

Operating Instructions

ATMOS LS 31 LED

English



CE

GA1GB.150304.0

2021-06 Index 04

Table of contents

1	Introduction.....	3	5	Cleaning and disinfection	14
1.1	Notes on operating instructions.....	3	5.1	Disinfection of the product	14
1.2	Explanation of pictures and symbols.....	4	5.2	Recommended disinfectant	15
1.3	Intended use	6	5.2.1	Surface disinfectant	15
1.4	Function.....	7	6	Maintenance and service.....	16
1.5	Scope of delivery	7	6.1	Periodic tests.....	16
1.6	Transport and storage	7	6.2	Function check.....	16
2	Hints for your safety.....	8	6.3	Replacing the fuse	16
2.1	General safety information	8	6.4	Sending in the device.....	16
2.2	Dangers for users, patients, and third parties.....	8	7	Troubleshooting	18
2.3	Damage to the device	9	8	Accessories	19
3	Setting up and starting up	10	9	Disposal.....	20
3.1	Device overview	10	10	Technical data	21
3.2	Use with other devices.....	10	11	Notes on EMC	23
3.3	Connecting the device	11			
4	Operation.....	13			
4.1	Ambient conditions during operation.....	13			
4.2	Switch on the device	13			
4.3	Switch off the device	13			
4.4	Connect the light guide cable	13			
4.5	Remove the light guide cable.....	13			
4.6	Adjust the color temperature	13			
4.7	Change the adapter	13			

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.

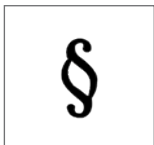
The instructions are intended for the training and teaching of operating personnel and are intended as a reference. Reproduction, even partial, is only permitted with written permission from ATMOS.

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



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

Maintenance, repairs, and periodic tests may only be carried out by persons who have the appropriate technical knowledge and are familiar with the product. To carry out these measures, the person must have the necessary test devices and original spare parts.



Read Chapter “2 Hints for your safety” on page 8 before using the device for the first time. This helps you avoid potentially dangerous situations.

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

The ATMOS LS 31 LED complies with all applicable requirements of the directive 2011/65/EU 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 at ATMOS has been certified according to international standards EN ISO 13485.

These operating instructions are valid for the following devices:

- ATMOS LS 31 LED 507.4800.0
- ATMOS LS 31 LED (S 61 Servant vision) 531.2100.0




















1.2 Explanation of pictures and symbols

In the operating instructions

 DANGER
Warning of a danger which causes immediate death or serious injury. Observe the necessary measures.
 WARNING
Beware of a danger which can cause death or serious injury. Observe the necessary measures.
 CAUTION
Beware of a danger which can easily hurt you. Observe the necessary measures.
NOTICE
Indication of a danger where the product or other items can be damaged. Observe the necessary measures.
 Warning of a danger which can cause death or serious injury.
 Information regarding possible material damage which can be caused.
 Useful information on the handling of the device.
1. Action. Go step by step
» Result of an action.

On device, type plate, and packaging

	Follow operating instructions (blue)
	Observe operating instructions
	This device complies with the relevant requirements of EU regulations.
	This device complies with the relevant requirements of the Eurasian Economic Union.
	Manufacturer
	Manufacturing date 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 color temperature (light becomes whiter)
	Reduce color temperature (light becomes more yellow)
	Adjust color temperature
	Signal input and signal output
	This side up
	Handle with care
	Fragile, handle with care
	Keep dry
	Keep away from sunlight
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation

UDI application identifier

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

1.3 Intended use

Product name:	ATMOS LS 31 LED
Main functions:	LED cold light source for optical instruments. Provides adjustable color temperature and includes an external trigger function.
Intended use / intended purpose:	Illumination of natural orifices for diagnosis (e.g., ear/nose/throat)
Intended users / user profile:	Doctors and medical specialists
Intended patient population:	All patients without restrictions
Medical condition 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 centers
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 state:	Non-sterile
Single-use product / reprocessing:	Not a single-use device. Reprocessing according to the operating instructions.

