Operating Instructions

ATMOS Scope

English



CE

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1 Introduction

1.1 Notes on the operating instructions



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

This manual is used to train and instruct operating personnel and is also intended as a reference manual. This document may be reprinted, either in part or in whole, only with the written permission of ATMOS.

These operating instructions must always be kept available near the product.



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

Maintenance, repairs and period tests may be carried out only 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 “2 Notes on your safety” on page 19 before using the product for the first time. This will help you to avoid potentially dangerous situations.

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

The product meets all the applicable requirements of the directive 2011/65/EC 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 used at ATMOS has been certified according to the international standard EN ISO 13485.

These operating instructions apply to the following products:

- ATMOS Scope 507.7000.0
- ATMOS Scope Pro 507.7050.0
- ATMOS Scope iPrime 507.7060.0

1.2 Explanation of pictograms and symbols

In the operating instructions

DANGER	Warning of a danger resulting directly in fatal or serious injury. Observe the necessary measures.
WARNING	Warning of a danger of fatal or serious injuries. Observe the necessary measures.
CAUTION	Warning of a danger of minor injury. Observe the necessary measures.
ATTENTION	Notice of a danger of damage to the product or other objects. Observe the necessary measures.
	Warning of a danger of serious or fatal injury.
	Notice of potential material damage that can be caused.
	Useful information on handling the device.

1.	Call for action. Proceed step by step.
»	Result of an action.
→	Move/plug in this direction.
	Engage and check for tight fitting.

On the device and type plate

	Follow the operating instructions (blue)
CE	This product meets the relevant requirements of EU regulations.
	UL Recognized Component
	Manufacturer
	Date of manufacture

	Country of manufacture: Germany
SN	Serial number
REF	Item number
IP68	Degree of protection
	Device of protection class II
	No domestic waste
	Applied part of type BF
MD	Medical product
	This device meets the relevant requirements of the Eurasian Economic Union.

	Only available by prescription
	Caution! Fragile!
	Error message
	Warning message
	Standby mode

(01)	UDI-DI: identification of the manufacturer and product
(11)	Date of manufacture
(21)	Serial number

1.3 Intended use

Product name:	ATMOS Scope
Main function:	For short-term endoscopic application in natural orifices for the visualization of existing structures
Intended purpose:	For endoscopic examinations on humans
Intended users / user profile:	Physicians and medical specialists
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 each time beforehand.
Medical condition to be diagnosed, treated or monitored:	An endoscopy can be performed whenever visual examination of the internal anatomy of the defined organs is necessary.
Application organ:	Ear, mouth and pharynx, nose
Application time:	Temporary (< 60 min.)
Application environment:	Outpatient medical facilities, e.g. ENT practices, hospital outpatient departments, medical care centres
Patient selection criteria:	None

Indications:	Need for visual examination of the anatomy in specific organs
Medical contraindications:	Non-intact mucosa in the area of the application organs
Other contraindications:	None
Warnings:	None
The product is:	Active
Sterility / specific microbial condition:	Non sterile
Single-use product / re-sterilization:	Not a disposable product. Options for re-sterilization according to the operating instructions.

1.4 Function

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

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

Manual camera settings and white balance are no longer required thanks to the optimized video pre-settings.

1.5 Scope of delivery

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

Description	REF
ATMOS Scope The set includes: • Endoscope • Adapter for leakage test • Pressure compensation attachment including information tag for pressure compensation • Infection control return bag	507.7000.0

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



ATMOS Scope



Operating instructions

1.6 Transport and storage

Transport the device only in a padded shipping box that provides sufficient protection. The wooden packaging of the ATMOS Scope is not suitable for shipment in a service case and must be disposed of by ATMOS to meet the hygiene requirements.

If you notice any transport damage:

1. Document and report the transport damage.
2. Follow the procedure described in chapter “6.2 Procedure for repairs and service cases” on page 52.

Ambient conditions for transport, storage and operation:

Please refer to chapter “10 Technical data” on page 63.

- ☞ 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 pressure compensation attachment

Attach the pressure compensation attachment to the valve and turn it clockwise 90°. The attachment is now firmly connected to the endoscope and cannot be removed. Please observe the following chapter “3.2 Leakage tester and hose” on page 25.

Attach it before:

- Low-temperature sterilization
- Ventilation
- Shipping

1.8 Removing the pressure compensation attachment

Turn the pressure compensation attachment anti-clockwise 90°. The pressure compensation attachment can now be removed from the valve of the endoscope.

