

Operating Instructions

ATMOS LS 31 LED

Englisch



CE

GA1GB.150304.0

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1 Introduction

1.1 Notes on operating instructions



These operating instructions contain important notes on how to operate the ATMOS LS 31 LED safely, correctly, and effectively.

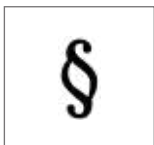
These operating instructions are designed for training and instructing new operating personnel and are also intended as a reference manual. This document must not be reprinted, either in part or in whole, without the written permission of ATMOS.

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



Care, period tests, regular cleaning and proper application are indispensable. They ensure the operational safety and usability of the ATMOS LS 31 LED.

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 necessary test devices and original spare parts required to carry out these measures.



Read chapter “2 Notices for your safety” on page 8 before using the device 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) no. 2017/745.

The ATMOS LS 31 LED meets all the applicable requirements of the directive 2011/65/EU that restrict the use of certain hazardous substances in electrical and electronic equipment (“RoHS”).

The declarations 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 the international standard EN ISO 13485.

These operating instructions apply to the following devices:

- ATMOS LS 31 LED 507.4800.0




















1.2 Explanation of pictures and symbols

In the operating instructions

 DANGER	Warning of a danger that will result in immediate fatal or serious injury. Observe the necessary measures.
 WARNING	Warning of a danger that can cause death or serious injury. Observe the necessary measures.
 CAUTION	Warning of a danger that can cause minor injury. Observe the necessary measures.
ATTENTION	Notice of a danger that can damage the product or other objects. Observe the necessary measures.
	Warning of a danger that can cause injury or death.
	Notice of potential material damage that can be caused.
	Useful information on the handling of the device.
1.	Action. Proceed step by step.
»	Result of an action.

On the device, type plate and packaging

	Follow the operating instructions (blue)
	Observe the operating instructions
	This product meets the relevant requirements of EU regulations.
	This product meets the relevant requirements of the Eurasian Economic Union.
	Manufacturer
	Date of manufacture Country of manufacture: Germany
	Reference number
	Unique Device Identifier of a medical device
	Medical device
	Serial number

IPX0	Specification of the degree of protection against the ingress of solids and moisture
	Type BF applied part
	Professional disposal
	Potential equalization
	Fuse
	Alternating current
	On, connected to the power supply
	Off, disconnected from the power supply
	Increase colour temperature (light becomes whiter)
	Reduce colour temperature (light becomes more yellow)
	Set the colour temperature
	Signal input and signal output
	This side up
	Handle with care
	Fragile, handle with care
	Store in a dry place
	Protect from sunlight
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation

UDI application identifier

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

1.3 Intended use

Product name:	ATMOS LS 31 LED
Main function:	LED cold light source for optical instruments. Provides adjustable colour temperature and includes an external trigger function.
Intended use/ purpose:	Illumination of natural orifices (e.g. ear/nose/throat) for diagnostics
Intended users / user profile:	Physicians and medical specialists
Intended patient population:	All patients without any restrictions
Medical conditions to be diagnosed, treated or monitored:	Diagnostic examination of anatomy of all kinds
Application organ:	No restrictions (mainly ear/nose/throat)
Application time:	< 60 min.
Application site:	Outpatient medical facilities, e.g. ENT practices, hospital outpatient departments, medical care centres
Patient selection criteria:	None
Indications:	The light source may be used along with other instruments for visual inspection of the anatomy.
Medical contraindications:	None
Other contraindications:	None
Warnings:	None
The product is:	Active
Sterility / specific microbial condition:	Non-sterile
Single-use product / re-sterilization	No single-use product. Re-sterilization according to the operating instructions.

1.4 Function

This product is a cold light source for medical use. In combination with a fibre optic light cable and an instrument connected to it, the light source enables the illumination of the viewing area for diagnostic purposes.

The device is an electrical product. It contains an LED whose luminous flux is focused on a small diameter output. Light guides can be adapted here for the transmission of light.

1.5 Scope of delivery



ATMOS LS 31
LED



Power cable



Storz adapter
REF 530.6100.0



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1.6 Transport and storage

Transport the device only in a shipping carton that is padded and provides sufficient protection.

If you notice any transport damage:

1. Document and report the transport damage.
2. Send the device to ATMOS; see chapter "6.4 Sending in the device" on page 18.

Ambient conditions for transport and storage:

See chapter "10 Technical data" on page 23.

2 Notices for your safety

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

2.1 General safety instructions

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

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

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

Note that the light source is illuminated even if there is no fibre optic light cable connected.

