) ethylbenzylammonium chloride	Wipes Ready-to-use
Helipur® H plus N, BBraun	Aldehydes Glutaraldehyde 12.0 g, propan-2-ol, 7.5 g, ethylhexanol 0.5 g, anionic surfactants	Liquid concentrate
Cleaning agents – mechanical reprocessing		
neodisher® MediClean forte, Dr. Weigert	<5 % nonionic and anionic surfactants, enzymes	Liquid concentrate

Intercept, Cantel	Quaternary ammonium compounds, benzyl-C12-18-alkyldimethyl, chlorides 1–5 % D-Glucopyranose, oligomeric, decyl octyl glycosides 0.72–1.44 %	Liquid concentrate
Intercept plus, Cantel	Trisodium phosphate 5–10 % Phosphoric acid, tripotassium salt 5–10 % Propylene glycol 10 %	Liquid concentrate
Isaclean	DTPA (diethylenetriaminepentaacetic acid) 0.07 g	Liquid concentrate
Disinfectants – mechanical reprocessing		
neodisher® Septo GA, Dr. Weigert	Glutaral 10.5 g	Liquid concentrate
neodisher® SEPT PA, Dr. Weigert	Peracetic acid 15.0 g	Liquid concentrate
Rapicide PA, Cantel	Hydrogen peroxide 22 % Acetic acid 9 % Peroxyacetic acid 5 %	Liquid concentrate

5.3.3 Manual cleaning and disinfection

Please observe the chapter “1.7 Attaching the attachment for pressure compensation” on page 16.

Cleaning: • Temp.: 30–35 °C, 0.8 % Cidezyme, drinking water • Soft cloth • Soft nylon brush 1 min (Brush length: 35 mm Brush width: 7 mm Total length: 175 mm Bristles: nylon Hardness: soft) • Disposable syringe (20 ml), rinse at least 5 times	• Completely immerse in cleaning solution. • Ensure that all accessible surfaces are moistened. • With the insertion tube lying in the solution, clean it with a soft cloth and clean the ATMOS Scope handle with a soft cleaning brush until no residue is visible on the surface. • Move the movable component (deflection lever) 5 times in each direction as far as it goes during cleaning. • Using a disposable syringe, thoroughly rinse these places with the cleaning solution at least 5 times. • Do not use metal cleaning brushes or other abrasives that could damage the product surfaces, as they could cause corrosion.
Intermediate rinsing: • Drinking water • Water jet gun for 60 s	• Fill the sink with enough drinking water so that the ATMOS Scope is completely immersed. • Set the pressure for the water jet gun to maximum 2 bar. • Using the water jet gun, rinse off the entire handle for 60 seconds and pay particular attention to gaps and hidden surfaces. Recommendation: Rinsing should be done under water to avoid splashing contaminated liquid.
Final rinse: • 1 min • Cold drinking water • Move 5 times	• Rinse the probes for 1 minute under cold running drinking water to remove any cleaning agent residues. • Move the deflection lever at least 5 times in each direction as far as possible.

Disinfection	
Disinfection: • Temp.: at least 20–25 °C, Cidex OPA, drinking water • 12 min	Completely immerse the ATMOS Scope in the disinfection solution.
Final rinse: • Temp.: 30–45 °C, Time 3 min • Water quality: drinking water	
Drying: • Temp.: 30–45 °C • 3 min	
Please observe the shelf life of the immersion disinfection, according to the manufacturer's instructions.	

5.3.4 Mechanical cleaning and disinfection

Check the device for leak tightness (see chapter "3.6.3 Performing a leakage test" on page 28).

General notes for mechanical cleaning

Inspect visible surfaces for residual contamination after mechanical cleaning/disinfection. Repeat the cleaning process if necessary.

The product is compatible with several washer-disinfectors for flexible endoscopes. For further details regarding operation, please refer to the operating instructions for the washer-disinfector.

If it is unclear whether the product can be cleaned and disinfected with the existing washer-disinfector for endoscopes, please contact the manufacturer of the washer-disinfector for endoscopes and, if necessary, check with the manufacturer which cleaning and disinfection program is suitable for the product.

Product damage due to excessive temperatures. During mechanical cleaning and disinfection, the temperature should not exceed 65 °C / 149 °F.

- Position and gently fix the endoscope in a cleaning basket lined with silicone mats in the washer-disinfector in accordance with the machine manufacturer's instructions.

The validation that the product can be cleaned and disinfected has been conducted using the washer-disinfector for flexible endoscopes from Belimed Type WD 430 with the rack Endoscopy 2 level.