Remove it before:

- Immersion in liquids
- Using it on patients

2 Notes on your safety

Read and observe the safety instructions carefully before using the product.

2.1 General safety instructions

Use only accessories and options that are explicitly defined as suitable for combination with the product and meet the performance and safety requirements.

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

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

Report any serious incidents that occur in connection with this product to the manufacturer and the national authority responsible for you.

2.2 Danger to users, patients and third parties

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

Minor injuries are possible.

- Check the device or cable for damage each time before using it. 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 30). 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 repairs.
- You can disconnect the device from the mains supply only by pulling the power cable.
- Position the device where it is easy to disconnect from the PC/laptop at any time.
- Never touch plugs or power cables with wet hands.
- Use only original accessories and original spare parts from ATMOS.
- Follow the instructions regarding period tests (see chapter “6.1 Period tests” on page 52).
- Assembly work, new settings, modifications, extensions, and repairs may be carried out only by authorized persons.
- Do not modify the device without the manufacturer’s permission.
- The distal endoscope tip may heat up to 53.5 °C in the event of prolonged use of the ATMOS Scope.
- Never leave the patient unattended near the device.

⚠ CAUTION

Patient endangerment

Endangerment of patients due to using products with sharp-edged surfaces or other dangerous surface damage.

Do not use these products any more.

Keep the product fully functional.

Malfunctions can cause injury to you and your patients.

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

Danger of infection by germs on the product!

Diseases can be transmitted.

- Always wear disposable gloves when using the product.
- Prepare the ATMOS Scope before using it on a patient, while observing chapter “5 Sterilization” on page 34.
- Clean and disinfect the device according to the operating instructions; see chapter “5 Sterilization” on page 34.

2.3 Avoiding damage to the device

Treat the system with the utmost care because 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 impact. Damage to the USB cable and the distal tube of the ATMOS Scope is possible.

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

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

2.3.2 Storage and operation in an unsuitable environment

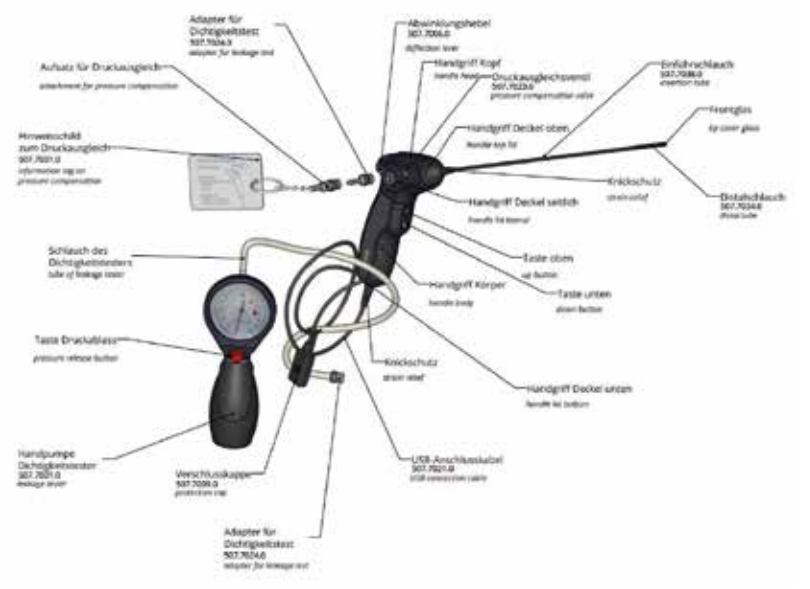
The product may become damaged.

- Observe the ambient conditions regarding transport, storage and operation. Please also observe chapter “10 Technical data” on page 63.

☞ Please also observe chapter “5.1.3 Avoiding damage to the device” on page 35.

3 Setting up the device and putting it into service

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 on 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 Using the device in combination with other devices

Only qualified personnel are authorized to install electrical systems. The manufacturer of a medical electrical 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 the standard 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 also observe chapter “2 Notes on your safety” on page 19.
- Sterilize the ATMOS Scope before using it on patients. Please observe chapter “5 Sterilization” on page 34.

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 always 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). ATMOS ensures safe operation of the ATMOS Scope only when using ATMOS’s own hardware. The colour reproduction of the ATMOS Scope has been adjusted to ATMOS’s hardware and may differ on third-party hardware. ATMOS assume no liability or service for third-party hardware.

Stable functioning of the ATMOS Scope will not be ensured if the mains supply is insufficient. The simultaneous operation of several USB devices, in particular, may be problematic. No USB hub may be used between the PC system and ATMOS Scope.