2.2 Danger to users, patients, and third parties

DANGER

Protect yourself from electric shocks!

Burns, cardiac arrhythmias and even fatal injury are possible.

- Disconnect the device from the power supply before cleaning or disinfecting it.
- Check whether the device is damaged each time before using it. Do not operate the device if you notice any damage. In this case, clean and disinfect the device and send it to ATMOS for repair.
- Connect the device only to a power supply with a protective conductor.
- Never touch the device's interfaces and the patient at the same time!
- Use only original accessories and spare parts from ATMOS.
- Observe the specifications regarding period tests in chapter "6.1 Period tests" on page 18.
- Do not modify the device without the manufacturer's permission.
- Assembly, new settings, modifications, extensions and repairs may be carried out only by authorized persons.

WARNING

Danger of glaring due to high light intensity.

Eye injuries are possible. There is a danger of blinding for people without a blink reflex or who are particularly sensitive to light.

- Never look directly into the light source or fibre optic light cable.
- Never direct the light source into the patient's eyes.
- Do not permit the patient to look into the light source or fibre optic light cable.
- The light source may be used only by instructed specialist personnel.

⚠ CAUTION

Heat development at the light source.

Burns are possible.

- Pay attention to the heat development of the light source.
- Switch off the light source whenever you do not need it.
- Do not reach into the connection for the fibre optic light cable.
- Do not position the product within a closed environment or next to other heat sources.

⚠ CAUTION

Keep the device fully functional.

Your patient can become injured during the treatment due to missing diagnostics or a light failure.

- ATMOS recommend always having another light source ready at hand.
- Conduct a function check each time before use.
- Please observe the notes on the electromagnetic compatibility (EMC) of the device.

⚠ CAUTION

Explosion and fire hazard!

Burns and injuries are possible.

- Never operate the product in potentially explosive areas or areas that are oxygenated.
- Use only original accessories and spare parts from ATMOS.

The product will meet the safety requirements of users, patients and third parties only when it is fully functional. Therefore, observe the following instructions on your product.

ATTENTION

Light failure when using the light source with a stroboscope.

Your patient can be injured.

- Connect only ATMOS stroboscopes.
- Use only the supplied interlink cable or an original ATMOS spare part.

2.3 Avoiding damage to the device

ATTENTION

Storage and operation in an unsuitable environment.

The electronics can become damaged.

- Observe the ambient conditions in chapter "10 Technical data" on page 23.

3 Setting up and starting up the device

3.1 Device overview

Front view



- ❶ COLOUR TEMPERATURE controller
- ❷ ADAPTER connector
- ❸ ON/OFF button

Rear view



- ❹ F I/O connector for ATMOS Strobo 21 LED
- ❺ Power cable connector
- ❻ Fuses
- ❼ Equipotential bonding connector

3.2 Combination with other devices

Only qualified personnel are allowed to set up electrical systems. The manufacturer of an electrical medical system is responsible for ensuring that the performance, installation and start-up, safety, technical data and intended use of the ATMOS LS 31 LED are not impaired.

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

- Observe the specifications of the standard IEC EN 60601-1 on medical electrical systems.
- Pay particular attention to the information on the patient environment, multiple sockets and leakage currents.

3.3 Connecting the device

Determining transport damage


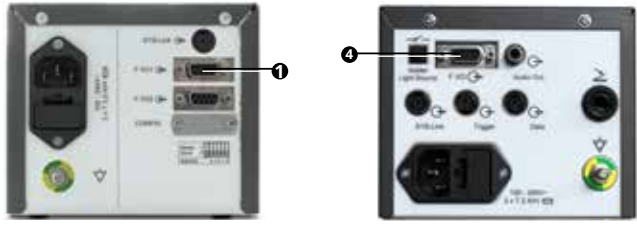
1. Check the device for any transport damage.
2. If the device is damaged: document and report the transport damage. Send the device to ATMOS; see chapter "6.4 Sending in the device" on page 18.

Connecting the adapter

1. Screw a suitable adapter into the adapter connector.
- ☞ You can find all suitable adapters provided by ATMOS in chapter "8 Accessories" on page 21.

