ATMOS MedizinTechnik

English

Operating Instructions

ATMOS® Scope
ATMOS® Scope Basic

CE

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Content

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

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1.0 Introduction

1.1 Notes on Operating Instructions

These operating instructions contain important notes on how to operate the ATMOS® Scope, correctly and effectively. Their reading helps to avoid risks, and also to avoid repair costs and down-times. This increases also the reliability and service-life of your device.

These operating instructions serve not only for new operating personnel to be instructed in its use, but also for use as a reference manual. This document may only be reprinted, either in part or in whole, with written permission from ATMOS.

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

Care and period tests in conjunction with professional execution provide for operational safety and readiness for use of your ATMOS® Scope and are therefore a must besides regular cleaning.

Repair work and period tests may be carried out only by expert personnel authorised by ATMOS. By applying only original spare parts you will have the guarantee that operational safety, readiness for work and the value of your ATMOS® Scope will be preserved.

- The product ATMOS® Scope bears CE marking CE according to the EC Directive of the council for medical products 93/42/EEC and meets the basic requirements of Appendix I of the directive.
- The product ATMOS® Scope complies with all applicable requirements of the Directive 2011/65/EC restricting 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 obtained on our website at www.atmosmed.com.
- The quality management system applied at ATMOS has been certified according to international standards EN ISO 13485.
- Prior to start-up please peruse chapter 2.0 „For your safety“, in order to be prepared for any possible dangerous situations.

These operating instructions are valid for the following devices:

- ATMOS® Scope REF 950.0300.0
- ATMOS® Scope Basic REF 950.0330.0

1.2 Intended use

Name	ATMOS® Scope / ATMOS® Scope Basic
Main function	During an endoscopy procedure the use of the ATMOS® Scope / ATMOS® Scope Basic is indicated for the temporary application in the oral cavity up to the throat and in the nasal cavity. It enables the visualization of body orifices and body cavities.
Medical indications/application	For the endoscopic visualisation and diagnosis in the mouth and the nasal cavities and in the upper airway anatomy and in the auditory canal with the eardrums.
Specification of the main function	With the all-in-one handle solutions and with the innovative chip-on-tip technology, the integrated camera and integrated LED light source makes endoscopy and stroboscopy possible: • Bright homogeneous illumination • 1/18” CMOS image sensor with a high resolution of 328 x 250 • Optical angle 85° • Distal outer diameter 3.8 mm • Working length 300 mm • Angulation angle 2 x 160° • 100% waterproof
Application organ	Nasal and oral cavities to the larynx, auditory canal to the ear drums
Application time	Temporary
Area of application	In clinics and practices for ENT doctors
Contraindications	The use of CMOS-Video-Nasopharyngoscope is contraindicated if endoscopic applications are contraindicated for any reason.
The product is:	Active
Sterility	Not sterile
Single-use product/re-sterilisation	Reprocessing is possible

1.3 Function

The flexible nasopharyngoscope with integrated camera and LED light source combines the following components in the handle:

- LED light source
- Microphone pre-amplifier and removable microphone (optional)
- Camera electronics
- Mechanics for controlling the angle

Thanks to optimised video pre-settings, camera setting and white balance are no longer required. The device automatically switches to the desired stroboscopy mode.

The handle provides the following keys:

- Start-stop for video recording
- Single image storage is possible in connection with the ATMOSoft / ATMOS® Capture Suite

1.4 Explanation of symbols

Short cuts / symbols contained in these operating instructions

Follow the arrows

Please press where dot indicates

Please read, important information

■ General information

● Numeration

→ Sub-numeration

Check

Move, plug... in this direction

Turn, shift... in this direction

Replace

click — Engage, check correct fit

Graphic symbols contained in these operating instructions

Warning; take extra care to observe

☞ Important information

Professional disposal

Symbols of ATMOS® Scope

SN	Serial number
REF	Order number
	Manufacturing date
	Manufacturer
+158°F +70°C / +68°F -20°C	Indicates the tolerable temperature
95% / 5%	Indicates the tolerable air humidity
106 kPa / 70kPa	Indicates the tolerable air pressure
CE	This product complies with the relevant requirements of the EU Directives.
	2nd-edition IEC 60601-1: Caution, observe accompanying documents 3rd-Edition IEC 60601-1: Caution
	Follow operating instructions
	Application part type BF acc. to EN 60601-1
Rx Only	The US Federal Law restricts this product to sale by or on the order of a physician
Latex	Indication that the product does not contain natural rubber latex
MR	Magnetic resonance unsafe
	Fuse
NON STERILE	Sterilize prior to each use

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).

ATMOS® Scope Basic: ATMOS® Scope handle, controller, leakage tester, pressure compensation cap, BNC video cable (2 pcs), silicone hose, power cable, BNC cinch adapter (2 pcs), USB 2.0 cable, remote cable for ATMOSoft / ATMOS® Capture Suite, ATMOSoft / ATMOS® Capture Suite demo CD, operating instructions.

ATMOS® Scope: ATMOS® Scope handle, controller, leakage tester, pressure compensation cap, microphone, stroboscope cable, BNC video cable (2 pcs), silicone hose, power cable, BNC cinch adapter (2 pcs), USB 2.0 cable, remote cable for ATMOSoft / ATMOS® Capture Suite, ATMOSoft / ATMOS® Capture Suite demo CD, transport case, operating instructions.

2.0 For your safety

For your safety

- The product may only be used observing the guidelines of this IFU. If instructions, warnings and precautions are not observed, this may lead to risks and serious consequences during use. Check and guarantee unrestricted function, completeness and integrity of the product and/or accessories before use.
- The system may only be operated with the delivered cables. Make sure that all devices operated nearby comply with the relevant EMC requirements. The image quality could be affected by the electromagnetic emissions of peripheral equipment (e. g. monitor, video equipment) which is connected.
  In case of extreme electromagnetic interferences, the image quality may be influenced (e. g. slight stripes, colour changes on the monitor).
- **Use in combination with MR**
  The product is MR unsafe - in areas with magnetic resonance imaging, the product is unsafe.
- To separate the device completely from the mains power supply, pull the plug out of the mains socket at the external power.
- The plug cap must be removed from the plug during storage and transport. Otherwise, under certain circumstances, an overpressure could occur within the connection cable and could damage the cable.
- When placing the product into the transport case, be careful that no parts are pinched or clamped when closing the lid. Otherwise the product could be damaged.
- Do not use the transport case for long-time storage.
- Accessories and/or peripheral devices, which are connected to the interfaces of the product must comply verifiably to the relevant normative specifications (e. g. IEC 60601-1). Furthermore, all configurations of the system standard IEC 60601-1-1 have to be fulfilled.
- **Unsterile parts – danger of infection**
  Parts, which are delivered unsterile, have to be processed before use.
- Improper use and maintenance, as well as application in deviance to its intended use may lead to risks for patient and user or early wear and tear of the product.
- Endoscopic procedures may only be carried out by specialists who have corresponding training, knowledge and experience.
- The product is susceptible in regard to bending, heavy kinking, torsion, tension or pressure load. This may damage the optical components and thus lead to operating failure.
- Only operate the product within the specified operating temperature range.
- Image interferences, image breakdown or breakdown of the integrated light source could lead to risks.
  ↳ In this case, release deflection lever and carefully withdraw the ATMOS® Scope.
- Do not look directly into the light emission at the distal end of the endoscope. This can lead to eye injury.
- Each light source can become warm due to absorption and therefore damage to the biological tissue could occur. Please make sure to reduce duration of use to a minimum, to switch off the light source when not in use and to check heat development if necessary.
- The ATMOS® Scope may be operated only in rooms used for medical purposes, but not in areas subject to explosion hazards and in oxygen rich environments.