3.5.2 Software system requirements

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

Despite being able to be used with a number of third-party software applications, ATMOS strongly recommend using the ATMOS Scope exclusively with the ATMOS Capture Suite Basic or ATMOS Capture Suite HD video software.

ATMOS shall assume no liability or provide service for using the ATMOS Scope with third-party software.

3.5.3 Installation of the ATMOS Capture Suite Basic

1. Plug the supplied USB flash drive into the designated jack.
2. Launch “Install.exe”.
3. Click on “Capture Suite Basic”.
4. Restart your computer.
5. The installation is complete.

3.5.4 Installation of the ATMOS Scope by means of 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. The 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 30).
2. Remove the pressure compensation attachment and the protection cap of the USB connector. Before use, check that there is no moisture on the plug connection of the USB connector.
3. Check the deflection mechanism (see chapter “3.6.4 Checking the deflection mechanism” on page 31).
4. Check the ATMOS Scope for leak tightness using the manual leakage tester (see chapter “3.6.3 Performing a leakage test” on page 30).

5. Check whether an image is displayed and the LED light is switched on. The endoscopic image must be crisp, clear and bright at the appropriate working distance.

⚠ CAUTION

Patient endangerment

Endangerment of patients due to using products with sharp-edged surfaces or other dangerous surface damage.

☞ Do not use these products any more.

⚠ CAUTION

Damage to the product

Do not use the product 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 centre authorized by the manufacturer for inspection. Authorized repair centres 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 this inspection, observe the notes on the cause and how to remedy it in chapter “7 Troubleshooting” on page 55.

3.6.3 Performing a leakage test

- Check whether the hose of the leakage tester is correctly attached to the leakage tester.
- Attach the adapter for the leakage test to the valve and turn it clockwise 90°. The tester is now firmly connected to the endoscope and cannot be removed.
- Generate a test pressure of max. 160 mmHg by pumping on the leakage tester.
- Wait 30 s and observe the pressure If the value on the vacuum gauge display drops continuously, do not place the endoscope in liquid, because the device is leaking.
- Vent the system by pressing the red button on the leakage tester.
- Remove the adapter from the endoscope valve after the leakage test. Unlock and remove the adapter for the leakage test by pressing and turning it 90°.

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

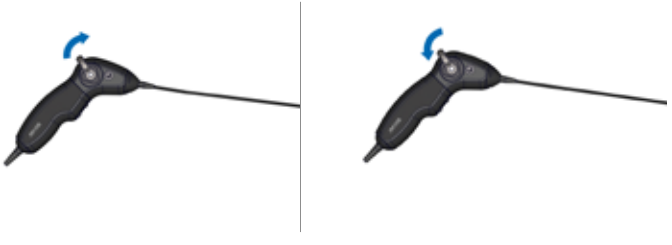
☞ A leaky device must not be applied to patients.

☞ A leaky device will become damaged by liquids entering it and will no longer be able to be sterilized. In this case, please send in the device for repairs.

- Never connect the leakage tester to or disconnect it 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 be cleaned only by wipe disinfection.

3.6.4 Checking the deflection mechanism

1. Slowly operate the deflection lever to check that it is working.
2. Move the deflection lever several times and check that it is easy to move and that the distal end is moving correctly



⚠ CAUTION

Any limitations in deflection may indicate an endoscope defect. To avoid major damage to the endoscope, use the endoscope only if the deflection is working absolutely smoothly.

4 Operation

4.1 Use/operation

Please observe also chapter “2 Notes on your safety” on page 19.

Please disconnect the ATMOS Scope at least once a day from the PC (by pulling the USB connector).

4.1.1 Switching on and setting the system

1. Please take the flexible ATMOS Scope in your hand.

☞ The system is switched on automatically.

4.1.2 Functions of the buttons with the ATMOS Capture Suite

When using the ATMOS Capture Suite Basic software, the top button is “Trigger Snapshot” and the bottom button is “Video Start/Stop”.

The two buttons on the handle can be set in the software ATMOS Capture Suite HD. In snapshot mode of the programs, “Trigger Snapshot” is stored by default in the top button and “Switch to Video Function” in the bottom button. In video mode of the programs, the top button is “Video Start/Stop” and the bottom button is “Switch to Snapshot Function”.

4.1.3 Standby mode

The ATMOS Scope has an automatic standby mode, which can be deactivated or activated by means of ATMOS Capture Suite HD or ATMOS Capture Suite Basic. Furthermore, it is possible to set the time until standby.

If standby mode is active, the following symbol is displayed:



Standby mode is left by pressing one of the two buttons on the device.