Connecting the stroboscope

1. Observe the instructions on medical electrical systems in chapter "3.2 Combination with other devices" on page 10.
2. Connect the ATMOS Strobo 21 LED as follows:

Type of stroboscope	Connection
ATMOS Strobo 21 LED with date of manufacture up to 2016-09	<p>Trigger cable 507.4837.0 (Y cable): F I/O 1 connector ❶ to LED light handle connector ❷ and F-Out connector ❸.</p>  <p>ATMOS LS 31 LED</p> <p>ATMOS Strobo 21 LED until 2016-09</p>
ATMOS Strobo 21 LED with date of manufacture from 2016-10	<p>Trigger cable 507.4838.0 F I/O 1 connector ❶ to F I/O connector ❹.</p>  <p>ATMOS LS 31 LED</p> <p>ATMOS Strobo 21 LED from 2016-10</p>

Potential equalization and power supply

1. Connect the potential equalization if necessary.
 - ☞ The potential equalization must be connected if required by the spatial environment in which the product is to be used.
2. Check whether the mains voltage and frequency of the device match the voltage and frequency of the power supply.
 - ☞ The device's specifications can be found on the type plate.
3. If the mains voltage and mains frequency match: Connect the device to an earthed power connection with the supplied power cable.
4. Conduct a function check; see chapter "6.2 Function check" on page 18.

4 Operation

4.1 Ambient conditions during operation

See chapter "10 Technical data" on page 23.

4.2 Switching on the device

☞ Subject the device to a function check each time before using it; see chapter "6.2 Function check" on page 18.

1. Press the ON/OFF button.
- » The light source is lit up.

4.3 Switching off the device

1. Press the ON/OFF button.
- » The light source is no longer lit up.

4.4 Connecting the fibre optic light cable

1. Switch off the device.
 2. Insert the fibre optic light cable into the adapter until it clicks into place easily.
- ☞ You can find all suitable fibre optic light cables provided by ATMOS in chapter "8 Accessories" on page 21.

4.5 Removing the fibre optic light cable

1. Switch off the device.
2. Remove the fibre optic light cable from the adapter.

4.6 Setting the colour temperature

1. Turn the COLOUR TEMPERATURE controller.
- ☞ Turn it clockwise to make the light whiter or anti-clockwise to make the light more yellowish.
2. If a camera is connected, perform white balance.

4.7 Exchanging the adapter

1. Switch off the device.
 2. Remove the fibre optic light cable from the adapter.
 3. Screw the adapter out of the adapter connector.
 4. Screw the desired adapter into the adapter connector.
 5. Insert the light guide cable into the adapter until it engages easily.
- ☞ Conduct a function check; see chapter "6.2 Function check" on page 18.
- ☞ You can find all suitable adapters provided by ATMOS in chapter "8 Accessories" on page 21.

5 Sterilization

5.1 Safety instructions for sterilization

5.2 General safety instructions

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

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

Sterilization may be carried out only by persons with the appropriate expertise. The person in question must possess the equipment required to carry out these measures.

5.2.1 Danger to users, patients and third parties

ATTENTION

Risk of infection due to unsuitable accessories.

Pathogens can be transmitted.

- Wear disposable gloves for all cleaning and disinfection measures.
- Only use aids and tools that are easy to sterilize or are disposable products.

ATTENTION

Risk of infection due to unsuitable sterilization.

Pathogens can be transmitted.

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

5.2.2 Avoiding damage to the device

ATTENTION

Electric shock due to liquid in the device.

Burns, cardiac arrhythmias and even fatal injury are possible.

- Do not rinse the device under running water and do not immerse it in any liquids.
- Make sure the cleaning cloth is only damp, not wet.
- Do not subject the device to autoclaving or sterilization.
- Do not immerse the device in disinfection solution.

ATTENTION

Damage to the device due to cleaning with fixatives!

Stains can no longer be removed permanently.

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

ATTENTION

Unsuitable accessories.

The product may become damaged.

- Use only lint-free, soft cloths.
- Observe the corresponding operating instructions for all accessories used.

5.3 Preparing and completing the sterilization

Prior to sterilization

1. Switch off the ATMOS 31 LED prior to cleaning and disinfection!
 2. Disassemble the product into the following components for sterilization:
 - ATMOS LS 31 LED control device
 - Accessories
 - Fibre optic light cable
- ☞ Clean and disinfect the light guide cable according to the operating instructions of the manufacturer of the fibre optic light cable.
- Storz adapter

After sterilization

1. Conduct a function check each time before use.

5.4 Preparing surfaces

5.4.1 Overview

Surface	After each application	Daily	Weekly	Every 14 days	Monthly	Pre-cleaning	Wipe cleaning	Wipe disinfection	Comment
ATMOS LS 31 LED housing		X					X	X	Daily sterilization or immediately in the event of visible dirt.