1.4 Function

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

The device is an electrically driven device. It contains an LED whose luminous flux is focused on a small diameter output. Here, light guide cables can be adapted for the transmission of light.

1.5 Scope of delivery



ATMOS LS 31
LED



Power supply
cord



Storz adapter



Operating
Instructions

1.6 Transport and storage

Only transport the device in a shipping carton which is padded and offers sufficient protection.

If damage occurs during transport:

1. Document and report the transport damage.
2. Send the device to ATMOS; see chapter "6.4 Sending in the device" on page 16.

Environmental conditions for transport and storage:

- Temperature: -20...+80 °C
- Humidity without condensation: 30...95 %
- Pressure: 500...1060 hPa

2 Hints for your safety

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

2.1 General safety information

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

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

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

Please ensure that the light source is illuminated even if there is no light guide cable connected.

2.2 Dangers for users, patients, and third parties

Protect yourself against an electric shock!

Burns and cardiac arrhythmia and even death are possible.

- Disconnect the device from the mains before cleaning or disinfecting it.
- Prior to each use check whether the device is damaged. 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.
- Only connect the device to a power supply with a protective conductor.
- Never touch the device's interfaces and the patient at the same time!
- Only use original accessories and original spare parts from ATMOS.
- Please pay attention to the periodic tests in chapter "6.1 Periodic tests" on page 16.
- Do not change the device without the manufacturer's permission.
- Assembly, new settings, modifications, extensions, and repairs may only be carried out by authorized persons.

Danger of blinding due to the high light intensity.

Eye injury is possible. People without blink reflex or with particular light sensitivity could go blind.

- Never look directly into the light source or in the light guide cable.
- Never direct the light source into the patient's eyes.
- Never permit the patient to look into the light source or light guide cable.
- The light source may only be operated by qualified personnel.

Heat development on the light source.

Burns are possible.

- Pay attention to the heat development of the light source.
- Switch off the light source when not in use.
- Do not touch the connection for the light guide adapter.
- Do not place the product in a closed environment or beside other heat sources.

The device must always be functional.

Your patient could be injured during the treatment as a result of a missing diagnosis or light failure.

- ATMOS always recommends having an alternative light source ready to hand.
- Prior to each use, a function check has to be performed.
- Please observe the notes on electromagnetic compatibility (EMC) of the device.

Explosion and fire hazard!

Burns and injuries are possible.

- Never operate the device in explosion-hazardous areas or areas which are oxygenated.
- Only use original accessories and original spare parts from ATMOS.

Only a fully functional product meets the safety requirements of users, patients, and third parties. Please therefore read the following instructions carefully.

2.3 Damage to the device

Storage and operation in an unsuitable environment.

The electronics could be damaged.

- Please observe the ambient conditions regarding transport, storage, and operation.

3 Setting up and starting up

3.1 Device overview

Front view



- ❶ Controller COLOR TEMPERATURE
- ❷ Connection ADAPTER
- ❸ ON/OFF key

Rear view



- ❹ Connection F I/O for the ATMOS Strobe 21 LED
- ❺ Connection power supply cord
- ❻ Fuses
- ❼ Connection equipotential bonding

3.2 Use with other devices

Only qualified personnel may install electrical systems. The manufacturer of a medical electrical system is responsible for ensuring that the performance, installation and commissioning, safety, specifications, and intended use of the ATMOS LS 31 LED are not affected.

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

- Refer to the specifications of IEC EN 60601-1 on medical electrical systems.
- Note in particular the information on the patient environment, multiple sockets, and leakage current.

3.3 Connecting the device

CAUTION

Light failure during a treatment.

Your patient could be injured.

- Only connect a stroboscope from ATMOS.
- Only use the provided interlink cable or an original spare part from ATMOS.

Heat development on the light source.

Burns are possible.

- Do not place the product in a closed environment or beside other heat sources.