5 Sterilization

5.1 Safety instructions for sterilization

5.1.1 General safety instructions

Sterilize the ATMOS Scope before using it on patients.

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

The sterilization process may be carried out only by persons with the necessary expertise. The person in question must possess the equipment required to take the mentioned measures.

5.1.2 Danger to users, patients and third parties

Risk of infection due to unsuitable aids

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 still contaminated.
- Use only aids and tools that are easy to sterilize or are disposable products.

Danger of infection due to unsuitable sterilization

Deadly diseases can be transmitted.

- Make sure all areas of the device are easy to reach.

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 sterilization.

Damage to the device due to fixative cleaning

- Do not use any aldehydes before and during cleaning.

Unsuitable aids

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 for 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 or any accessories:**

- Chloramines
- Phenol derivatives

Incorrect cleaning and disinfection

Corrosion due to moisture.

- Remove the products immediately at the end of the program.
- Place the device only in suitable load carriers with silicone pads to avoid damage to the device. Please clean it carefully because the hose and bendable end can become damaged by kinking, twisting, pushing or pulling them. Any coarse contamination should be removed carefully with a soft cloth or brush.
- The insertion tube must not be bent less than a minimum bending radius of 40 mm during the sterilization process.

5.1.4 Additional cleaning instructions

The image quality can be impaired by the slightest dirt, such as fingerprints on the cover glass.

You can protect the ATMOS Scope from dust by storing it on a soft cloth and covering it after using it.

5.2 Preparing and completing the sterilization process

Prior to sterilization

1. Prior to cleaning, put the protection cap onto the USB connector.
2. Make sure the protection cap is fitted firmly 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 30).

After sterilization

Perform a function check. Please observe chapter “3.6.1 Carrying out the function check” on page 28.

5.3 Sterilizing 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)	X	

5.3.2 Selecting process chemicals

Material compatibility tests have been carried out for the following cleaning agents and disinfectants for the ATMOS Scope. Please follow the instructions of the manufacturer of the cleaning agents and disinfectants, in particular with regard to concentrations, temperature, duration of use, and exposure time as well as protective measures.

Cleaning agent (manufacturer)	Active ingredients in 100 g (if published or released by the manufacturer)	Type
Cleaning agents – Manual sterilization		
mikrozid® sensitive wipes, Schülke & Mayr	0.25 g Alkyl (C12–16) dimethyl benzyl ammonium chloride 0.25 g didecyl dimethyl ammonium chloride 0.25 g alkyl (C12–14) ethyl benzyl ammonium chloride	Ready-to-use wipes
MetriSponge, Metrex	Water and non-hazardous ingredients, 30-60% Propylene glycol, 10-30% Non-ionic surfactants, 10-20% Fragrance oil, 5-10% Proteinase subtilisin, 0.1-1% Octamethylcyclotetrasiloxane < 0.2%	Ready to use
Prolystica, Steris	Alcohols, C9–11, 5% ethoxylated surfactant Glycerin, 5% Citric acid, 5% N,N-dimethyloctadecylamine oxide, 2% Proteolytic enzymes, 1%	Liquid concentrate
Gigazyme, Schülke & Mayr	Non-ionic surfactants, enzymes, fragrances, 5-15%	Liquid concentrate
Helizyme, BBraun	Surfactants, enzymes, complexing agents, corrosion inhibitors, additives	Liquid concentrate
Cidezyme, ASP	Subtilisin (proteolytic enzymes) 1.2 propanediol, 10-20% Di-sodium tetraborate decahydrate, 1-3% Sodium diethylenetriamine pentamethylene phosphonate, 1-2.5%	Liquid concentrate

Disinfectants – Manual sterilization		
Metricide 28, Metrix	Water and non-hazardous 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	Ortho-phthalaldehyde, 0.55%	Ready to use
Gigasept FF, Schülke & Mayr	93.9 g reaction product of DMO-THF, ethanol and water	Liquid concentrate
Helipur® H plus N, BBraun	Glutaraldehyde, 12.0 g Propane-2-ol, 7.5 g Ethylhexanol, 0.5 g Anionic surfactants, 5-15 g Non-ionic surfactants < 5 g	Liquid concentrate
Cidezyme, ASP	Subtilisin (proteolytic enzymes) 1.2 propanediol, 10-20% Di-sodium tetraborate decahydrate, 1-3% Sodium diethylenetriamine pentamethylene phosphonate, 1-2.5 %	Liquid concentrate

Cleaning agents – Mechanical sterilization		
neodisher® MediClean forte, Dr. Weigert	< 5% non-ionic and anionic surfactants, enzymes	Liquid concentrate
Intercept, Cantel	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, 5-10% tripotassium salt Propylene glycol, 10%	Liquid concentrate
Isaclean	DTPA (diethylenetriaminepentaacetic acid), 0.07 g	Liquid concentrate
Disinfectants – Mechanical sterilization		
neodisher® endo SEPT 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% Peracetic acid, 5%	Liquid concentrate

5.3.3 Manual cleaning and disinfection

Please observe chapter “1.7 Attaching the pressure compensation attachment” on page 17.

