ATMOS
MedizinTechnik

Instructions for Use

ATMOS LS 21 LED

English



CE

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Table of contents

1 Introduction ... 3
1.1 Notes on the Instructions for Use ... 3
1.2 Explanation of pictograms and symbols ... 4
1.3 Intended purpose ... 6
1.4 Function ... 6
1.5 Scope of delivery ... 7
1.6 Transport and storage ... 7

2 Notes for your safety ... 8
2.1 General safety instructions ... 8
2.2 Danger to users, patients, and third parties ... 8
2.3 Avoiding damage to the device ... 9

3 Operation ... 10
3.1 Functional check ... 10
3.2 Environmental conditions during operation ... 10
3.3 Attaching the application instrument ... 10
3.4 Connection possibilities of the LED light source ... 11
3.5 Operation of the optional LED battery ... 11
3.5.1 Capacity indicator ... 11
3.5.2 Charging the LED battery ... 12
3.5.3 Maintaining the battery ... 12

4 Reprocessing ... 13
4.1 Safety instructions for reprocessing ... 13
4.1.1 General safety instructions ... 13
4.1.2 Procedure ... 13
4.1.3 Material resistance ... 14

5 Maintenance and service ... 15
5.1 Sending in the device ... 15

6 Troubleshooting ... 16

7 Accessories ... 17

8 Disposal ... 18
8.1 Expected service life ... 18

9 Technical Data ... 19

10 Notes on EMC ... 21

11 Notes ... 22

1 Introduction

1.1 Notes on the Instructions for Use



These Instructions for Use contain important information on how to operate your product safely, correctly, and effectively.

These Instructions for Use are designed for training and instructing new operating personnel in the use of the system and also for use as a reference manual. This document may only be reprinted, either in part or in whole, with written permission of ATMOS.

These Instructions for Use must always be kept available near the product.



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

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

§

Read chapter “2 Notes for your safety” on page 8 before using the product for the first time. This will help you to avoid potentially dangerous situations.

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

The product complies with all applicable requirements of Directive 2011/65/EU restricting the use of certain hazardous substances in electrical and electronic equipment (“RoHS”).

The Declarations of Conformity and our General Terms and Conditions can be viewed on our website at www.atmosmed.com.

The quality management system applied at ATMOS has been certified according to the international standard EN ISO 13485.

These Instructions for Use are valid for the following products:

- ATMOS LS 21 LED 507.4600.0
- ATMOS LS 21 LED, warm white 507.4602.0
- ATMOS LS 21 LED 541.4300.0

1.2 Explanation of pictograms and symbols

In the Instructions for Use

⚠ DANGER	Warning of a hazard that will result in death or serious injury. Observe the necessary measures.
⚠ WARNING	Warning of a hazard that could result in death or serious injury. Observe the necessary measures.
⚠ CAUTION	Warning of a hazard that may result in minor or moderate injury. Observe the necessary measures.
NOTICE	Indicates a hazard that may result in damage to the product or other property if not avoided. Observe the necessary measures.
⚠	Warning of a hazard that could cause serious injury or death.
ⓘ	Notice of potential material damage.
☞	Useful information on handling the device.
1.	Action. Proceed step by step.
»	Result of an action.
→	Move/plug in this direction.
click	Engage and check for secure fit.

On device, type plate, and packaging

	Follow Instructions for Use
	Consult Instructions for Use
	Warning; pay special attention
	This device complies with the relevant requirements of EU regulations.
	This device complies with the relevant requirements of the Eurasian Economic Union.
	Manufacturer
	Date of manufacture Country of manufacture: Germany

REF	Reference number
UDI	Unique Device Identifier of a medical device
MD	Medical device
SN	Serial number
	Type BF applied part
	Professional disposal
	Connection for light handle to rechargeable LED battery
	Connection for charging power pack with polarity marking
	Test button for battery test
	Recyclable
	Handle with care
	Fragile, handle with care
	Keep dry
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation
IPX0	Specification of the degree of protection against the ingress of solids and moisture

UDI application identifier

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

1.3 Intended purpose

Product name:	ATMOS LS 21 LED
Main function:	LED cold light source for optical instruments. Includes external trigger function.
Intended use / intended purpose:	Illumination of natural orifices (e.g., ear, nose, throat) for diagnosis.
Intended users / User profile:	Doctors and medical specialists
Intended patient target group:	Patients of all age groups without 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 period:	< 60 min
Application environment:	Outpatient medical facilities, e.g., ENT practices, hospital outpatient departments, medical care centers
Patient selection criteria:	None
Indications:	Light source may be used along with other instruments for visual inspection of anatomy.
Medical contraindications:	None
Other contraindications:	None
Warnings:	None
The product is:	Active
Sterility/specific microbial status:	Non-sterile
Single-use device / reprocessing:	Not a single-use product. Reprocessing according to instructions for use.