2.1 Instructions for combination with other medical products

- **Multiplication of leakage current - risk for patients**
  If the product is used with electro medical devices and/ or power driven endoscopic accessories, the leakage currents could multiplicate. Check external electrical devices before use.
- If the product or endoscopic accessories are used with products of different manufacturers and in combination with medical electrical products, ensure that the BF conditions (insulated, earth-free application part) are fulfilled.
- Ensure that the corresponding interconnection conditions are kept. Also, the relevant standard and the respective national tolerances must be followed.

3.0 Setting up and starting up

3.1 Overview

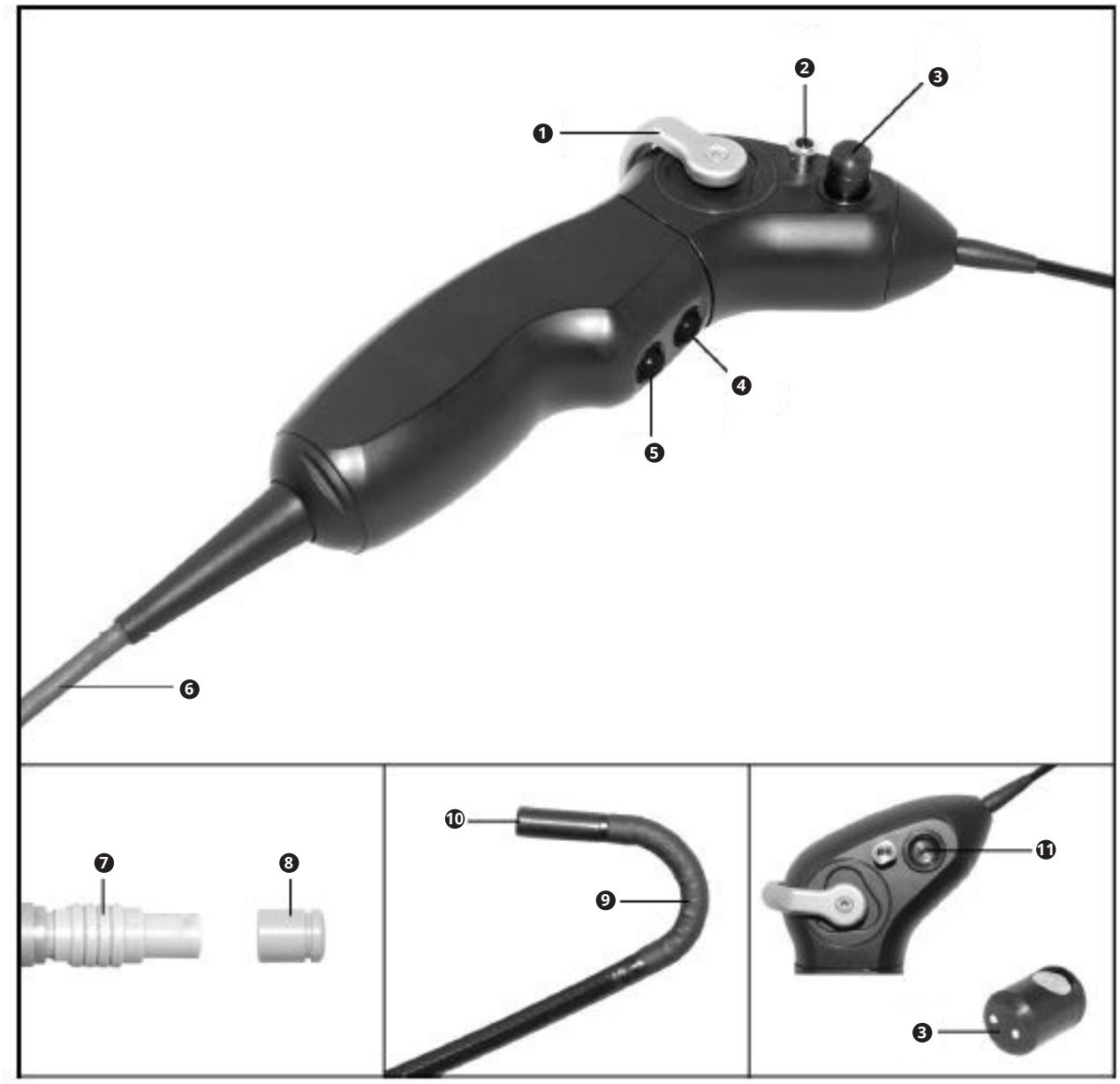


Fig. 1

1. Deflection lever
2. Pressure compensation valve with dust protection cap
3. Microphone (optional)
4. Button A
5. Button B
6. Connection cable
7. Plug
8. Plug cap
9. Deflectable tip
10. Tip cover glass
11. Microphone interface

3.2 Front view ATMOS® Scope controller

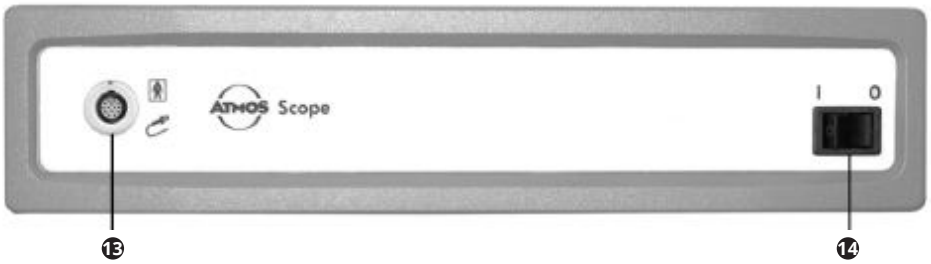


Fig. 2

⓭ Socket for connection cable ❻
⓮ ON/OFF switch

3.3 Rear view ATMOS® Scope controller

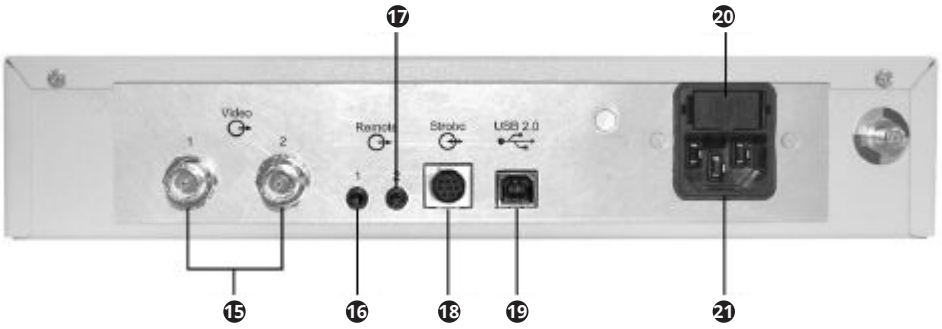


Fig. 3

⓯ BNC video outputs (composite/CVBS signal)
⓰ 3.5 mm jack plug (Remote 1 signal)
⓱ 3.5 mm jack plug (Remote 2 signal)
⓲ Plug for stroboscope cable
⓳ USB 2.0
⓴ Fuse holder with fuses
㉑ Mains connection