5.3.4 Manual cleaning with MetriSponge

Cleaning: • MetriSponge, Metrex • Wipe the insertion tube five times	Take the MetriSponge out of the bag and press it out until it foams. Wipe the surface of the samples thoroughly to remove any visible dirt. Pay particular attention to cavities and concealed surfaces. Wipe the insertion tube five times from the handle towards the tip.
Intermediate rinsing: • Drinking water • Wipe the insertion tube five times • Move the deflection lever five times	Rinse out the MetriSponge and repeat step 1. Move the deflection lever as far as possible five (5) times in each direction.
Rinse after cleaning: • 2 min. • Drinking water	Rinse the ATMOS Scope for two (2) minutes under cold running water to remove any cleaning agent residue.
Visual inspection	Repeat the manual cleaning if there is any visible dirt on the device.
Drying	Place the ATMOS Scope on a clean surface covered with a lint-free cloth and cover it with another lint-free cloth to dry it. The ATMOS Scope must be completely re-sterilized. Continue with the disinfection and/or sterilization.

5.3.5 Manual cleaning with Cidezyme

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 • Overall length: 175 mm • Bristles: nylon • Hardness: soft) • Disposable syringe (20 ml); rinse at least five times	• Immerse the ATMOS Scope completely in the cleaning agent 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 components (deflection lever) five times in each direction as far as they will go during cleaning. • Then use a disposable syringe to thoroughly rinse these points with the cleaning solution at least five times. • Do not use metal brushes or other abrasives that could damage the product surfaces. There will otherwise be a danger of 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. • Use the water jet gun to rinse the entire handle for 60 seconds while paying particular attention to gaps and hidden surfaces. Recommendation: Rinsing should be done under water to avoid splashing contaminated liquid.

• Rinse after cleaning: 2 min. • Cold drinking water • Move five times	Rinse the samples for one minute under cold running drinking water to remove any cleaning agent residue. Move the deflection lever as far as possible at least five times in each direction.
Visual inspection	Repeat the manual cleaning if there is any visible dirt on the device.
Drying	Place the ATMOS Scope on a clean surface covered with a lint-free cloth and cover it with another lint-free cloth to dry it. The ATMOS Scope must be completely re-sterilized. Continue with the disinfection and/or sterilization.

5.3.6 Manual disinfection with Cidex OPA

Disinfection: • Temp.: at least 20-25 °C, Cidex OPA, drinking water • 18 min.	Immerse the ATMOS Scope completely in the disinfectant solution.
Final rinsing: • Temp.: 30-45 °C, time: 3 min. • Water quality: drinking water	
Drying: • Temp.: 30-45 °C • 3 min.	Place the ATMOS Scope on a clean surface covered with a lint-free cloth and cover it with another lint-free cloth to dry it. The ATMOS Scope must be completely dry before it can be reused or stored.
Please observe the shelf life of the immersion disinfectant according to the manufacturer's specifications.	

5.3.7 Mechanical cleaning and disinfection

Check the device for leak tightness (see chapter “3.6.3 Performing a leakage test” on page 30).

General notes on 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 details regarding operation, please refer to the operating instructions for the washer-disinfector for endoscopes.

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. The temperature must not exceed 65 °C / 149 °F during mechanical cleaning and disinfection.

- 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 specifications.

It has been verified that the product can be cleaned and disinfected with the washer-disinfector for flexible endoscopes of Belimed type WD 430 with rack endoscopy level 2.