1.4 Function

The device is intended to illuminate natural orifices (e.g. ear/nose/ throat) for visual diagnosis.

The product is an electrical product. It contains an LED whose luminous flux is focused on a small diameter output. Here, instruments can be adapted for illumination.

1.5 Scope of delivery

- ATMOS LS 21 LED
- Wolf endoscope adapter
- Instructions for Use

1.6 Transport and storage

Prior to dispatch, this ATMOS device was subjected to an extensive functional test and carefully packed. Nevertheless, check the contents of the shipment for completeness immediately upon receipt (see scope of delivery). If you notice any transport damage, or if the packaging has been accidentally opened or the product has been transported or stored under environmental conditions other than those specified in the Technical Data, document and report this.

Transport the product only in a shipping box that is padded and offers sufficient protection.

If you notice any transport damage:

1. Document and report the transport damage.
2. Send the device to ATMOS; see section “5.1 Sending in the device” on page 15.

Environmental conditions for transport and storage:

Observe the information in chapter “9 Technical Data” on page 19.

2 Notes for your safety

2.1 General safety instructions

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

- Ensure that the ATMOS LS 21 LED is used in an EMC area described in the appendix.
- Use the ATMOS LS 21 LED light source only in connection with an ATMOS LED battery or ATMOS power supply.
- Also follow the safety instructions for the connected devices/parts and the safety instructions in the following chapters.
- The ATMOS LS 21 LED may be operated only in rooms used for medical purposes, but not in areas subject to explosion hazards and in oxygen-rich environments.
- Before each use, ensure that the device is functioning properly and is in good condition. Damaged cables must be replaced immediately.
- Pay attention to the correct fit of the light source in the holders.
- Prior to starting up the ATMOS LS 21 LED light source, read these Instructions for Use carefully.
- Attention: The light handle gets warmer during application.
- ATMOS is not liable for personal injury, damage to property, or malfunctions if:
  - no original ATMOS parts are/were used,
  - the instructions on proper use in these Instructions for Use are/were disregarded,
  - assembly, new settings, alterations, extensions, and repairs have been carried out by personnel not authorized by ATMOS.
- Report any serious incidents that have occurred in connection with this product to the manufacturer and your national competent authority.

2.2 Danger to users, patients, and third parties

Only a fully functional product meets the safety requirements of users, patients, and third parties. Therefore, observe the following instructions for your product.

⚠ CAUTION

Always ensure that you do not shine the light into the patient's eyes and that the patient does not look directly into the light source! Never look directly into the light source yourself!

» EYE INJURY!

2.3 Avoiding damage to the device

- There are no warranty claims for damages caused by the use of third-party accessories or consumables.
- For cleaning, never use alcohol or cleaning agents that contain alcohol. Avoid any contact of the lens with alcohol!

⚠ CAUTION

Damage to the device!

If the light source is used with unsuitable adapters, the lens could be badly damaged!

- Use optics only with the supplied and/or optional adapters.
- Make sure the endoscopes with adapter engage in the light source.

3 Operation

3.1 Functional check

Perform a functional check before each 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 or the connecting cable are damaged.
2. Check that the connecting cable is correctly plugged into the power source.
3. Aim the light source at a white surface and switch on the power source to activate the light source.

» The light source illuminates.

4. When using the lithium-ion battery (REF 507.4510.0), check that the light source illuminates in both battery switch positions, Power and Eco.

