ATMOS
MedizinTechnik

Instructions for Use

ATMOS HL 21 LED

English



CE

GA1GB.150303.0

2026-08 Index 13

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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 possess the test devices and original spare parts required 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 HL 21 LED (examination set)	REF 507.4505.0
ATMOS HL 21 LED (OT set)	REF 507.4506.0
ATMOS HL 21 LED	REF 507.4500.0
ATMOS HL 21 LED	REF 530.4020.0
ATMOS HL 21 LED	REF 506.7551.0

1.2 Explanation of pictograms and symbols

In the operating instructions

⚠ 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.	Call for 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 (blue)
	Consult Instructions for Use
	Warning; pay special attention
CE	This device complies with the relevant requirements of EU regulations.
EAC	This device complies with the relevant requirements of the Eurasian Economic Union.
	Manufacturer
	Date of manufacture
DE	Date of manufacture Country of manufacture: Germany

REF	Reference number
UDI	Unique Device Identifier of a medical device
MD	Medical device
SN	Serial number
IPX0	Specification of the degree of protection against the ingress of solids and moisture
	Professional disposal
	Recyclable
	Do not look directly into the light source
	Connection for headlamp to LED battery
	Connection for charging power pack with polarity marking
	Test button for battery test
ECO	LED of the headlamp is operated at reduced power
POWER	LED of the headlamp is operated at full power
O	Off
	Handle with care
	Fragile, handle with care
	Keep dry
	Keep away from sunlight
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation

UDI application identifier

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

1.3 Intended use

Product name:	ATMOS HL 21 LED
Main functions:	Medical LED cold light source with headband for fixation on the head of examiner
Intended purpose:	Illumination of orifices (e.g. ear/nose/throat) for visual diagnostics
Intended Users / User profile:	Doctors 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:	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:	Whenever visual examination is indicated
Medical contra-indications:	None
Other contra-indications:	None
Warnings:	None
The product is:	active
Sterility/specific microbial status:	Non sterile
Single use product / reprocessing:	Not a single-use product. Reprocessing according to Instructions for Use.

1.4 Function

This product is a cold light source for medical use. The light source can be worn on the head and 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 an output of adjustable diameter at a suitable working distance.

1.5 Scope of delivery

REF	507.4500.0	507.4505.0	507.4506.0	530.4020.0	506.7551.0
Headlamp ATMOS HL 21 LED	1	1	1	1	1
Charging power pack (Euro/UK/US/ Aus)	-	1	1	-	-
LED battery	-	1	2	-	-
Cable 40 cm	-	1	1	-	-
Cable 140 cm	-	-	1	-	-
Cable 200 cm	-	-	-	1	1
Battery holder	1	1	1	-	-
Cable clip	-		1	1	1

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 “6.1 Sending in the device” on page 16.

Environmental conditions for transport and storage:

See chapter “10 Technical Data” on page 20.

2 Notes for your safety

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

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

ATMOS neither guarantees error-free operation nor assumes liability for personal injury or property damage if non-original ATMOS parts are used, if the Instructions for Use are not observed, or if installation, recalibration, modifications, extensions, or repairs are performed by persons not authorized by ATMOS.

There are no warranty claims whatsoever on defects or malfunctions that arise from the use of third-party accessories or consumables.

2.2 Danger to users, patients and third parties

⚠ WARNING

Danger of eye injury.

Your patient can be severely injured.

- Please make sure you never point or direct the beam into the patient's eyes. Before the examination, instruct the patient not to look directly into the light source.

⚠ CAUTION

Keep the device fully functional.

Your patient could be injured due to a missed diagnosis or light failure during treatment.

- Before each use, ensure that the device is functioning properly and is in good condition. Damaged cables must be replaced immediately.
- Please make sure that the ATMOS HL 21 LED is used in the described EMC environment.
- During each application, pay attention to proper fit of the headlamp ATMOS HL 21 LED.
- During surgery, please note that the headlamp ATMOS HL 21 LED is not sterile.
- If the headlamp ATMOS HL 21 LED is used by several users, regular cleaning and disinfection must be carried out.
- Charging of the LED battery must be checked regularly, as the light goes out very quickly when the battery goes flat.
- Switch off the headlamp ATMOS HL 21 LED when not in use.
- Please observe that the light source of the headlamp may reach a temperature of up to 49 °C in continuous operation. Therefore, take care not to touch the patient with the light source during the examination.
- Only use the charging power pack supplied by ATMOS.
- Use the headlamp ATMOS HL 21 LED only in connection with the rechargeable ATMOS LED battery or ATMOS current sources.
- Disconnection of the charging power pack from the power supply is only guaranteed when the charging power pack is unplugged from the power socket.