Pre-cleaning: • Drinking water, wipe five times • Soft nylon brush, 1 min. (Brush length: 35 mm Brush width: 7 mm Overall length: 175 mm Bristles: nylon Hardness: soft)	Step 1: Remove any coarse dirt with a cloth moistened with cold drinking water. Wipe the hose five times from the handle towards 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: • 3 min. pre-cleaning with cold tap water • Drain • 7 min. cleaning with 55 °C tap water and 5.0 ml/L of neodisher MediClean forte cleaning solution • Drain • 2 min. (measure) rinsing with 55 °C deionized water • Drain • 5 min. disinfection with 55 °C tap water and 10 ml/L of neodisher endo SEPT GA • Drain • 2 min. rinsing with 55 °C deionized water • Drain • 2 min. condensation • 3 min. drying	• Place the ATMOS Scope on the silicone bubble mat and secure the hose in place at a minimum of two points. • Select a suitable program for cleaning and disinfection with the adjacent parameters. • Washer-disinfector: in accordance with EN ISO 15883-4.

Comments:	The specified temperatures and times refer to the water supply and the nominal value of the washer-disinfector. Temperature of cold drinking water: 10-25 °C and of cold deionized water: 10-25 °C.
Checking and care:	• Check whether the sterilization was successful with a suitable light magnifier. The ATMOS Scope must be free of particles and organic material.

5.3.8 Sterilization with STERIS® SYSTEM 1E

☞ This wet chemical sterilization process is a “just-in time” process.

⚠ WARNING

The STERIS® SYSTEM 1E system is allowed only for chemical liquid sterilization of cleaned, immersible and reusable semi-critical, heat-sensitive medical products like the ATMOS Scope. Please observe the STERIS® SYSTEM 1E operating instructions and use compatible STERIS® trays. You can find information on the STERIS® SYSTEM 1E device on the website of STERIS®.

Do not by any means use the pressure compensation attachment for the STERIS® SYSTEM 1E process! With the pressure compensation attachment screwed on, liquid would enter the ATMOS Scope and destroy the inner components during the process with the STERIS® SYSTEM 1E.

Inserting the ATMOS Scope in the STERIS® tray	Insert the device in one of the following STERIS® trays: • C1200E General Processing Container/Tray • C1220E Directed Flow Processing Container/Tray • C1140E Flexible Endoscope Processing Container/Tray • C1160E Universal Flexible Processing Tray
STERIS® SYSTEM 1E process	Follow the instructions in the STERIS® SYSTEM 1E operating instructions.
Visual inspection	Repeat the manual sterilization if there is any visible dirt on the device.
Drying	To dry the ATMOS Scope, lay it on a lint-free cloth in a clean environment and cover it with a soft cloth. The ATMOS Scope must be dried completely before using, storing or re-sterilizing it.

5.3.9 Low-temperature plasma sterilization STERIS® V_PRO™

☞ The product must not be autoclaved.

Prior to sterilization, make sure 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 28.

Make sure the sterilizing agent reaches all surfaces. The implementation of the mentioned sterilization processes with respect to achieving the desired or required sterilization effect is the responsibility of the user.

☞ Observe the operating instructions for your sterilizer.

⚠ WARNING

Important! Before the sterilization process, place the pressure compensation attachment onto the valve of the endoscope (see chapter “1.7 Attaching the pressure compensation attachment” on page 16) and document the sterilization cycle by means of the serial number on the deflection lever. ATMOS recommend maintenance of the ATMOS Scope after 99 sterilization cycles (see chapter “6 Maintenance and service” on page 52).

The ATMOS Scope with the pressure compensation attachment should be placed on a sterilization mat in a STERIS® sterilization tray and packed with H600 OneStep Wrap in accordance with the operating instructions for the V-PRO low-temperature sterilization systems.

After the sterilization process and directly before using the device on the patient, the pressure compensation attachment must be removed from the valve of the endoscope (see chapter “1.8 Removing the pressure compensation attachment” on page 18) and a functional inspection conducted in accordance with chapter “3.6 Checks and tests” on page 28.

Validated V-PRO low-temperature plasma sterilization cycles:

Sterilizer/cycle	Lumen	Non lumen	Flexible	Fast non lumen	Fast
V-PRO® maX	x	√	√		
V-PRO® maX2	x	√**	√	√	
V-PRO® 60	x	√	√*		
V-PRO® s2	x	√	√		√

√	Compatible cycles	x	Not compatible
√*	Material compatibility verified	√**	Effectiveness verified

5.3.10 Storage after sterilization

Make sure the environment is safe, clean and dust free.



After the sterilization process, the ATMOS Scope and its accessories must be transported and stored separately from contaminated devices. Contamination of the re-sterilized endoscope or accessories could pose a risk of infection to the patient and/or user.



Do not bend the insertion tube of the ATMOS Scope with a diameter of less than 20 cm. The endoscope can become damaged by inappropriate storage.



To store the ATMOS Scope, it must be completely dry and protected against contamination.