3.4 Overview cables

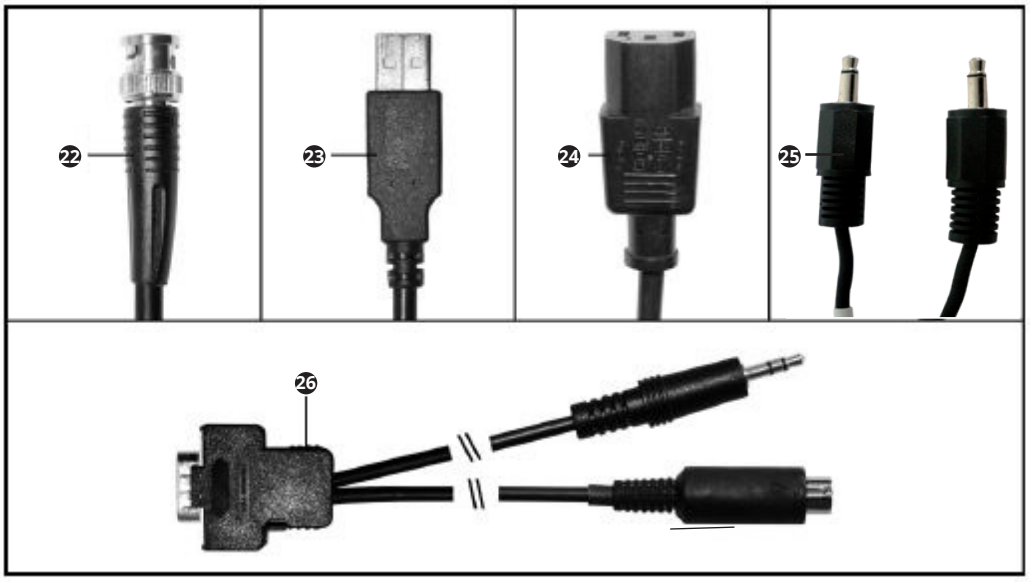


Fig. 4

- 22 BNC video cable
- 23 USB 2.0 cable
- 24 Power cable
- 25 Remote cable
- 26 Stroboscope cable (optional)

3.5 Leakage tester and hose

Fig. 5

- 27 Leakage tester
- 28 Silicone hose
- 29 Pressure compensation cap
- 30 Pressure release valve

3.6 Assembly/First Installation

3.6.1 Required additional devices

- Monitor according to the medical device directive 93/42/EEC.

3.6.2 Installation at the place of operation

Connecting the controller to the mains supply

⚠ Ensure that the correct power cable is used for the respective country.

- Connect power cable ㉔ with power connection ㉑ at the controller.
- Plug the power cable ㉔ into a mains socket and thus connect the system to the mains supply.

Connecting the monitor

- Connect BNC video cable ㉒ with the BNC video output ⑮ of the controller and composite/CVBS input of the monitor.

Connecting the PC (optional)

The PC has to conform to the medical device directive 93/42/EEC.

Installing the USB Driver on the PC

- Connect the ATMOS® Scope to the PC using the USB 2.0 connection cable ㉓.
- Install the driver from the enclosed CD
  ↳ After the installation is completed the ATMOS® Scope will appear as a "USB 2820 Device" in the Device Manager.
- Remove software CD from the drive.
- Restart the PC.

PC minimum requirements depend on the used software.

- Follow instructions on the software CD.

Recommendation when using the software on a PC and the availability of a medical grade monitor:

As an alternative to directly connecting the monitor via the BNC video output (composite/CVBS signal) ⑮, it is recommended to connect the medical grade monitor directly to the PC via the PC's external VGA output. The prerequisites for this are proper connectors on the PC and monitor, as well as the proper connection cables (not included).

Connect stroboscope ATMOS® Strobo 21 LED (optional)

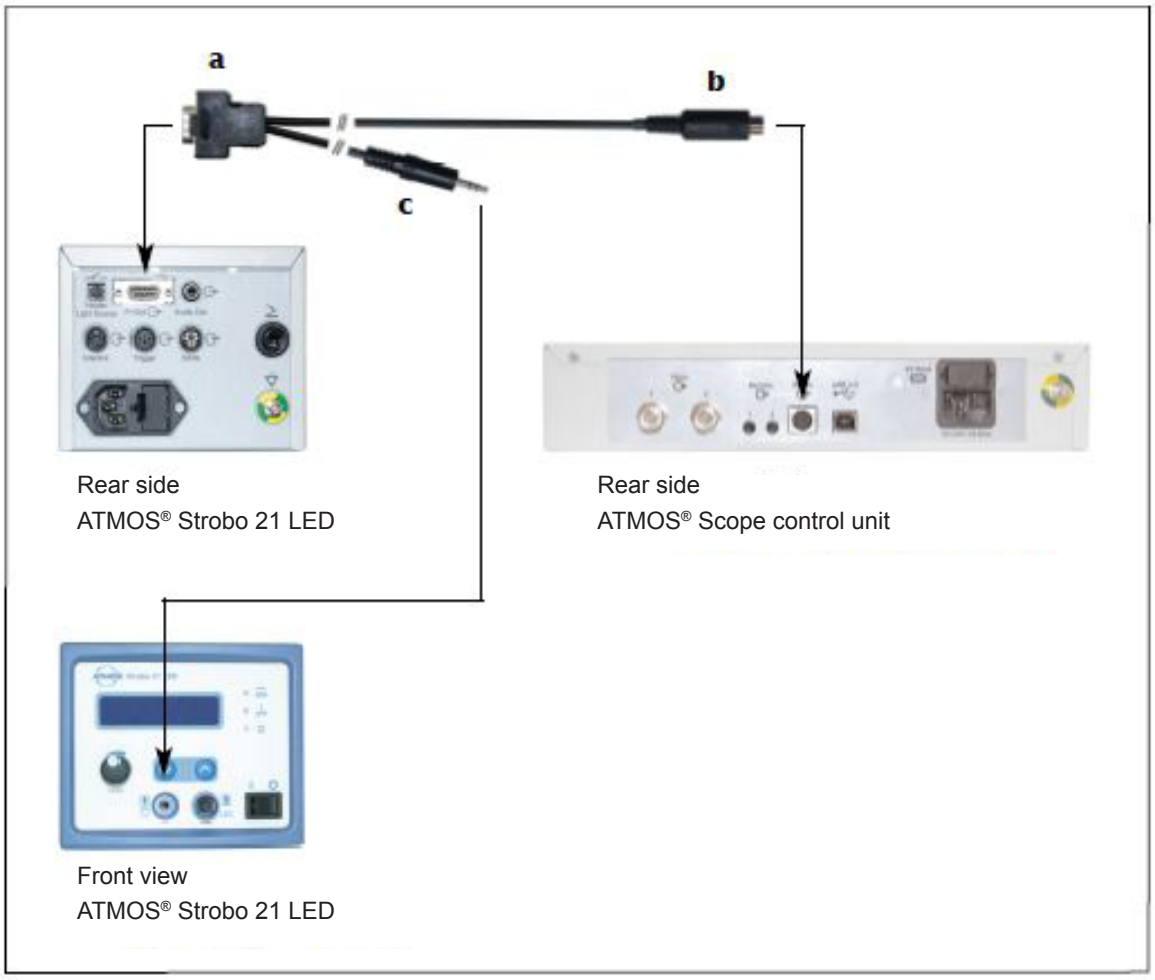


Fig. 15

- Connect ATMOS® Strobo 21 LED with stroboscope cable ㉖ to the ATMOS® Scope controller: Connect plug (a) with "optional connection for ATMOS® Strobo 21 LED and EndoStroboscope L (F-Out)" at the rear side of the Stroboscope. Connect plug (c) with "connection for microphone" at the front side of the stroboscope. Connect plug (b) with connection for stroboscope cable ⑱ at the controller of the ATMOS® Scope.
- For further details, refer to ATMOS® Strobo 21 LED operating instructions.