2.3 Prevent damage to the device

NOTICE

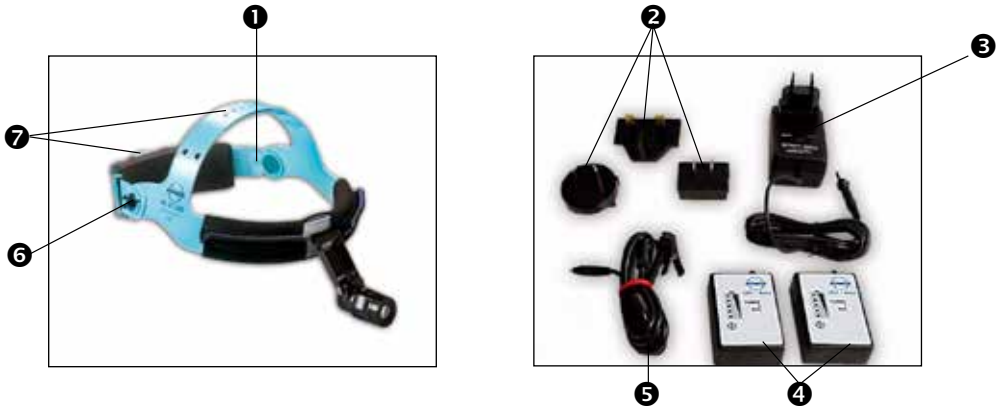
Storage and operation in an unsuitable environment.

The electronics can become damaged.

- Observe the environmental conditions in chapter “10 Technical Data” on page 20.

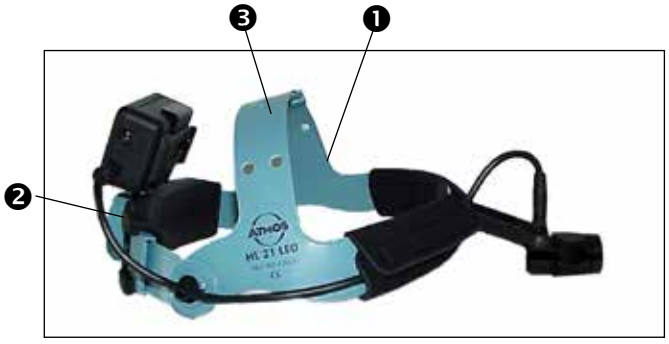
3 Setting up and starting up

3.1 Device overview



3.2 Individual components of the headlamp

1. Headlamp ATMOS HL 21 LED
2. Different power plugs for charging power pack (Euro/UK/US/Aus)
3. Recharging unit, 12 V DC
4. LED rechargeable battery
5. Connecting cable 40 cm, 140 cm and 200 cm long
6. Cable holder on the headlamp frame
7. Adjusting instruments on the headlamp frame



1. Headlamp frame
2. Locking screw for adjusting the circumference
3. Strap for adjusting the height

Make sure you observe the safety instructions in “2 Notes for your safety” on page 8 before initial start-up.

Prior to using the headlamp for the first time, charge the LED battery by means of the supplied charging power pack.

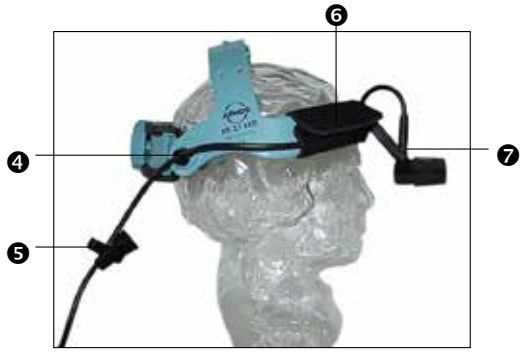
3.3 Adjustment to the head circumference

1. First, take the headlamp frame incl. headlamp and put it on a table in front of you.

Adjusting the headlamp frame:

1. Use the locking screw to set the headlamp frame gradually to a comfortable and correct fit, according to the circumference of the head. The height of the headlamp frame is adjusted by means of a strap.