The ATMOS Scope can be stored in a suspended as well as lying position, such as:

- In an endoscope cabinet (contamination-protected storage without drying function and without standardized ambient conditions),
- In closed tray and box systems,
- In a storage cabinet and storage systems with or without drying function with standardized ambient conditions (DIN EN 16442).

6 Maintenance and service

Maintenance, repairs, and period tests may be carried out only 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.

ATMOS recommend assigning an authorized ATMOS service partner. This will ensure that repairs and inspections are carried out professionally, original spare parts are used and warranty claims remain unaffected.

Please observe that leaks can be caused by wear, resulting in the ingress of liquid, causing high repair costs.

6.1 Period tests

Conduct a repeated electrical safety test at least every 24 months together with the connected PC system.

6.2 Procedure for repairs and service cases

Contact your authorized ATMOS dealer to clarify the further procedure.

Please observe the following procedure when sending in your ATMOS Scope:

1. Clean and disinfect the product and accessories in accordance with the operating instructions.
2. Send in the ATMOS Scope without accessories (except for any accessories involved in the malfunction)
3. Please note that the pressure compensation adapter (REF 507.7029.0) must be screwed on for shipment.
4. Use a tightly sealable shipping bag to send in the ATMOS Scope (recommendation: the supplied infection control return bag, REF 090.0297.0).
5. Use **service shipping packaging** recommended by ATMOS to ship your ATMOS Scope. The wooden packaging of the ATMOS Scope is not suitable for shipment in a service case. In a service case, ATMOS would have to dispose it to meet the hygiene requirements.
6. Fill in the **repair data sheet** and the **decontamination certificate** included in it and place it in an envelope.
7. Affix the envelope to the outside of the packaging.
8. Send in the product to ATMOS or your dealer.

Please use the “Repair Data Sheet” form for repairs to devices or the return shipment of devices already in use:

- Germany, Austria, Switzerland: https://atmosmed.com/download_file/2795
- Other regions: https://atmosmed.com/download_file/2798

6.3 Warranty

The manufacturer grants a 24-month warranty on the working order of the product. This warranty is restricted to claims submitted in written form within the warranty period starting from the date of the invoice, if necessary with reference to repairs and specification of the invoice number.

Any legal warranty claims are not restricted by this warranty. This warranty applies only to defects based on the product design and production errors. Normal wear and tear, misuse, incorrect handling, external effects, insufficient or incorrect sterilization and defects caused by force majeure are not covered by the warranty. Any damage due to liquid entering the device is excluded from warranty claims, due to omission of the prescribed leakage test. You can find further information in our general terms and conditions of business.

No liability claims arising from incorrect usage or usage in combination with other devices or accessories can be made.

No warranty claims shall be accepted if the users themselves or an unauthorized repair centre perform repair work on or alterations to the product.

If a product requires maintenance, the same shall apply to maintenance not expressly permitted.

No liability claims arising from incorrect usage or usage in combination with other devices or accessories can be made.

7 Troubleshooting

Error symptom	Possible cause	Remedy
ATMOS Scope is not recognized by the PC	Insufficient power supply via USB interface	Make sure the system requirements are met (USB 3.0), while removing any connected USB devices
	USB port has switched off	The USB port must be permanently switched on by means of the power settings in Windows
	ATMOS Scope is defective	See chapter “6.2 Procedure for repairs and service cases” on page 52.

No image on the PC	Insufficient power supply via USB interface	Make sure the system requirements are met (USB 3.0), while removing any connected USB devices
	The ATMOS Scope is not identified by the USB interface. The USB interface may have been switched off	Switch on the USB interface permanently via Windows / Control Panel / Power Settings
	Camera USB driver is not installed on the PC	Install the current version of the ATMOS Capture Suite software (installs all software components required for operation)
Image “freezes” (no live video)	“Buffer overflow”	Disconnect the ATMOS Scope from the PC (pull the USB plug) and re-connect it
Poor colour reproduction	Screen not set correctly	Check the screen settings
Colour bands on the screen	ATMOS Scope is defective	See chapter “6.2 Procedure for repairs and service cases” on page 52.

Cloudy image	Glass surfaces dirty	Clean the glass surfaces in accordance with chapter “5.3 Sterilizing surfaces” on page 38
	Leaky, defective lens system	See chapter “6.2 Procedure for repairs and service cases” on page 52.
Image too dark; insufficient illumination	Glass surfaces dirty	Remove any residue in accordance with chapter “5.3 Sterilizing surfaces” on page 38 and check the water quality
	Stubborn residue on the glass surfaces	Clean again, rub thoroughly if necessary
	Brightness is set incorrectly	Set the brightness in the software
	LED defective	See chapter “6.2 Procedure for repairs and service cases” on page 52.
Leakiness	Leakage tester is connected incorrectly	Check the connections between the pressure compensation attachment, leakage tester hose and leakage tester
	Insertion tube defective	See chapter “6.2 Procedure for repairs and service cases” on page 52.