5.4.2 Selecting the surface disinfectant

ATTENTION

Unsuitable cleaning agents and disinfectants

The product may become damaged.

Do not use any:

- Disinfectants that contain organic or inorganic acids or bases, because they can cause corrosion damage.
- Disinfectants containing chloramides or phenol derivatives, because they cause stress cracks in the plastic material used.
- Alcohol-based disinfectant.

<p>Manual cleaning</p>	<ol style="list-style-type: none"> 1. Use a moist (never wet), clean and lint-free cloth moistened with cleaning agent to wipe evenly the surfaces of the device. <ul style="list-style-type: none"> ☞ Make sure the colour temperature controller and the On/Off button are cleaned carefully. ☞ Do not include the device openings to prevent liquid from entering the device interior. 2. If there is still some dirt, repeat the cleaning to avoid impairing the disinfection effect.
<p>Manual disinfection</p>	<ol style="list-style-type: none"> 1. Wipe all surfaces of the device evenly with a moist (not wet), clean and lint-free cloth moistened with a recommended surface disinfectant. <ul style="list-style-type: none"> ☞ Make sure they are wetted completely, in particular the colour temperature controller and the On/Off button, to ensure effective disinfection. ☞ Do not include the device openings to prevent liquid from entering the device interior. 2. Wait for the exposure time of the disinfectant to work.
<p>Drying</p>	<p>Allow the device to dry completely before putting it back into service.</p>
<p>Maintenance, check and inspection</p>	<ol style="list-style-type: none"> 1. Check the success of the sterilization by means of visual inspection. 2. If the sterilization was unsuccessful, sterilize the device again. 3. Mount the fibre optic light cable onto the device and conduct a function check; see chapter "6.2 Function check" on page 18.

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 necessary test devices and original spare parts required to carry out these measures.

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

6.1 Period tests

Please comply with the country-specific guidelines regarding regular testing, especially with regard to electrical safety.

ATMOS recommend a test every 24 months.

6.2 Function check

Conduct a function check each time before use.

Do not operate the device if you notice any damage. In this case, clean and disinfect the device and send it to ATMOS for repair.

1. Check whether the device, the power cable or connected parts are damaged.
2. Check that the adapter is connected correctly.
3. Connect a fibre optic light cable or check whether the fibre optic light cable is connected properly.
4. Align the fibre optic light cable on a white surface.
5. Push the ON/OFF button to switch on the device.
 - » The light source is lit up.
6. Turn the COLOUR TEMPERATURE controller and check whether the light changes accordingly.

6.3 Exchanging fuses

1. Switch off the device.
2. Remove the power cable from the device.
3. Disconnect the fuse holder from the power supply.
4. Replace both fuses.
5. Mount the fuse holder.
6. Connect the device to the power supply.

6.4 Sending in the device

1. Clean and disinfect the product and accessories in accordance with the operating instructions.
2. Submit any used accessories with the product.
3. Fill in the form QD 434 "Delivery complaint / return shipment" and the corresponding **decontamination certificate**.
 - ☞ This form is enclosed with each delivery and can be found at www.atmosmed.com.
4. Pack the device well padded in suitable packaging.

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

7 Troubleshooting

The ATMOS LS 31 LED was subjected to a thorough quality control in the factory. If a fault occurs nevertheless, you may be able to resolve it yourself.

Light source

Error symptom	Possible cause	Remedy
No light.	Device not switched on.	1. Switch on the device.
	Device is not connected to the power supply.	1. Connect the device. 2. Check that all connections are established firmly.
	Defective power cable.	1. Replace the power cable.
	Defective fuse.	1. Exchange the fuses.
Insufficient light.	Adapter not mounted correctly.	1. Check that the adapter is fitted correctly.
	Adapter not suitable for fibre optic light cables.	1. Use an adapter that is suitable for the fibre optic light cable.
	The fibre optic light cable is defective.	1. Replace the fibre optic light cable.
The colours are unnatural.	Colour temperature not coordinated.	1. Adjust the colour temperature. 2. If a camera is connected, perform a white balance.

Stroboscopy

Error symptom	Possible cause	Remedy
Stroboscopy is not working.	Trigger cable not connected correctly.	1. Check the trigger cable. ☞ Please observe the different trigger cables; see chapter "3.3 Connecting the device" on page 11.