Connecting the ATMOS® Scope

- Connect the ATMOS® Scope handle with the controller, plugging the plug of connection cable ❻ into the socket for connection cable ⑱.

Application with the ATMOSoft / ATMOS® Capture Suite

The ATMOSoft / ATMOS® Capture Suite has separate operating instructions.

Please note:

Read these separate operating instructions very carefully.

3.7 Tests

Depending on the working distance (see technical data) the endoscopy image must be high-resolving, bright and clear.
The following test sequence must be conducted on the device before processing and immediately before application.

Testing the glass surfaces

- Visual inspection of the glass surfaces. The surfaces must be clean and smooth.
- If damages are discovered during inspection please see chapter Troubleshooting.

Leakage test

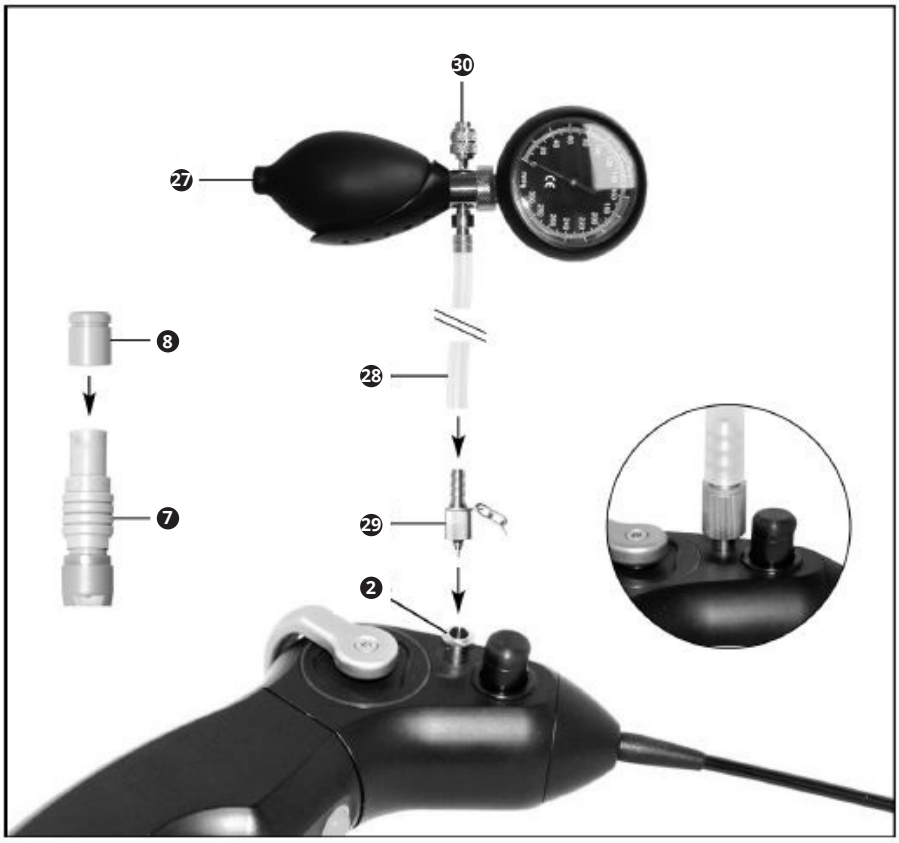


Fig. 17

- Connect plug cap ❽ onto plug ❼.
- Close pressure release valve ㉚ on the leakage tester ㉗.
- Remove dust protection cap from pressure compensation valve ❷.
- Screw on pressure compensation cap ㉙ to pressure compensation valve ❷.
- Connect silicone hose ㉘ with pressure compensation cap ㉙ and leakage tester ㉗.
- Pump up the system to a pressure of 300 mmHg.
- Wait for 30 seconds. By pressing the pressure release valve ㉚, drop the pressure to 160 mmHg.
- Wait 30 seconds and watch the pressure. The pressure must not drop down by more than 2 mmHg. If the pressure drops more than 2 mmHg, then the system has a leak and needs to be serviced.

⚠ After the leakage test, remove pressure compensation cap ㉙. Refasten dust protection cap.
The leakage test must be performed after each application.

3.0 Setting up and starting up

Testing the deflection mechanism

- Slowly operate the deflection lever ❶ (Fig. 1), to check the function.
- Check if full deflection is achieved (see chapter Technical Data).

⚠ Limitations in deflection can indicate an endoscope defect. To avoid serious damage to the endoscope, only use the endoscope if the deflection works smoothly and without limitation.

⚠ **Risk for patients**

Risk for patients due to the use of products with sharp edges or damaged surfaces.

- Do not use these products.

⚠ **Damaged products**

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

Send damaged products to the manufacturer or authorized repair centre. Authorized repair centres can be inquired from the manufacturer.

4.1 Use/Operation

Handle the system very carefully, as it contains sensible optical, mechanical and electronic components. Do not bump the distal end on hard surfaces.

⚠ Do not jolt or drop the ATMOS® Scope, protect it from shocks and impacts.

Do not bend or kink the flexible endoscope part, nor tear or squeeze it. The outer coating and inner components could be damaged.

Never move the tip of the flexible endoscope against a resistance. The tip contains optical components, which may scratch or break when used incorrectly.

4.1.1 Switching on and adjusting the system

⚠ Proper system operation cannot be guaranteed if the controller is switched on before the ATMOS® Scope handle is connected.

- Ensure, that the ATMOS® Scope is connected to the controller before switching on the system.