Moisture on USB connector	Protection cap not on USB connector	Slip the protection cap firmly onto the USB connector
Deflection lever hard to move, not working	Defective tip mechanism	See chapter “6.2 Procedure for repairs and service cases” on page 52.
Corrosion, staining, discolouring	Inadequate cleaning (e.g. protein residue)	Clean again and rub thoroughly if necessary
	Insufficient rinsing of the endoscope between the sterilization steps (especially before the sterilization process)	Ensure sufficient rinsing between the sterilization phases
	Disinfectant and cleaning solutions contaminated or used too frequently	Replace disinfectants and cleaning solutions regularly
	Extraneous rust (e.g. from rusty steam or sterilization together with pre-damaged or non-stainless instruments)	Check supply systems; ensure material compatibility during common sterilization, pay attention to prior damage and avoid mutual contact

7.1 Error message from the firmware



Error code	Description
0xF0000000	Unspecified error during processing
0xF0000001	Error on the status display
0xF0000002	Error in the USB module
0xF0000003	General error in the camera module
0xF0000004	Error in the camera interface
0xF0000005	Faulty sensor connection

7.2 Warning messages from the firmware



The following modules may generate warning messages:

Module	Restrictions
Status indicator	Unspecified error during processing
Integrated LED lighting	The integrated LED lighting is not working or is working only to a limited extent.
USB transmission	Reliable USB transmission is not possible or no enumeration could be performed.
Settings	No setting data are present or they were faulty. Under certain circumstances, adjustable components (e.g. auto standby) may work again according to the default factory settings. In addition, the calibration for the image may be faulty or not available, and the colours etc. in the image will not be displayed correctly.

The warning message can be closed by pressing one of the two buttons on the device.

8 Accessories

Accessories	REF
ATMOS Capture Suite HD licence dongle	700.0047.0
ATMOS Controller for visualization	507.6200.0
ATMOS Medical Monitor 21.5" Touch	507.3128.0

9 Disposal

Packaging

1. Submit the product packing to recycling.

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

In principle, the housing is fully recyclable. Nevertheless, always observe the national laws and regulations.

9.1 Expected service life

If the ATMOS Scope device is used according to the operating instructions, it will have an expected service life of five years. Regular, thorough cleaning and disinfection of the device and its applied parts as well as the operation of the device in line with the operating instructions are assumed.

10 Technical data

Voltage	5 V⎓ (USB 3.0)
Current consumption	Max. 0.73A (USB 3.0; 5 V≈)
Power consumption	Max. 3.65 W
Other power sources	None
Operating mode	Continuous operation
Protective earth conductor resistance Earth leakage current Housing leakage current Patient leakage current	N/a N/a N/a N/a
Ambient conditions for transport/storage • Temperature • Humidity without condensation • Air pressure	 -30...+50 °C 5...90% 700...1060 hPa

Ambient conditions for operation • Temperature • Humidity without condensation • Air pressure	 +10...+32 °C 20...80% 700...1060 hPa
Maximum operating altitude	3000 m (NN)
Contamination level	2
Overvoltage category	I
Dimensions (H x W x D)	189 x 445 x 40 mm
Dimensions of the distal tube	Length: 300 mm; Ø: 3.9 mm
Weight	0.4 kg
Period tests	Follow the instructions for the individual components
Protection class (EN 60601-1)	II
Classification of applied part	Type-BF applied part 
Type of protection	IP68
CE mark	CE
Article number (REF)	507.7000.0

11 Notes on EMC

☞ Electric medical devices are subject to special precautions with regard to EMC and must be installed according to the EMC instructions described in the following.

Guidelines and manufacturer's declaration – Ambient conditions

The ATMOS Scope is suitable for use in the following environments:

- Environment in professional healthcare facilities such as physicians' practices, clinics or first-aid facilities as well as operating theatres and outside the RF-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.

Guidelines and manufacturer's declaration – Key features

☞ Observe the respective technical data in this manual. The essential key features are fully usable even in the presence of electromagnetic disturbances.

Guidelines and manufacturer's declaration – Removable components that can be replaced by the operating company

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

Guidelines 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, resulting 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, this could result in degradation of the key features of the device.

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

12 Notes



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