Carefully read the safety instructions in chapter “2 Hints for your safety” on page 8 before using the product.

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 16.

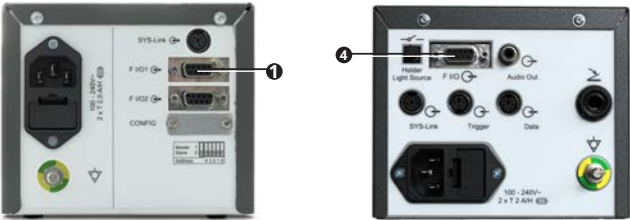
Connect the adapter

1. Insert a suitable adapter into the connection adapter.

Connect a stroboscope

1. Refer to the guidelines for medical electrical systems in Chapter “3.2 Use with other devices” on page 10.
2. Connect the ATMOS Strobe 21 LED as follows:

Type of stroboscope	Connection
ATMOS Strobe 21 LED with date of production up to 2016-09	<p>Trigger cable 507.4837.0 (Y-cable): Connection F I/O 1 1 to the connection LED light handle 2 and connection F-Out 3.</p>  <p>ATMOS LS 31 LED</p> <p>ATMOS Strobe 21 LED up to 2016-09</p>

Type of stroboscope	Connection
ATMOS Strobo 21 LED with date of construction from 2016-10	Trigger cable 507.4838.0 Connection F I/O 1 1 to connection F I/O 4 .  <div style="display: flex; justify-content: space-around; margin-top: 10px;"> <div data-bbox="683 622 938 656">ATMOS LS 31 LED</div> <div data-bbox="1023 622 1369 656">ATMOS Strobo 21 LED from 2016-10</div> </div>

Equipotential bonding and power supply

1. Connect the equipotential bonding if required.
 - ⊞ The equipotential bonding must be connected if the spatial environment in which the product is used requires this. Refer to the specifications of IEC EN 60601-1.
2. Check that the mains voltage and device voltage match.
 - ⊞ The device's details can be found on the type plate.
3. If the mains voltage and mains frequency correspond: connect the device with the supplied power supply cord to a power supply with a protective conductor.
4. Perform a function check, see Chapter "6.2 Function check" on page 16.

4 Operation

4.1 Ambient conditions during operation

- Temperature: +10...+35 °C
- Humidity without condensation: 30...95 %
- Pressure: 700...1060 hPa

4.2 Switch on the device

- ☞ Prior to each use, perform a function check; see chapter "6.2 Function check" on page 16.
1. Press the button ON / OFF.
 - » The light source is illuminated.

4.3 Switch off the device

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

4.4 Connect the light guide cable

1. Switch off the device.
2. Insert the light guide cable into the adapter until it engages easily.

4.5 Remove the light guide cable

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

4.6 Adjust the color temperature

1. Turn the controller COLOR TEMPERATURE.
 - ☞ Turn it clockwise and the light becomes whiter or anti-clockwise and the light becomes more yellow.
2. If a camera is connected, perform white balance.

4.7 Change the adapter

1. Switch off the device.
2. Remove the light guide cable from the adapter.
3. Unscrew the adapter from the adapter connection.
4. Insert the desired adapter into the adapter connection.
5. Insert the light guide cable into the adapter until it engages easily.
 - ☞ Perform a function check; see chapter "6.2 Function check" on page 16.

5 Cleaning and disinfection

We recommend that you always document all maintenance work and exchange of parts in writing.

It is the responsibility of the operator to ensure that the required results for cleaning and disinfection are adhered to. Generally, validation, and routine monitoring of the procedure are necessary.

⚠ WARNING

Risk of infection due to germs on equipment and accessories.

Diseases may be transmitted.

- Wear disposable gloves during all cleaning and disinfection measures.
- Clean and disinfect the device if required.
- Clean and disinfect the device according to the operating instructions.

5.1 Disinfection of the product

⚠ WARNING

Electric shock caused by liquid inside the device.

Burns and cardiac arrhythmia and even death are possible.