Pre-cleaning: • Drinking water, wipe 5 times • Soft nylon brush, 1 min (Brush length: 35 mm Brush width: 7 mm Total length: 175 mm Bristles: nylon Hardness: soft)	Step 1: Remove any gross contamination with a cloth dampened in cold drinking water. Wipe the insertion tube 5 times from the handle toward the tip. Step 2: Brush the handle using a nylon brush with soft bristles for 1 minute under running drinking water. Pay particular attention to crevices and hidden areas.

Mechanical cleaning and disinfection: • Pre-rinse: 3 min • Drain • Cleaning: 7 min, 55 °C / 131 °F with 5 ml neodisher® Mediclean forte • Drain • Rinse: 2 min, 55 °C with drinking water • Drain • Accessories for storage: screen basket, silicone mat	• Lay the ATMOS Scope on the silicone bubble mat and fix the insertion tube at a minimum of 2 places. • Select a suitable program for cleaning and disinfection with the adjacent parameters. • Washer-disinfector: in accordance with EN ISO 15883-1.
Comments:	The specified temperatures and times refer to the water supply and the set value of the washer-disinfector. Temperature of cold drinking water: 10–25 °C and of cold deionized water: 10–25 °C.
Checking and maintaining:	• Check whether reprocessing was successful using a suitable light magnifier. The ATMOS Scope must be free of particles and organic material.

5.3.5 Sterilization

☞ Do not autoclave the product.

Prior to sterilization, ensure that the product does not show any reduction in usability and no visible moisture on the surface (crevices or blind holes) in accordance with chapter “3.6 Checks and tests” on page 26.

Ensure that the sterilizing agent reaches all surfaces. The implementation of the sterilization procedures mentioned, with respect to achieving the desired or required sterilization effect, lies within the user’s responsibility.

☞ Observe the operating instructions for your sterilizer.

☞ Important! Prior to sterilization, attach the attachment for pressure compensation on the valve of the endoscope (see chapter “1.7 Attaching the attachment for pressure compensation” on page 16).

After sterilization, remove the attachment for pressure compensation from the valve of the endoscope, see chapter “1.8 Removing the attachment for pressure compensation” on page 16.

Material compatibility approvals exist for:

Low-temperature plasma sterilization

- STERRAD® 100NX (Advanced Sterilization Products)
- Steris V-Pro (Steris Company)

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. To carry out these measures, the person must have the necessary test devices and original spare parts.

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

We recommend that you always document any maintenance work and also any exchange of parts.

6.1 Periodic tests

At least every 24 months a repeat test of the electrical safety should be performed according to IEC 62353.

6.2 Sending in the device

1. Clean and disinfect the product and accessories according to the operating instructions.
2. Enclose any used accessories with the product.
3. Use a tightly sealable shipping bag for sending in the endoscope (for example, the supplied infection control return bag, REF 090.0297.0).

4. Fill in the form QD 434 “Delivery complaint / return shipment” and the respective **decontamination certificate**.

☞ This form is enclosed with each delivery and can be found at www.atmosmed.com.

5. The product must be well padded and packed in suitable packaging.

☞ Please ensure that the adapter for pressure compensation is screwed on.

6. Place the QD 434 “Delivery complaint / return shipment” form and the respective **decontamination certificate** in an envelope.
7. Affix the envelope to the outside of the package.
8. Send the product to ATMOS or your dealer.

6.3 Warranty

The manufacturer grants a 24-month warranty on the product’s function. This warranty is restricted to claims made immediately in written form within the specified warranty period after the invoice date, where appropriate with reference to repairs and stating the invoice number. Statutory warranty claims are not limited by this warranty.

This warranty only applies to defects that cannot be attributed to normal wear and tear, misuse, improper handling, extraneous cause, lack of or incorrect reprocessing, or force majeure.

All guarantee and warranty claims will be lost if the user himself or an unauthorized repair company carries out repairs or modifications to the product. In the event

that a product requires maintenance, the same applies to maintenance that is not expressly permitted.

Liability claims arising from improper handling or the combination with other devices or accessories cannot be made.

This warranty only applies to defects that cannot be attributed to normal wear and tear, misuse, improper handling, extraneous cause, lack of or incorrect reprocessing, or force majeure.

All guarantee and warranty claims will be lost if the user himself or an unauthorized repair company carries out repairs or modifications to the product. In the event that a product requires maintenance, the same applies to maintenance that is not expressly permitted.

Liability claims arising from improper handling or the combination with other devices or accessories cannot be made.