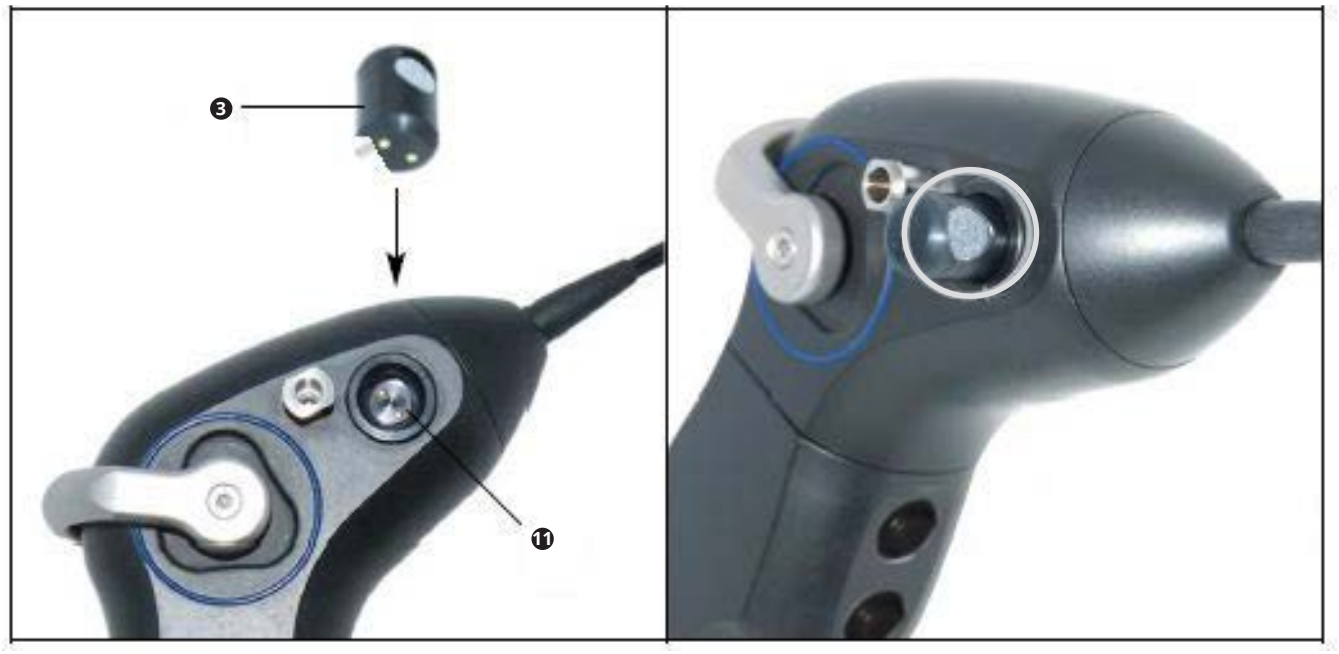


Fig. 17

- Plug the microphone ❸ into the microphone interface ⓫ of the ATMOS® Scope handle. Magnets inside the microphone automatically orientate the microphone ❸ to face in the direction of the flexible endoscope part.
- Switch on controller with the ON/OFF switch ⓮. Switch on all additional devices.
- Switch on the monitor in the order to receive the signal from the controller.
- The tip can be moved in two directions with the deflection lever ❶. Please do not press the deflection lever with violence.
- Switch off controller with the ON/OFF switch ⓮ after use.

4.1.2 Controller fine adjustment

Generally the product does not need to be configured. However the user has the option to make fine adjustments.

- Turn the controller off by pressing the ON/OFF switch ⓮.
- Press and hold either button A ❹ or B ❺ and turn controller ON. The Set-up menu will appear on the monitor.
- Release button A ❹ or B ❺.
- By pressing button A ❹, the various setting options can be selected.
- By pressing button B ❺ the selected function can be activated.
- When all the settings are accepted, please select "exit and save" with the button A ❹ and confirm with button B ❺.
- The settings menu is then hidden.

SET-UP menu options

"SHOW/HIDE FREQUENCY”	Show or hide the stroboscopy frequency on the monitor
“STROBOFUNCTION MANUAL/ AUTO”	**Manual Mode:** The stroboscopy function is activated by operating the foot switch. If the stroboscope is not yet synchronized with the voice frequency, minimal image inference may occur. **Automatic Mode:** The stroboscopy function begins once the system is synchronized with the voice frequency.
"SWITCH FUNCTIONS"	Assigns different functions to buttons.
“COLOUR-SATURATION”	Adjusts the colour saturation of the images in 5 steps
“FACTORY RESET”	Returns the settings back to the factory values
“EXIT”	Closes the menu and returns to live image without saving the settings
“SAVE AND EXIT”	Saves the new settings, closes the menu and returns to the live image

4.1.3 Functions of the buttons with ATMOSoft / ATMOS® Capture Suite

The ATMOSoft / ATMOS® Capture Suite has separate operating instructions.

Both cables must be plugged in (see diagram). The Remote 1 in the Remote 1 and Remote 2 in Remote 2.

Button A: Remote 1

Button B Remote 2

Control box for connecting the ATMOS® Scope with the computer (USB connection)

Photo mode: Taking photo.

Video mode: Start and end recording.

Photo mode: Switch to the next storage space. This function must be activated in the software.

Video mode: Pause and continue recording.

4.2 Disassembly

- Remove the microphone from the microphone interface ⓫ and clean the ATMOS® Scope (see chapter Cleaning and Disinfection).
- Disconnect connection cable ❻ from the controller. Tightly fix plug cap ❽.

5.0 Cleaning and care

5.1 General instructions

Adhere to national legal regulations, national and international standards and regulations as well as internal hygiene regulations for reprocessing.

Reprocessing has to be carried out according to the manufacturer's rules and instructions. Only use recommended agents and procedures. Prior to each reprocessing a leakage test must be performed to prevent the endoscope from damage by liquids.

Mechanical processing provides better and safer results and should therefore be preferred to manual cleaning.

Successful processing of this medical product can only be ensured if processing is performed through a validated processing procedure. The user/processor is responsible for the validation.

To prevent contamination of a loaded instrument tray during the procedure, do not put contaminated instruments back onto the tray, but collect them separately.

Encrusted or fixated residues from surgery can make the cleaning process more difficult or ineffective, and can cause corrosion of the stainless steel. To avoid this, the time interval between procedure and processing must not exceed 6 h. Furthermore do not use any pre-cleaning temperature >45 °C or cleaning or disinfection agents (active ingredients: aldehyde, alcohol) which could fixate the residues even further.

Excessive doses of neutralizers or basic detergents can cause chemical degradation and/or fading of laser inscriptions on stainless steel surfaces.

Residues containing chlorine or chlorides e.g. in surgical residues, medicines, saline solutions and in the industrial water used for cleaning, disinfecting and sterilization will cause corrosion damage (pitting, stress corrosion) and result in the destruction of stainless steel products. To remove such residues, the products must be rinsed sufficiently with fully desalinated water and dried thoroughly.

Only use process chemicals that have been tested and approved (e.g. VAH/DGHM or FDA approval or CE mark) and which are compatible with the product's materials according to the chemical manufacturers' recommendations. All process parameters specified by the chemical's manufacturer, such as temperature, concentration and exposure times, must be strictly observed. Failure to do so could result in the following problems:

- Optical deterioration of materials, e.g. fading or discolouration of titanium or aluminium surfaces. Visible surface changes could occur for aluminium, with a pH > 8 in the application/process solution.
- Material damage, e.g. corrosion, cracks, breakage, premature aging or swelling.

Clean product directly after use.

Further detailed information for hygienically safe and gentle cleansing/reprocessing can be found under: www.a-k-i.org.

Preparation at the place of use

- If applicable, remove adapters and sealing cap (e. g. Luer Lock).
- If applicable, open valves/taps.
- Put the dry product into a closed disposal container and have it transferred to cleaning and disinfection within 6 h.

5.0 Cleaning and care

Cleaning/Disinfection

⚠ The product should not be cleaned and/or disinfected in an ultrasonic bath.

Conduct a leakage test before soaking the product in any liquids (see chapter Tests).

A leaking device can be damaged by ingress of liquids.

- Before cleaning, put plug cap ❽ onto plug ❼.
- Ensure that the plug cap ❽ is firmly connected to the plug ❼.

Only use detergents and disinfectants which are approved for the product. Observe manufacturer's instructions. Observe the concentration, temperature, duration of use and contact time according to manufacturer's instructions.

Avoid excessive pressure and tension onto the flexible videoscope components.

Please clean carefully to prevent the device from damage. Hose and bendable end can be damaged by bending, twisting, pushing or pulling. Coarse contaminations can be removed with a soft cloth or a soft brush.

Do not exceed a bending radius of 40 mm during reprocessing.

5.2 Manual cleaning and disinfection

5.2.1 Cleaning and disinfection: Controller and microphone

⚠ Controller and microphone should only be wiped off with a moist cloth. Do not immerse the controller and microphone in liquids.

- Wipe off the outer surfaces of the controller with a soft cloth, moistened with water, a mild soap solution or isopropanol.
- Stains, which are difficult to remove, can be removed with a mild cleaning agent on ammoniac basis.
- Do not use scrubbing agents or dissolvers, as these may damage the coating or labels.
- Do not use wet sponges or cloths. Excessive cleaning agents could come into contact with electrical parts and could damage the unit.
- Only reconnect the system to the mains supply when all cleaned parts are completely dry.

5.2.2 Cleaning and disinfection: ATMOS® Scope handle with flexible endoscope part

Manual cleaning with Tristel Wipes System

Please follow the manufacturer's information and operating instructions.

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

Optical surfaces should not be cleaned with a brush. Remove residues on optical surfaces with a pad moistened with alcohol (70 % ethanol) or neutral cleaning agent.