- Do not rinse the device under running water and do not immerse it in liquids.
- Make sure that the cleaning cloth is only damp and not wet.
- Do not subject the device to an autoclave or sterilization.
- Do not immerse the device in disinfectant solution.

NOTICE

Liquid in the light channel.

Damaged lens.

- Please ensure that liquid does not penetrate the light channel.
1. Switch off the device.
 2. Remove the light guide cable.
 3. Clean the device with a damp, clean, lint-free cloth.
 4. Disinfect the device with a clean, lint-free cloth and a recommended disinfectant. See chapter "5.2 Recommended disinfectant" on page 15.
- ☞ Clean and disinfect the light guide cable according to the respective operating instructions of the manufacturer.
5. Attach the light guide cable.
 6. Perform a function check; see chapter "6.2 Function check" on page 16.

5.2 Recommended disinfectant

NOTICE

Unsuitable disinfectant.

Damage to the device surface, corrosion damage, and stress cracks are possible.

- Only use disinfectants which are recommended by ATMOS.
- Do **not use** disinfectants which contain the following ingredients:
 - Alcohol.
 - Organic or inorganic acids or bases.
 - Chloramines.
 - Phenol derivatives.
 - Anionic surfactants

5.2.1 Surface disinfectant

Observe the instructions for use of the disinfectant manufacturers. Note in particular the information on the concentration and material compatibility.

Disinfectant	Ingredients	in 100 g	Manufacturer
Green & Clean SK	Di alkyl dimethyl ammonium chloride Alkyl dimethyl ethyl benzyl ammonium chloride Alkyl dimethyl benzyl ammonium chloride	< 1 g < 1 g < 1 g	Metasys, Rum (Austria)
Dismozon® plus (Granulate)	magnesium monoperoxyphthalate hexahydrate	95.8 g	Bode Chemie, Hamburg
Incidin® Plus (application concentrate)	glucoprotamin	26 g	Ecolab, Düsseldorf

6 Maintenance and service

Maintenance, repairs, and periodic tests may only be carried out by persons who have the appropriate technical knowledge and are familiar with the product. To carry out these measures, the person must have the necessary test devices and original spare parts.

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

6.1 Periodic tests

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

ATMOS recommends an inspection according to the manufacturer's specifications.

6.2 Function check

Prior to each use, a function check has to be performed.

Never operate the device if you detect any damage. In this case, clean and disinfect the device and send it to ATMOS for repair.

1. Check whether the device, the power supply cord, or connected parts are damaged.
2. Check whether the adapter is connected properly.
3. Connect a light guide cable or check whether the light guide cable is connected properly.
4. Aim the light guide cable at a white surface.
5. Press the ON/OFF button to switch on the device.
 - » The light source is illuminated.
6. Turn the controller **COLOR TEMPERATURE** and check whether the light changes accordingly.

6.3 Replacing the fuse

1. Switch off the device.
2. Remove the power supply cord from the device.
3. Remove the fuse holder from the mains connection.
4. Replace both fuses.
5. Attach the fuse holder.
6. Connect the device to the mains supply.

6.4 Sending in the device

1. Clean and disinfect the products and accessories according to the operating instructions.
2. Place used accessories with the device.
3. Fill in the form QD 434 "Delivery complaint / return shipment" and the respective **Decontamination certificate**.
 - ☞ This form is enclosed with each delivery and can be found at www.atmosmed.com.
4. The device must be well padded and packed in suitable packaging.
5. Place form QD 434 "Delivery complaint / return shipment" and the corresponding **Decontamination certificate** in an envelope.

6. Stick the envelope on the outside of the package.
7. Send the product to ATMOS or to your dealer.

7 Troubleshooting

The ATMOS LS 31 LED was subjected to a thorough quality control in the factory. However, should an error occur, you may be able to solve this yourself.