8 Accessories

Accessories	REF
LED Light Cube Adapter ATMOS/Storz	530.6100.0
LED Light Cube Adapter Olympus	530.6101.0
LED Light Cube Adapter Pentax	530.6102.0
LED Light Cube Adapter Wolf	530.6103.0
High-performance fibre optic light cable, Ø 4.8 mm, L = 1.8 m	950.0152.0
Fibre optic light cable, Ø 3.5 mm, L = 1.7 m	508.0663.0
Fibre optic light cable, Ø 3.5 mm, L = 1.8 m, 90° angled	508.0664.0

9 Disposal

Packaging

1. Please submit the packaging for recycling.

ATMOS LS 31 LED

Do not dispose of the device with household waste.

The ATMOS LS 31 LED does not contain any hazardous goods.

1. Clean and disinfect the device.
2. Dispose of the device properly and in accordance with country-specific laws and regulations.



In principle, the housing is fully recyclable. Observe the national laws and regulations.



9.1 Expected service life

If it is used according to the operating instructions, the device ATMOS LS 31 LED 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	100-230 V~ ± 10 %; 50/60 Hz
Power consumption	Max. 55 VA
Other power sources	n/a
Fuses	2 x T 2.0 A / H
Power cable	2 m long, Schuko IEC connectors
Illuminance	Max. 150 klx (at 5 cm distance to a 4.7 mm high-performance fibre optic light cable)
Colour temperature	Can be set between 5500 and 6500 K
Flash frequency	70 to 1000 Hz flash light and permanent light
Duty cycle	Max. 20%
Operation time	Continuous operation for permanent light, short-time operation for flash light. Short-term operation = 15 min operation; 15 min interval (= 50 % ED)
Cooling	Fanless
Protective earth conductor resistance	Max. 0.1 Ω
Earth leakage current	Max. 0.5 mA
Touch current	Max. 0.1 mA
Patient leakage current	Max. 0.1 mA
Ambient conditions for transport/ storage	
• Temperature	-20...+80 °C
• Air humidity without condensation	30...95 %
• Pressure	500 to 1060 hPa
Ambient conditions for operation	
• Temperature	+10...+35 °C
• Air humidity without condensation	30...95 %
• Pressure	700 to 1060 hPa
Max. operational altitude	≤ 3000 m
Heat output	Max. 35 Joule/s
Noise level	Silent permanent light, flash light @ max. power / 1000 Hz: < 35 dBA
Overvoltage category	II
Dimensions HxWxD	117 x 138 x 290 mm
Weight:	5.0 kg
Period tests	Repeat test of electrical safety every 24 months. Recommended: inspection according to manufacturer's specifications.
Protection class (EN 60601-1)	I
Degree of protection	Type BF applied parts 
Degree of protection	IPX0
CE mark	
Ident-No. (REF)	507.4800.0 ATMOS LS 31 LED

11 Notes on EMC

- Medical electrical devices are subject to special precautions with regard to EMC and must be installed according to the following EMC notes.

Guidelines and manufacturer's declaration – ambient conditions

The ATMOS LS 31 LED is suitable for use in the following environments:

- In the fields of home healthcare in any buildings, outdoor areas and means of transport.
- At professional health care facilities, e.g.: Medical practices, hospitals, first-aid facilities and operating theatres.
It is not suitable for use in the vicinity of HF surgical devices and in settings outside an HF-shielded room of a magnetic resonance imaging system.

The customer or user of the ATMOS LS 31 LED must ensure that the device is used in a prescribed environment.

Guidelines and manufacturer's declaration – key features

- Please observe the technical data in this manual. The essential features are fully usable even in the presence of electromagnetic disturbances.

Guidelines and manufacturer's declaration – electrical components

The ATMOS LS 31 LED has the following electrical components:

Type	REF	Max. cable length
ATMOS LS 31 LED trigger cable (Strobo up to 09/16)	507.4837.0	0.85 m
ATMOS LS 31 LED trigger cable	507.4838.0	1 m

Guidance and manufacturer's declaration – warnings

WARNING

The use of electrical components and accessories other than those specified or provided by the manufacturer may cause increased electromagnetic interference or reduced immunity to electromagnetic interference and result in faulty operation of the device.

WARNING

Portable RF communications equipment (e.g. radios, antenna cables) should be used no closer than 30 cm* to any parts of the ATMOS LS 31 LED, including cables, specified by the manufacturer. Failure to do so may lead to a reduction in the device's performance.

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

WARNING

Avoid placing it on top of or next to another device. This could result in faulty operation. If such placement cannot be avoided, the proper functioning of the device must be monitored regularly. If possible, please switch off any nearby devices that are not in use.

12 Notes

Notes

Notes



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