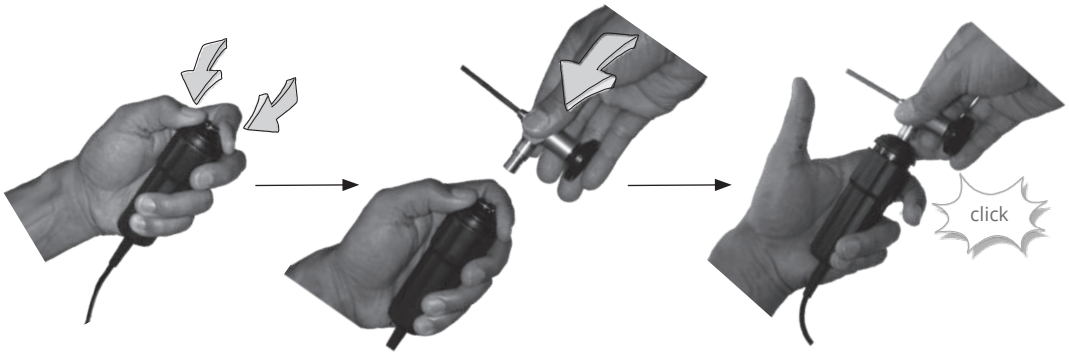
⚠ CAUTION

The light source can heat up to 45 °C during continuous operation. Therefore, take care not to touch the patient with the light source.

3.2 Environmental conditions during operation

Observe the information in chapter “9 Technical Data” on page 19.

3.3 Attaching the application instrument



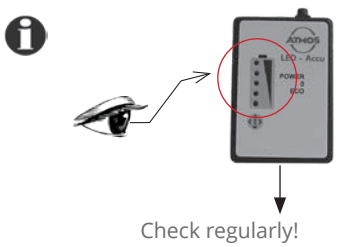
3.4 Connection possibilities of the LED light source



3.5 Operation of the optional LED battery

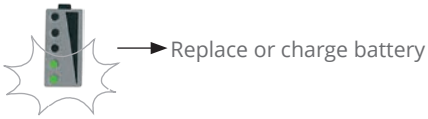
3.5.1 Capacity indicator





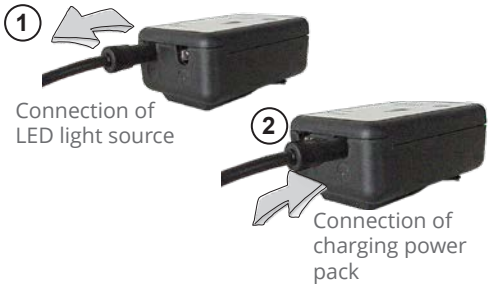
At the end of the battery capacity, the light expires quickly.

- We therefore recommend:

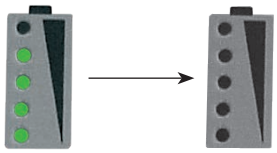


3.5.2 Charging the LED battery

- Use the charger's primary adapter (Euro/US/UK/Aus) that matches your power supply.
- The device cannot be operated while charging.



During the charging process



Constant indication of the current battery capacity

Fully charged: all 5 LEDs are off again

3.5.3 Maintaining the battery

During storage

Do not:	Always do:
• Store discharged over a longer period of time. • Continuously connect the light handle to the charging unit. Overcharging will destroy the batteries.	• Store in charged condition. • Charge at least every 3 months. • Always store the battery with the switch set to "0".

The cooler you store the LED battery, the longer it works.

- Store frost-free!
- Store charged up and cool.

During use

Do not:
Do not continue using the battery if the battery capacity indicator shows "empty" (all LEDs are off). » Charge immediately. The battery needs some residual capacity to function properly. Do not expose the battery to direct sunlight or place it near heaters. » This will reduce the lifespan of the battery.

After approximately 500 charging cycles, the battery is worn out.

☞ Get a replacement in time.

4 Reprocessing

4.1 Safety instructions for reprocessing

4.1.1 General safety instructions

We recommend that you always document all maintenance work and part replacements in writing.

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 are generally necessary.

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

4.1.2 Procedure

	Instructions
Warnings ⚠ WARNING ⚠ WARNING	**Danger to users, patients, and third parties** • Always wear your own personal protective equipment. • Risk of infection due to unsuitable reprocessing. Ensure complete wetting of all surfaces during disinfection. Incomplete wetting may result in insufficient reduction of germs. • The cleaning and disinfection measures described do not replace the applicable regulations at the place of use. • Use only aids that are suitable for reprocessing or are disposable products. **Prevent damage to the device** • Use only lint-free, soft cloths. • Prevent liquids from entering the lens of the ATMOS LS 21 LED light source and the connector. • Unsuitable cleaning agents and disinfectants can damage the product or impair the effectiveness of reprocessing. • Do not expose the product to temperatures above 40 °C before and during cleaning. • Do not put the product into operation until it is completely dry.
Limitations of reprocessing	Products with visible damage must not continue to be used. They must be disposed of properly and replaced with a new, fully functional product. When reprocessing the product, ensure material compatibility. For information on possible limitations, refer to the section “Material resistance”.