☞ The lower edge of the headlamp frame is to be positioned directly above the ears.



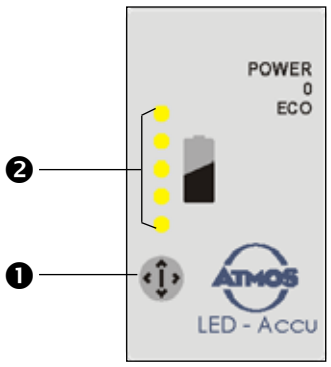
❹ Cable holder
❺ Cable clip
❻ Front pad
❼ Headlamp connection

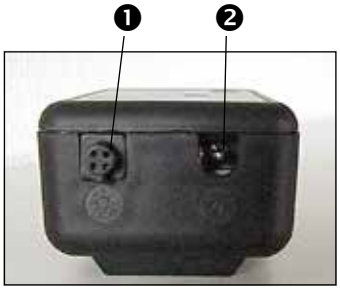
Connection of LED light battery



- Take one of the enclosed connecting cables and join it to the ATMOS HL 21 LED headlamp connection (❼).
- Use the short connecting cable if you want to carry the LED battery on the headband.
- Use the long connecting cable if you want to carry the LED battery in your coat pocket, in your trouser pocket, or on your belt or if it is to be supplied by an ATMOS power source. If necessary, lead the cable under the front pad and through the cable holders in the joint of the headlamp ATMOS HL 21 LED.
- Use the enclosed cable clip (❺) to fix the long cable to your clothes.
- Join the other end of the connecting cable with the socket on the rechargeable LED battery or the power source in your ATMOS treatment unit.

☞ By means of its rear cable clip, the LED battery can be fixed to your coat pocket, to your belt, or to the battery holder on the headlamp ATMOS HL 21 LED.





❶ Test button

❷ Battery capacity indication (green LED)

❶ Connection socket for headlamp

❷ Charging socket of LED battery

3.4 Functionality of the LED battery

3.4.1 Capacity indication

ⓘ Charging of the LED battery must be checked regularly, as the light goes out very quickly when the battery goes flat. We recommend changing or charging the battery when the capacity is <50%.

☞ As long as the test button of the LED battery is pressed, the battery capacity is shown for approx. 3 seconds.

3.4.2 Charging the LED battery

- Use the primary adapter fitting your power supply (Euro/US/UK/Aus). See information enclosed with the recharging unit.
- To charge the LED battery, disconnect it from the headlamp ATMOS HL 21 LED.
- Join the round connector of the recharging unit to the charging socket of the LED battery.
- The current battery capacity is constantly indicated during the charging process. The battery is fully charged when all five LEDs go out again.

ⓘ During charging, operation of the headlamp is impossible!



Headlamp without battery holder



Headlamp with battery holder

4 Operation

4.1 Functional inspection before each use

To ensure safe and intended operation, the ATMOS HL 21 LED headlamp must undergo a visual and functional inspection before each use on a patient.

Test steps and acceptance criteria:

1. **Visual Inspection:**
   Check the headlamp frame, lamp housing, and all connecting cables and connectors for signs of mechanical damage.

» Acceptance criterion: No housing fractures, cracks, exposed cable conductors, or cable damage are visible. The lens is clean.

2. **Battery capacity:**
   Press the test button on the LED battery.

» Acceptance criterion: The green status indicator shows sufficient battery capacity (recommended: > 50%).

3. **Functional inspection:**
   Turn on the headlamp.

» Acceptance criterion: The light turns on immediately, provides uniform illumination without flickering, and the focus ring rotates freely and smoothly.

Actions to be taken if inspection criteria are not met:

If the product fails to meet one or more of the above acceptance criteria (failed functional inspection), the medical device must not be used. A safe application on the patient can no longer be guaranteed.

Try to correct the fault using the information provided in Chapter “7 Troubleshooting” on page 17.

If the fault cannot be corrected, the device must be taken out of service and ATMOS Service or an authorized service partner must be contacted.