Manual cleaning with immersion disinfection and cleaning with a brush

Phase	Step	T (°C/°F)	t (min)	Conc. (%)	Water quality	Chemistry
I	Cleaning	34-45/ 95-113	3	0.8	D-W	Enzymatic cleaning agent, e.g. Cidezyme/Enzol
II	Intermediate rinsing	RT (cold)	3 x 1	---	D-W	---
III	Disinfection	20-25/ 68-77	12	---	D-W	0.55 % orthophtalaldehyde solution, e.g. Cidex OPA
IV	Final rinsing	RT (cold)	3 x 2	---	VE-W sterile	---
V	Drying	RT	---	---	---	---

D-W Drinking water
RT Room temperature
VE-W Purified water (demineralized, low germs, maximum 10 germs/ml and endotoxin-poor, maximum 0.25 endotoxin units/ml)

5.0 Cleaning and care

Stage I

- Fully immerse the product in the cleaning solution. Ensure that all accessible surfaces are moistened.
- Clean the product while it is in the cleaning solution, using a soft cloth or a suitable cleaning brush, until all visible residues have been removed from the surfaces.
- Brush all surfaces which are not accessible to visual inspection, such as hidden crevices, lumens or complex geometry for at least 1 minute until no more residues can be removed. During cleaning mobilize non-fixed components, such as set screws, joints, lever etc. 3 times in each direction as far as possible.
- Thoroughly rinse these components with the cleaning solution (at least 5 times), using a disposable syringe (20 ml).
- Do not use metal cleaning brushes or other abrasives which could damage the product surfaces and could cause corrosion.

Stage II

- Thoroughly rinse the product 3 times (all accessible surfaces) for at least 1 minute. Mobilize non-fixed components, such as set screws, joints, lever, etc. 3 times in each direction as far as possible. Use fresh water for each rinsing cycle.
- Thoroughly rinse all surfaces which are not accessible to visual inspection, such as hidden crevices, lumens (e. g. working channel) or complex geometry with a disposable syringe (20 ml) for at least 5 times.
- Allow water to drip off for a sufficient length of time.

Stage III

- Fully immerse the product in the disinfecting solution. Ensure that all accessible surfaces are moistened.
- Mobilize non-fixed components, such as set screws, joints, lever, etc. 3 times in each direction as far as possible.
- Thoroughly rinse all surfaces which are not accessible to visual inspection, such as hidden crevices, lumens (e. g. working channel) or complex geometry with a disposable syringe (20 ml) for at least 5 times.

Stage IV

- After disinfection the product should be thoroughly rinsed 3 times (all accessible surfaces) for at least 2 minutes. Mobilize non-fixed components, such as set screws, joints, lever, etc. 3 times in each direction as far as possible. Use fresh water for each rinsing cycle.
- Thoroughly rinse all surfaces which are not accessible to visual inspection, such as hidden crevices, lumens (e. g. working channel) or complex geometry with a disposable syringe (20 ml) for at least 5 times.
- Allow water to drip off for a sufficient length of time.

Phase V

- Dry the product with a soft, lint-free tissue.
- Areas, which cannot be reached with the lint-free tissue, can be dried with compressed air (p max. = 0.5 bar).

Material compatibility releases exist for:

- Gigasept FF (new)
- Helipur HplusN (B. Braun Medical AG)
- Cidex OPA (Johnson & Johnson)
- Cidezyme/Enzol (Johnson & Johnson)
- Neodisher MediClean forte (Chem. Fabrik Dr. Weigert GmbH & Co. KG)

5.3 Mechanical cleaning and disinfection

Hints for mechanical processing

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

The product is compatible with several automatic flexible endoscope reprocessors (AFER). For further details regarding the operation refer to the operating instructions of AFER.

If it is unclear whether the product and all channels can be cleaned and disinfected with the existing AFER, contact the manufacturer of the AFER, and check with the manufacturer which cleaning and disinfection programme is suitable for the product.

⚠ Risk of infection for patients and/or user due to

- residues of cleaning and disinfectants on the product.
- Insufficient cleaning, disinfection and sterilization of the product and accessories.

Depending on the degree of pollution of the product especially its working channel has to be pre-cleaned or brushed.

⚠ Product damage due to excessive temperatures.

During mechanical cleaning and disinfection the temperature should not exceed 65°C.

- Position the endoscope according to the instructions of the manufacturer in the AFER.
- Connect tube of the AFER for the leakage test to the pressure compensation valve ❷ of the ATMOS® Scope handle. If necessary, use adapters.

The validation that the product can be cleaned and disinfected has been conducted using the automatic endoscope reprocessors of Wassenburg Typ WD 440 in standard programme. Thereby the cleaning agent AdaptaClean (Johnson & Johnson) and the disinfectant Cidex OPA-C (Johnson & Johnson) have been used.

The material compatibility has been tested and guaranteed using the AFER of Wassenburg, type WD 440.

Material compatibility releases exist for:

- neodisher® MediClean forte (Dr. Weigert)
- Cidex OPA-C (Johnson & Johnson)
- AdaptaClean (Johnson & Johnson)

Colour anodized parts or plastic components (e.g. serial rings, ocular) could fade during mechanical cleaning.

5.4 Sterilization

5.4.1 General instructions

⚠ Do not autoclave the product.

Before sterilization ensure that the endoscope has no restrictions in use. See chapter Start of Operation (section Tests).

Ensure that the sterilization agent can reach all surfaces. The implementation of the sterilization lies within the responsibility of the user in order to attain the required degree of sterilization.

5.4.2 Sterilization methods

Validated method

Gas sterilization (EtO)

- Ethylene oxide (Sterivit method)

⚠ Screw on pressure compensation cap before sterilization.

Screw off pressure compensation cap after sterilization.

Validated EtO parameters

Gas mixture:	6 % EtO, 94 % CO2
Temperature:	131 °F +/- 5 °F, 55 °C +/- 2 °C
Relative air humidity:	40 - 90 %
Pressure (overpressure):	1,7 bar (170 kPa)
Exposure time:	120 min
Aeration time:	12 h at 131 °F +/-5 °F, 55 °C +/- 2 °C

Material compatibility releases exist for:

Low temperature plasma sterilization

- STERRAD® 50 (Advanced Sterilization Products)
- STERRAD® 100S (Advanced Sterilization Products)
- STERRAD® 200 (Advanced Sterilization Products)

⚠ Screw on pressure compensation cap before sterilization.

Screw off pressure compensation cap after sterilization.

Observe manufacturer's instructions for all named methods.

The use of different sterilization methods in turn can lead to a shortened lifespan of the product. Only use one of the approved methods.

5.0 Cleaning and care

Sterilization of the ATMOS® Scope with the STERRAD® sterilization method 100S

Please observe the operating instructions of the STERRAD® sterilizer and the STERRAD sterility guide from ASP.

- Clean and disinfect the ATMOS® Scope manually or mechanically.
- Allow the ATMOS® Scope to dry thoroughly before you sterilise it in the STERRAD sterilizer. Humidity can lead to a termination of the sterilisation cycle.
- Tighten the pressure compensation cap.
- Place the ATMOS® Scope in a sterilisation basket.
- Place a STERRAD® indicator strip in the basket.
- Double wrap the sterilisation basket with non-woven polypropylene.
- Position the basket as follows:
  - Sterilisation must be performed on every part.
  - No parts can touch the sterilisation wall.
- Start the sterilisation cycle according to the manufacturers instructions, e.g. STERRAD® 100S Short Cycle.
- Please ensure that the sterility is ensured after reprocessing.
- Remove the sterile goods from the sterilisation device.
- Remove the pressure compensation cap.