Instructions	
Preparation before cleaning	1. Disconnect the ATMOS LS 21 LED from the ATMOS Strobo 21 LED main device before reprocessing. Disconnect the ATMOS Strobo 21 LED main device from the power supply. 2. Disassemble the product for reprocessing into the following components: • ATMOS LS 21 LED • Wolf adapter • Storz adapter (optional)
Manual cleaning	1. Wipe the surfaces of the ATMOS LS 21 LED and, if applicable, the Wolf adapter or Storz adapter evenly. Use a clean, lint-free cloth dampened (never wet) with cleaning agent. ☞ Do not clean the lens of the ATMOS LS 21 LED light source, the device connection, or the inner surfaces/ cavities of the adapters. 2. If visible contamination remains, repeat the cleaning process to avoid impairing the effectiveness of disinfection.
Manual disinfection	1. Wipe the surfaces of the ATMOS LS 21 LED evenly. Use a clean, lint-free cloth dampened (never wet) with disinfectant. Ensure complete wetting to achieve effective disinfection. ☞ Do not disinfect the lens of the ATMOS LS 21 LED light source, the device connection, or the inner surfaces/ cavities of the adapters. 2. Allow the disinfectant to act for the full contact time.
Maintenance, checks, and inspection	1. Verify that reprocessing was successful by performing a visual inspection. 2. If reprocessing was not successful, reprocess the product again.

4.1.3 Material resistance

⚠ WARNING

Unsuitable cleaning agents and disinfectants.

The product may become damaged.

Do not use:

- alcohol or cleaning agents and disinfectants containing alcohol.
- disinfectants containing concentrated organic or inorganic acids, as these may cause corrosion damage.
- disinfectants containing chloramines, phenol derivatives, or anionic surfactants, as these may cause stress cracks in the plastics used.
- disinfectants containing oxidizing agents (e.g., hydrogen peroxide) or halogens (chlorine, bromine, iodine), as these may cause embrittlement and discoloration.
- strongly alkaline solutions (maximum permissible pH value: 9). Neutral or enzymatic cleaning agents are recommended.

☞ Follow the disinfectant manufacturer's instructions for use, especially regarding concentration information and material compatibility.

☞ Use only approved disinfectants with verified efficacy (VAH/DGHM listed).

5 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. The person must have the necessary test equipment and original spare parts to carry out these measures.

ATMOS recommends that the work 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.

- Comply with country-specific requirements regarding regular testing, in particular electrical safety testing. ATMOS recommends a test every 24 months.
- Make sure prior to every application of the equipment that it is technically safe and in proper condition. Damaged cables must be replaced immediately.
- The light source ATMOS LS 21 LED is low-maintenance. The instructions and regulations for the respective field of application should be observed.
- Repair work may be carried out only by expert personnel authorized by ATMOS. In this context, the safety instructions in chapter “2 Notes for your safety” on page 8 must be observed.
- There are no warranty claims whatsoever on defects or malfunctions which arise from the use of third-party accessories or consumables.

5.1 Sending in the device

- Remove and properly dispose of consumables.
- Clean and disinfect the product and accessories according to the Instructions for Use.
- Place any used accessories with the product.
- Fill in the form QD-434 “Delivery complaint / return shipment” and the corresponding **Decontamination certificate**.

☞ This form is enclosed with the product and can be found at www.atmosmed.com.

- Pack the product in suitable packaging with adequate padding.
- Place the form QD-434 “Delivery complaint / return shipment” and the corresponding **Decontamination certificate** in an envelope.
- Affix the envelope to the outside of the package.
- Send the product to ATMOS or to your dealer.

6 Troubleshooting

The ATMOS LS 21 LED was subjected to a thorough quality inspection at the factory. However, should a fault occur, you may be able to remedy it yourself by following the instructions below.