Light source

Error indication	Possible cause	Remedy
No light.	Device is not switched on.	1. Switch on the device.
	Device is not connected to the power supply.	1. Connect the device. 2. Check that the connections are fitted properly.
	Defective power supply cord.	1. Change the power supply cord.
	Defective fuse.	1. Replace the fuse.
Insufficient light.	Adapter is not connected properly.	1. Check whether the adapter is fitted properly.
	Adapter is not suitable for the light guide cable.	1. Use an adapter which is suitable for the light guide cable.
	Light guide cable is defective.	1. Replace the light guide cable.
The colors are unnatural.	Color temperature is not coordinated.	1. Adjust the color temperature. 2. If a camera is connected, perform a white balance.

Stroboscopy

Error indication	Possible cause	Remedy
Stroboscopy does not work.	Trigger cable is not connected properly.	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-perf. light guide cable, Ø 4.8 mm, L = 1.8 m	950.0152.0
Light guide cable, Ø 3.5 mm, L = 1.7 m	508.0663.0
Light guide cable, Ø 3.5 mm, L = 1.8 m, 90° angled	508.0664.0
ATMOS LS 31 LED trigger cable (Strobo up to 09/16)	507.4837.0
ATMOS LS 31 LED trigger cable	507.4838.0

9 Disposal

Packaging

1. Please recycle the packaging.

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. In Germany: send in the device to ATMOS or your specialized dealer. They will dispose of the device professionally.
3. In other countries: dispose of the device professionally and according to country-specific laws and regulations.

In Germany, the device is excluded from the Electrical and Electronic Equipment Act (ElektroG) in accordance with the National Register for waste electric equipment because it may be contaminated. Do not dispose of the device with electronic waste.

The housing is fully recyclable. Refer to the country-specific laws and regulations.



10 Technical data

Voltage	100–230 V~ ± 10%; 50/60 Hz
Power consumption	Max. 55 VA
Fuses	2 x T 2.0 A / H
Power supply cord	2 m length, earthing contact plug, non-heating
Light intensity	Max. 150 klx (in 5 cm distance of a 4.7 mm high-performance light guide)
Color temperature	Adjustable 5500 K to 6500 K
Flash frequency	70 to 1000 Hz flash light and continuous light
Duty cycle	Max. 20%
Operating time	Continuous operation with continuous light, short-term operation with 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
• Humidity without condensation	30...95 %
• Pressure	500...1060 hPa
Ambient conditions operation	
• Temperature	+10...+35 °C
• Humidity without condensation	30...95 %
• Pressure	700...1060 hPa
Max. operational altitude	≤ 3000 m
Heat release	Max. 35 Joule/s
Noise level	Continuous light, soundless, flash light @ max. power / 1000 Hz: <35 dBA
Overvoltage category	II
Dimensions HxWxD	117 x 138 x 290 mm
Weight	5.0 kg
Periodic tests	Repeat test of the 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 
Type of protection	IPX0
CE marking	

ID no. (REF)	507.4800.0 ATMOS LS 31 LED 531.2100.0 ATMOS LS 31 LED (S 61 Servant vision)
--------------	---

11 Notes on EMC

☞ Medical electrical equipment is subject to special precautions with regard to EMC and must be installed acc. to following EMC notes.

Guidance and manufacturer's declaration – ambient conditions

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

- In fields of home health care in any buildings, outdoor areas, and means of transport.
- In professional healthcare facilities such as medical practices, hospitals/clinics, first-aid facilities, and operating rooms.
It is not suitable for use in the vicinity of HF surgical devices and in settings outside of an HF-shielded room of a magnetic resonance imaging system.

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

Guidance and manufacturer's declaration – key features

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

Guidance and manufacturer's declaration – 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	85 cm
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 part of the ATMOS LS 31 LED, including cables, specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

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

WARNING

Avoid placing the device 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.



MedizinTechnik

 ATMOS MedizinTechnik GmbH & Co. KG

Ludwig-Kegel-Straße 16
79853 Lenzkirch / Germany

Phone: +49 7653 689-0

info@atmosmed.de

www.atmosmed.com