7 Troubleshooting

Error symptom	Possible cause	Remedy
Cloudy image	Glass surfaces are dirty	Clean glass surfaces in accordance with chapter “5.3 Preparing surfaces” on page 35
	Leaky, defective lens system	Send in the ATMOS Scope for repair
Image is too dark, insufficient illumination	Glass surfaces are dirty	Remove residues according to chapter “5.3 Preparing surfaces” on page 35; check water quality
	Stubborn residue on the glass surfaces	Clean again, rub thoroughly if necessary
	LED is defective	Send in the ATMOS Scope for repair
	Brightness is set incorrectly	Adjust brightness in the software settings

Corrosion, staining, discolorations	Inadequate cleaning (e.g., protein residue)	Clean again, rub thoroughly if necessary
	Inadequate rinsing of the endoscope between reprocessing phases (especially before sterilization)	Ensure adequate rinsing between the reprocessing phases
	Contaminated disinfectant and cleaning solutions that are used too frequently	Replace the disinfecting and cleaning solutions at regular intervals
	Extraneous rust (e.g., from rusty steam or reprocessing together with damaged or non-stainless instruments)	Check supply systems; ensure material compatibility during common reprocessing, pay attention to existing damage, and avoid mutual contact

Leakage	Leakage tester is connected incorrectly	Check connections between the attachment for pressure compensation, tube of leakage tester, and leakage tester
	Insertion tube is defective	Send in the ATMOS Scope for repair
	Protection cap is not on connector	Push protection cap firmly onto connector
Deflection lever is stiff, not working	Defective tip mechanism	Send in the ATMOS Scope for repair
No image on the PC	Camera USB driver is not installed on the PC	Install camera USB driver
	ATMOS Scope is not recognized by USB interface; the USB interface may be turned off	USB port via Windows/control panel/power settings must be permanently activated
Poor color reproduction	Monitor not properly adjusted	Check the monitor settings
Colored stripes on the monitor	ATMOS Scope is defective	Send in the ATMOS Scope for repair

ATMOS Scope is not recognized by the PC	USB port has switched off	USB port must be permanently activated via the power settings in Windows
	ATMOS Scope is defective	Send in the ATMOS Scope for repair

7.1 Error message of firmware

Error code	Description
0xF0000000	Unspecified error in processing
0xF0000001	Error in the status indicator
0xF0000002	Error in the USB module
0xF0000003	Error in the image module (e.g. communication with the sensor, data interface, etc.)

7.2 Warning messages from the firmware

The following modules may generate warning messages:

Module	Restrictions
Status indicator	Unspecified error in processing
Integrated LED lighting	The integrated LED lighting does not work or is not fully functional.
USB transmission	Reliable USB transfer is not possible, or enumeration could not be performed.
Settings	Setting data do not exist or were incorrect. After the factory default settings, adjustable components (e.g. auto standby) may work again under certain circumstances. In addition, the calibration for the image may be faulty or not available, and the colors, etc. in the image will not be displayed correctly.

8 Accessories

Accessories	REF
ATMOS Capture Suite HD License Dongle	700.0047.0
ATMOS Controller for visualization	507.6200.0
ATMOS Medical Monitor 21.5” Touch	507.3128.0

9 Disposal

Packaging

1. Please recycle the product packaging.

Product

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. Dispose of the product properly and in accordance with country-specific laws and regulations.

In principle, the case is fully recyclable. However, please observe country-specific laws and regulations.

10 Technical data

Input voltage	5V≈ (USB 2.0)
Current consumption	max. 0.73A (USB 2.0; 5 V≈)
Power consumption	max. 3.65W
Other power sources	None
Mode of operation	Continuous operation
Protective earth conductor resistance Earth leakage current Touch current Patient leakage current	n/a n/a n/a n/a
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 • Air pressure	20...80 % 700...1060 hPa
Maximum operational altitude	3000m (NN)
Contamination level	2
Overvoltage category	I
Dimensions (H x W x D)	189 x 445 x 40 mm
Dimensions of the insertion tube	Length 300 mm; Ø 3.9 mm
Weight	0.4 kg
Periodical tests	Follow the instructions for the individual components
Protection class against electric shock (acc. to EN 60601-1)	II
Classification of applied parts	Type BF applied parts 
Degree of protection	IP68
Risk classification acc. to MDR 2017/745	Class I
CE marking	CE
Risk classification (MDR)	Class I according to Rule 5

Reference number (REF)	507.7000.0

11 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 Scope is suitable for use in the following environments:

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

The customer or user of the ATMOS Scope must ensure that the device is used in a prescribed environment.

Guidance and manufacturer's declaration – key features

☞ Please note the Technical Data in these instructions. The essential features are fully usable even in the presence of electromagnetic disturbances.

Guidance and manufacturer's declaration – removable components that can be replaced by the operator

The ATMOS Scope has the following removable components that can be replaced by the operator:

Type	REF	Max. cable length
ATMOS Scope	507.7000.0	2 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 cause increased electromagnetic emissions or reduced immunity to electromagnetic interference and result in faulty operation.

⚠ WARNING

Portable RF communications equipment (e.g. radios, antenna cables) should be used no closer than 30 cm* to any part of the ATMOS Scope , including cables, specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

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

12 Notes

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