Error indication	Cause of error	Remedy
No light	LED battery is flat	Charge the LED battery
	Cable is not connected properly	Connect the cable
	Cable is defective	Replace the cable
LED battery cannot be charged	LED battery is defective	Replace the LED battery
	Charging power pack is defective	Replace the charging power pack

7 Accessories

Accessories	REF
ATMOS LS 21 LED adapter (Storz)	507.4611.0
ATMOS LS 21 LED adapter (Wolf flex. light guide)	507.0949.0
Lithium-ionic battery	507.4510.0

8 Disposal

- The light source ATMOS LS 21 LED does not contain any hazardous goods.
- The LED battery (lithium-ion) must be disposed of correctly.
- Device and accessories must be decontaminated prior to disposal.
- Pay attention to careful separation of the different materials.
- Comply with applicable national regulations for disposal.

8.1 Expected service life

When used according to the Instructions for Use, the ATMOS LS 21 LED has an expected service life of 5 years. This assumes regular, thorough cleaning and disinfection of the device and its applied parts, as well as operation in accordance with the Instructions for Use.

9 Technical Data

Light source

Current consumption	max. 750 mA DC
Voltage	max. 3.2 V DC
Power consumption	max. 2.4 W
Light emitter “white” Light intensity Light flux Color temperature	 min. 220 klx min. 175 lm typ. 6000 K
Light emitter “warm white” Light intensity Light flux Color temperature	 min. 150 klx min. 120 lm typ. 3900 K
Mode of operation	Continuous operation
Maximum operating altitude	3000 m
Contamination level	2
Overvoltage category	II
Dimensions Diameter Length	 max. Ø 37 mm 104 mm
Weight	200 g
Classification of applied part	ATMOS LS 21 LED: Type BF
Degree of protection	IPX0
CE marking	CE
Protection class against electric shock (acc. to EN 60601-1)	II
Reference numbers (REF)	507.4600.0 ATMOS LS 21 LED 507.4602.0 ATMOS LS 21 LED, warm white 541.4300.0 ATMOS LS 21 LED

Rechargeable battery

Technology	Li-Ion Battery 1S1P	
Battery Voltage	Nominal: 3.6 V DC	
Capacity	2200 mAh	
Energy	7.92 Wh	
Output current	Power mode: ECO-Mode:	700 mA DC ± 10% 400 mA DC ± 10%
Operating time	Power-Mode: ECO-Mode:	min. 120 min min. 300 min
Charging input voltage	12 V DC	
Charging cycles	min. 500	

Dimensions (length x width x height)	73 x 33 x 47 mm
Weight	80 g
Degree of protection	IPX0
Reference number (REF)	507.4510.0

Charging power supply

Input voltage	100 – 240 V AC 50/60 Hz
Output voltage	12 V DC
Output current	max. 1000 mA DC
Protection class against electric shock (acc. to EN 60601-1)	II
CE marking	CE
Reference number (REF)	011.1199.0

General data

Environmental conditions: Transport/storage • Temperature range • Air humidity without condensation • Air pressure	 –20...+50 °C 5...90 % 700...1060 hPa
Environmental conditions: Operation • Temperature range • Air humidity without condensation • Air pressure	 +10...+35 °C 20...80 % 700...1060 hPa
Periodic tests	Recommended: Check every 24 months

10 Notes on EMC

☞ Medical electrical equipment is subject to special precautions regarding EMC and must be installed in accordance with the EMC instructions provided below.

Guidance and manufacturer's declaration – ambient conditions

The ATMOS LS 21 LED is suitable for use in the following environments:

- The ATMOS LS 21 LED may be operated only in rooms used for medical purposes, but not in areas subject to explosion hazards and in oxygen-rich environments. The customer or user of the ATMOS LS 21 LED must ensure that the device is used in the specified environment.

Guidance and manufacturer's declaration – essential performance

☞ Refer to the Technical Data in these Instructions for Use. The essential performance is fully maintained even in the presence of electromagnetic disturbances.

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

The ATMOS LS 21 LED has the following removable components that can be replaced by the operator:

Type	REF	Max. cable length
Power cable	008.0840.0	2 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 21 LED including cables specified by the manufacturer. Failure to comply may result in degradation of the essential performance of the device.

☞ * 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 device must be monitored regularly for proper functioning. If possible, switch off any nearby devices that are not in use.

11 Notes

Notes

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