6.0 Maintenance and Service

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

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

Period tests

At least every 24 months a repeat test of the electrical safety should be performed according to IEC 62353.
ATMOS recommends conducting this inspection in accordance with the manufacturer‘s specifications.

Fuse exchange

- Before changing the fuse, switch off the unit and disconnect it from the power network.
- Using a small screwdriver, press the upper and lower latch toward the middle of the fuse holder ⓴.
- Pull the fuse holder straight out.
- Replace the damaged fuse(s).
- Reinsert the fuse holder.
- Make sure both latches snap back into locked position.

Sending in the device

- Remove all consumables and dispose of them properly.
- Clean and disinfect the product and accessories in accordance with the operating instructions.
- Place any used accessories with the product.
- Fill in the QD 434 “Delivery complaint/return shipment” form and the corresponding **decontamination certificate**.

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

- The device must be well padded and packed in suitable packaging.
- Place the QD 434 “Delivery complaint/return shipment” form and the corresponding **decontamination certificate** in an envelope.
- Affix the envelope to the outside of the package.
- Send the product in to ATMOS or your dealer.

Warranty

The manufacturer commits to a 24 months guarantee on the function of the product. This guarantee is restricted to claims, which are sent in written form within the guarantee period starting from the date of the invoice, resp. with reference to repairs, indicating the invoice number. Legal guarantee claims are not restricted by this warranty.

This guarantee is only applicable to defects which cannot be attributed to normal wear and tear, misuse or wrong handling, lack of proper care or force majeure.

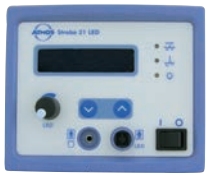
Guarantee and warranty claims will not be accepted if the user himself or a non-authorized repair centre performs maintenance or repair work. In case a product needs to be maintained the same applies for maintenances, which are not permitted explicitly.

Liability claims which arise from improper handling or combination with other devices or accessories cannot be claimed.

7.0 Troubleshooting

Problem	Possible cause	Solution
Cloudy image	Glass surfaces dirty	Clean glass surfaces according to chapter Cleaning and Disinfection
	Leaky, defective lens system	Send ATMOS® Scope in for repair
Image is too dark, insufficient illumination	Glass surfaces dirty	Clean glass surfaces according to chapter Cleaning and Disinfection
	Stubborn residue on the glass surfaces	Remove residues according to chapter Cleaning and Disinfection; check water quality
Corrosion, staining, discolouring	Inadequate cleaning (e.g. protein residue)	Clean again, resp. rub thoroughly
	Inadequate rinsing of the endoscope between re-sterilisation steps (especially before actual sterilisation)	Ensure adequate rinsing between the processing phases
	Disinfecting and cleaning solutions contaminated or used too frequently	Replace the disinfecting and cleaning solutions at regular intervals
	Extraneous rust (e.g. by rusty steam or processing with damaged or non-stainless instruments)	Check supply systems; ensure material compatibility during common processing, pay attention to existing damage and avoid mutual contact
Leakiness	Leakage tester is connected incorrectly	Check the connections of the pressure compensation cap, silicone tube and the leakage tester
	Probe tube is defective	Send ATMOS® Scope in for repair
	Plug cap is not on plug	Push plug cap tightly onto plug
Distortion is tight, defective	Defective peak mechanism	Send ATMOS® Scope in for repair
Image is blurred	Probe tip is dirty	Clean probe tip with alcohol and cotton swabs
No image on the monitor	Controller is without power	Connect controller according to chapter Assembly/First Installation and switch it on
	Fuse defect	Replace fuse (see chapter Maintenance and Repair)
	Faulty connection of the controller to the monitor	Make sure that the controller is correctly connected to the monitor
	Connection cable is defect or not connected to controller	Connect the ATMOS® Scope handle to the controller. Ensure that the plug is dry
	Monitor is not adjusted to the correct input channel	Adjust the monitor to the correct input channel
	No light at the tip of the flexible endoscope part	Make sure that the ATMOS® Scope is properly attached to the controller
No image on the monitor	Camera USB driver is not installed on the PC	Install camera USB driver via software CD
	ATMOS® Scope is not recognized by USB port. Perhaps the USB port is turned off	USB port via Windows/control panel/power settings must be permanently activated
Poor colour recording	Monitor is adjusted incorrectly	Adjust the monitor screen settings
Colour bands on monitor	Defective video cable	Replace video cable or send the endoscope system in for repair
	ATMOS® Scope is defective	Send ATMOS® Scope in for repair
Stroboscope does not react	Microphone is not connected or is connected incorrectly	Connect microphone correctly
	Microphone is defective	Replace microphone
	Stroboscope cable is connected incorrectly	Send ATMOS® Scope in for repair
		Connect stroboscope cable correctly
	Stroboscope cable is defective	Replace stroboscope cable
ATMOS® Scope is not identified by the PC	USB port has switched off	The USB port via the energy options in Windows must be permanently activated

8.0 Accessories and spare parts

Name	REF	
ATMOS® Strobo 21 LED	507.4700.0	
ATMOS® Capture Suite lite ATMOS® Capture Suite ATMOS® Capture Suite HD	700.0045.0 700.0046.0 700.0047.0	
ATMOS® Medical Monitor HD 21.5“ ATMOS® Medical Panel PC Touch 21.5“ i7	507.3115.0 507.3122.0	
Microphone	950.0310.0	
ATMOS® Scope case	950.0321.0	
Leakage tester	950.0322.0	
Controller	950.0319.0	
ATMOS® Scope handle	950.0320.0	

8.0 Accessories and spare parts

Name	REF	
Silicone hose for leakage tester	On request	
Instruction card for cleaning with pressure compensation cap	On request	
Fuse 0.63 A (T); 5 x 20 mm (2 pcs)	On request	
HF adapter	950.0323.0	
BNC-BNC.2 1.5 m	008.0670.0	
USB cable 2.0 m	950.0324.0	
Remote cable for analogue control	950.0325.0	
ATMOSoft Remote, USB ATMOS® Capture Suite remote, USB	700.0032.0 700.0051.0	
Mains supply cable	507.0859.0	
Stroboscope cable	950.0327.0	
Structure-borne sound microphone adapter	507.4775.0	

9.0 Technical data

Voltage	115-230 V~ ± 10 %; 50/60 Hz
Current consumption	Max. 0.5 A
Power consumption	30 VA
Fuses	2 x T 630 mA L / 250 V
Probe diameter	3.8 mm
Probe length	300 mm
Deflection	2 x 135°
Direction of view	0°
Opening angle	85°
Focus area	6-60 mm
Image sensor	1/18" CMOS (82.000 pixels)
Analogue TV system	NTSC
Outputs	2 x Composite video (FBAS) 1 x USB 2.0 2 x Remote 1 x Stroboscope output
Operating time	Continuous operation
Protective earth conductor resistance	Max. 0,1 Ω
Earth leakage current	Max. 0.5 mA
Housing leakage current	Max. 0.1 mA
Patient leakage current	Max. 0.1 mA
Ambient conditions for transport/storage • Temperature • Humidity without condensation • Pressure	 -20...+70 °C 5...95 % 700...1060 hPa
Ambient conditions for operation • Temperature • Humidity without condensation • Pressure	 +15...+35 °C 5...95 % 700...1060 hPa
Maximum operational altitude	≤ 3000 m (NN)
Contamination level	2
Overvoltage category	II
Dimensions HxWxD Controller	 60 x 277 x 268 mm
Weight Controller Applied part	 2.9 kg 0.4 kg
Period tests	Repeat test of the electrical safety every 24 months. Recommended: inspection according to the manufacturer‘s specifications.
Protection class (EN 60601-1)	I
Degree of protection	Application parts type BF 
Type of protection	IP X0
Classification according to Annex IX, EC Directive 93/42/EEC	Class 1
CE marking	CE
GMDN code	15967
UMDNS code	15-967
ID No. (REF)	950.0300.0

10.0 Disposal

- The ATMOS® Scope does not contain any hazardous materials.
- The housing material is fully recyclable.
- Device and accessories must be decontaminated prior to disposal.
- Pay attention to a careful separation of the different materials.
- Please observe national disposal regulations (e.g. waste incineration).