4.2 Different variants of the headlamp ATMOS HL 21 LED

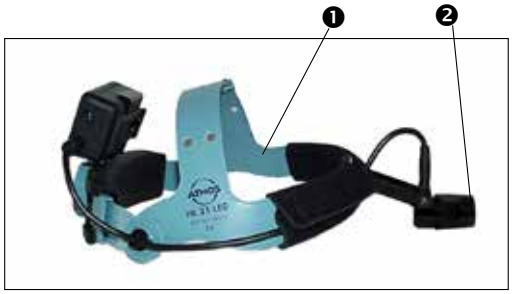
1. Headlamp ATMOS HL 21 LED with long cable, supply from the LED battery in the coat pocket or from a suitable ATMOS power source in an ENT treatment unit.

ⓘ Also pay attention to the respective Instructions for Use of the ATMOS ENT treatment unit.

2. Headlamp ATMOS HL 21 LED with short cable, LED battery in battery holder on the headlamp.

For removing the battery holder, proceed as follows:

1. Use the locking screw to adjust the headlamp frame quite tight.
2. Remove the center cover in the locking screw and then take a Phillips-head screwdriver to remove the screw.
3. Remove the locking screw, then remove the battery holder.
4. Add the locking screw again. Make sure that the tight adjustment of the headlamp frame has not changed. Otherwise, the headlamp frame must be pushed together again.
5. Insert screw and replace the cover cap.



❶ Headlight frame
❷ Focusing ring

4.3 Switching on

Adjust the lateral switch on the LED battery to the desired position:

- **ECO mode:** operation for approx. 4 hours.
- **POWER mode:** operation for approx. 2 hours.

4.4 Focusing the headlight

The size of the light spot can be set by turning the focusing ring.

5 Reprocessing

5.1 Cleaning

The described actions relating to cleaning and disinfection or sterilization do not substitute the relevant instructions which must be adhered to prior to operation!

- Follow the disinfectant manufacturer's instructions for use, especially regarding concentration information and material compatibility.
- Do **not** use:
  - disinfectants containing concentrated organic or inorganic acids or bases since these may cause corrosion damage.
  - disinfectants containing chloramines, phenol derivatives, or anionic surfactants since these may cause stress cracks in the plastics used.
- If the headlamp ATMOS HL 21 LED is used by several users, regular cleaning and disinfection must be carried out.
- Do not touch the lens in the lamp housing.

  Fingerprints can be wiped down with a soft cloth. If necessary, you may use ethanol.
  - The surfaces can be cleaned with a moist cloth. If necessary, you may use ethanol.
  - The headlamp ATMOS HL 21 LED cannot be sterilized.
  - The light body and the rigid headlamp frame can be wiped down on the outside with a cloth moistened with a surface disinfectant (see chapter 5.1).
  - The front pad can be cleaned using a brush, clear water, and soap. If necessary, you may use a 70%-ethanol solution. The cleaning agent must not contain toluene. The front pad may also be washed in the washing machine at 30 °C. It may not be spin-dried or be put in the tumble dryer.

5.2 Recommended surface disinfectants

Disinfectant	Ingredients	(in 100 g)	Manufacturer
Incidin® Plus (Application concentrate)	Glucoprotamine non-ionic surfactants Solvents, complexing agents	26.0 g	Henkel, Düsseldorf
Dismozon® plus (Application concentrate)	Magnesium monoperoxyphthalate hexahydrate	95.8 g	Bode Chemie, Hamburg
Green & Clean SK (Application concentrate)	Alkyldimethylbenzylammoniumchloride Dialkyl-dimethyl-ammonium chloride	< 1 g	Metasys, Rum (Austria)

6 Maintenance and service

- Before each use, ensure that the device is functioning properly and is in good condition. Damaged cables must be replaced immediately!
- The headlamp ATMOS HL 21 LED is low-maintenance. However, the regulations and instructions applying to the respective field of application have to be observed.
- 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 possess the 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 repairs and tests are carried out professionally, original spare parts are used and warranty claims remain unaffected.
- Comply with the country-specific guidelines regarding regular testing, especially with regard to electrical safety. ATMOS recommends an inspection every 24 months.
- For repair, this device can be returned to ATMOS.
- ATMOS neither guarantees for fault-free operation nor for personal injuries and damage to property if
  - no original ATMOS parts are being used,
  - the advice for use in these operating instructions is not being observed,
  - assembly, new settings, alterations, extensions, and repairs have not been carried out by personnel authorized by ATMOS.
- There are no warranty claims whatsoever on defects or malfunctions which arise from the use of third-party accessories or consumables.
- Rechargeable batteries are wearing parts and therefore excluded from the general 2-year product liability!