Disposal within the EC

The device described above is a high-quality medical product with a long service life. After its life cycle it must be disposed of professionally. According to the EC directives (WEEE and RoHS) the device may not be disposed of in domestic waste. Please observe existing national laws and rules for disposal of old devices in the respective country.

Disposal within the Federal Republic of Germany

In order to guarantee a proper disposal of your old device, please either pass on your old device to your specialised dealer or send it to ATMOS MedizinTechnik for disposal.

Before disposal respectively before transport, all parts, which came into contact with the patient must be thoroughly cleaned, disinfected. The device surface must be disinfected.

11.0 Notes on EMC

- Medical electrical equipment is subject to special precautions with regard to EMC and must be installed acc. to following EMC notes.
- Portable and mobile HF communication facilities can influence medical electrical equipment.
- The use of other accessories, other transducers and cables than stated may lead to an increased emission or a reduced interference immunity of the equipment or system.

11.1 Guidelines and Manufacturer's Declaration - Emissions

The ATMOS® Scope is intended for use in the electromagnetic environment specified below. The customer or user of the ATMOS® Scope should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions acc.to CISPR 11	Group 1	The ATMOS® Scope uses RF energy only for its internal function. Therefore, its HF emissions are very low and it is unlikely that nearby electronic devices will be affected.
RF Emissions acc.to CISPR 11	Class B	The ATMOS® Scope is suitable for use in all establishments, including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions according to IEC 61000-3-2	Class A	
Voltage fluctuations/flicker according to IEC 61000-3-3	Corresponds	

11.2 Guidelines and Manufacturer's Declaration - Immunity

The ATMOS® Scope is intended for use in the electromagnetic environment specified below. The customer or user of the ATMOS® Scope should ensure that it is used in such an environment.

Immunity Test	IEC 60601- Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) according to IEC 61000-4-2	± 6 kV Contact ± 8 kV Air	± 6 kV Contact ± 8 kV Air	Floors should be made of wood or concrete or tiled with ceramic tiles. If floors are synthetic, the relative humidity should be at least 30 %.
EFT IEC 61000-4-4	± 2 kV Mains ± 1 kV I/Os	± 2 kV Mains Inapplicable ± 1 kV I/Os	The quality of the supply voltage should correspond to a typical commercial or hospital environment.
Surges IEC 61000-4-5	± 1 kV differential mode ± 2 kV common-mode	± 1 kV differential mode ± 2 kV common-mode	The quality of the supply voltage should correspond to a typical commercial or hospital environment.
Magnetic field at power frequency 50/60 Hz acc. to IEC 61000-4-8	3 A/m	applicable 3 A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.

11.0 Notes on EMC

Immunity Test	IEC 60601- Test Level	Compliance Level	Electromagnetic Environment - Guidance
Voltage Dips / Dropout IEC 61000-4-11	< 5 % U_T (> 95 % Dip of the U_T) for 0.5 Cycle 40 % U_T (60% Dip of the U_T) For 5 cycles 70 % U_T (30 % Dip of the U_T) For 25 cycles < 5 % U_T (>95 % Dip of the U_T) for 5 s	< 5 % U_T (> 95 % Dip of the U_T) for 0.5 Cycle 40 % U_T (60% Dip of the U_T) For 5 cycles 70 % U_T (30 % Dip of the U_T) For 25 cycles < 5 % U_T (>95 % Dip of the U_T) for 5 s	The quality of the supply voltage should correspond to a typical commercial or hospital environment. If the user of the ATMOS® Scope requires continued function during interruptions of the energy supply, it is recommended to supply the ATMOS® Scope from an uninterruptible power supply or a battery.
NOTE U_T is the AC mains voltage prior to application of the test level.			

11.3 Guidelines and Manufacturer's Declaration - Immunity

The ATMOS® Scope is intended for use in the electromagnetic environment specified below. The customer or user of the ATMOS® Scope should ensure that it is used in such an environment.

Immunity Test	IEC 60601- Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	V1 = 3 V_{eff} 150 kHz to 80 MHz	3 V	Portable and mobile communications equipment should be separated from the ATMOS® Scope including the cables by no less than the distances calculated/listed below. Recommended distances: d = [3.5 / 3] √P d = [3,5 / 3] √P 80 MHz to 800 MHz d = [7,0 / 3] √P 800 MHz to 2.5 GHz Where „P“ is the max. power in watts (W) and d is the recommended separation distance in meters (m). Field strengths from fixed transmitters, as determined by an electromagnetic site (a) survey, should be less than the compliance level (b). Interference may occur in the vicinity of equipment containing following symbol: 
Radiated RF IEC 61000-4-3	E1 = 3 V/m 80 MHz to 2.5 GHz	3 V/m	

NOTE 1

With 80 MHz and 800 MHz the higher frequency range applies.

NOTE 2

These guidelines may not be applicable in all cases. The emanation of electromagnetic waves is affected by absorption and reflection of buildings, objects and people.

a

The field strength of stationary transmitters, such as base stations of cellular phones and mobile terrain radio equipment, amateur radio transmitters, cbm broadcast and TV stations cannot be predestined exactly.

To determine the electromagnetic environment in regard to stationary transmitters, a study of the location is to be considered. If the measured field strength at the location where the ATMOS® Scope is used exceeds the above compliance level, the ATMOS® Scope is to be observed to verify the intended use. If abnormal performance characteristics are noted, additional measures might be necessary, e. g. a changed arrangement or another location for the ATMOS® Scope.

b

Within the frequency range of 150 kHz to 80 MHz the field strength should be below 3 V/m.

11.4 Recommended safety distance between portable and mobile RF Communications equipment and the ATMOS® Scope

The ATMOS® Scope is intended for use in electromagnetic environment in which radiated disturbances are controlled. The customer or user of the ATMOS® Scope can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications equipment and the ATMOS® Scope as recommended below, according to the maximum output power of the communications equipment.

	Safety distance, depending on transmit-frequency m		
Nominal output of the transmitter W	**150 kHz to 80 MHz** $d = [3.5 / 3] \sqrt{P}$	**80 MHz to 800 MHz** $d = [3.5 / 3] \sqrt{P}$	**800 MHz to 2.5 GHz** $d = [7.0 / 3] \sqrt{P}$
0.01	0.12	0.12	0.233
0.1	0.37	0.37	0.74
1	1.16	1.16	2.33
10	3.69	3.69	7.38
100	11.66	11.66	23.33

For transmitters for which the maximum nominal output is not indicated in the above table, the recommended safety distance d in meters (m) can be determined using the equation belonging to the respective column whereas P is the maximum nominal output of the transmitter in watts (W) acc. to manufacturer's specification.

NOTE 1

With 80 MHz and 800 MHz the higher frequency range applies.

NOTE 2

These guidelines may not be applicable in all cases. The emanation of electromagnetic waves is affected by absorption and reflection of buildings, objects and people.

MedizinTechnik

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