6.1 Sending in the device

1. Clean and disinfect the product and accessories in accordance with the operating instructions.
2. Place any used accessories with the product.
3. Fill in the form VT-0184 “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. The device must be well padded and packed in suitable packaging.
5. Place the form VT-0184 “Delivery complaint / return shipment” and the corresponding **Decontamination certificate** in an envelope.
6. Affix the envelope to the outside of the package.
7. Send the product to ATMOS or your dealer.

7 Troubleshooting

The ATMOS HL 21 LED was subjected to a thorough quality control in the factory. If there is, nevertheless, some malfunction, you possibly might solve this problem yourself if you observe the following instructions.

Error symptom	Cause of error	Troubleshooting
No light	LED battery is flat	Charge LED battery
	Cable is not connected properly	Connect cable
	Cable is defective	New cable
LED battery cannot be charged	LED battery is defective	New battery
	Charging power pack is defective	New charging power pack

8 Accessories

Accessories	REF
Lithium-ionic battery	507.4510.0

9 Disposal

Packaging

1. Recycle the device packaging.

ATMOS HL 21 LED



Do not dispose of the device with household waste.

The ATMOS HL 21 LED does not contain any hazardous goods.

1. Clean and disinfect the device.
2. In Germany: return the device to ATMOS or your specialist dealer. They will dispose of the device properly.
3. In other countries: dispose of the device properly and in accordance with applicable national 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.

In principle, the housing is fully recyclable. However, comply with applicable national laws and regulations.

9.1 Expected service life

When used according to the Instructions for Use, the ATMOS HL 21 LED has an expected service life of 10 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.

10 Technical Data

Light source

Current consumption	max. 700 mA DC
Voltage	max. 3.1 V DC
Power consumption	max. 2.2 W
Light intensity	min. 100 klx
Color temperature	Typ. 5500 K
LED service life:	max. 50,000 h
Illuminated Field Diameter:	25-55 mm (focused at 17 cm)
Mode of operation	Continuous operation
Maximum operating altitude	3000 m
Contamination level	2
Overvoltage category	II
Dimensions:	Headlamp frame: Adjustable circumference: 50–64 cm, adjustable height: 92–115 mm Connecting cable: 40 cm, 140 cm and 200 cm long
Weight:	Approx. 200 g
Degree of protection	IPX0
CE marking	CE
Protection class against electric shock (acc. to EN 60601-1):	II
Reference numbers (REF)	507.4500.0 ATMOS HL 21 LED 507.4505.0 ATMOS HL 21 LED (examination set) 507.4506.0 ATMOS HL 21 LED (OT set) 506.7551.0 ATMOS HL 21 LED 530.4020.0 ATMOS HL 21 LED

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	90 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:	–20...+50 °C
– Air humidity without condensation:	5...90 %
– Pressure:	700...1060 hPa
Environmental conditions: Operation	
– Temperature:	+10...+35 °C
– Air humidity without condensation:	20...80 %
– Pressure:	700...1060 hPa
Periodical tests:	Recommended: Check every 24 months

11 Notes on EMC

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

Guidance and manufacturer's declaration – ambient conditions

The ATMOS HL 21 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 theatres/rooms.

The following environments are not suitable:

- It in the vicinity of HF surgical devices and in settings outside of an HF-shielded room of a magnetic resonance imaging system.
- Special environments such as factory or military facilities and medical areas near HF surgical devices, short-wave therapy equipment, or within an HF-shielded room of a magnetic resonance imaging system.

The customer or user of the ATMOS HL 21 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 – removable components that can be replaced by the operator

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

Type	REF	Max. cable length
Charging power pack	011.1199.0	1.8 m
Connecting cable	507.4542.0	0.4 m
Connecting cable	507.4541.0	1.4 m
Connecting cable	507.4545.0	2.0 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 HL 21 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.

12 Notes

MedizinTechnik

ATMOS MedizinTechnik GmbH & Co. KG
Ludwig-Kegel-Str. 16
79853 Lenzkirch / Germany
Phone: +49 7653 689-0
info@atmosmed.de