



MedizinTechnik

English

Operating Instructions

ATMOS[®] LS 21 LED

Light source



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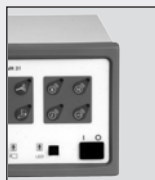
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1.1 Notes on Operating Instructions



These operating instructions contain important notes on how to operate the ATMOS® LS 21 LED safely, correctly and effectively. Their reading helps to avoid risks, and also to reduce repair costs and down-times. This increases, amongst other things, the reliability and service-life of the device.

These operating instructions serve not only for new operating personnel to be instructed in its use, but also for use as a reference manual. Reprints (also in extracts) only with permission in written form by ATMOS.

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



- The product ATMOS® LS 21 LED bears CE marking CE according to the EC Directive of the council for medical products 93/42/EEC and meets the basic requirements of Appendix I of the directive.
- The product ATMOS® LS 21 LED complies with all applicable requirements of the Directive 2011/65/EC restricting the use of certain hazardous substances in electrical and electronic equipment ("RoHS").
- The declaration of conformity and our general standard terms and conditions can be obtained on our website at www.atmosmed.com.
- The quality management system applied at ATMOS has been certified according to international standards EN ISO 13485.
- Prior to start-up please peruse chapter 2.0 „For your safety“, in order to be prepared for any possible dangerous situations.

1.2 Intended use

Name: ATMOS® LS 21 LED

Main function:

LED light source for optical instruments to illuminate body openings (ear, nose, throat).

Medical indications / application:

Illumination of body orifices (ear, nose, throat)

Specification of the main function:

Type of light source: LED lamp (high intensity)

Energy source: Rechargeable battery or current source

Application organ:

ENT examination: Ear, nose, throat

OT: For use in the OT by ENT doctors, gynaecologists, cardiologists, orthopaedics, cosmetic/plastic surgeons, proctologists

Application time:

ENT: temporary (up to 60 mins)

OT: for a maximum of 4 hours

Application site:

ENT examination: in clinic and practice of ENT doctors

OT: Operating theatre

The light source may only be used by medical trained staff.

Contraindications:

Do not use in explosive areas.

The product is: Active

Sterility:

Not necessary

Single-use product / reprocessing:

No single use product

1.3 Function

The light source ATMOS LS 21 LED is used to connect it to optical instruments like rigid and flexible endoscopes respectively laryngoscopes for illumination of throat, nose and ear.

The anodized aluminium lamp body of the ATMOS® LS 21 LED is slender which enables an ergonomic fixation to the instrument.

There is an adapter sleeve available for adaptation to current endoscopes which enables the connection of optics from Storz, Wolf and as per ACMI standard. The optical instruments with an ATMOS adapter sleeve snap in at the light source with a ball-shaped quick lock.

The power supply for the light source may either be an ATMOS power source (power source integrated in the ENT unit) for LED lamps or the rechargeable LED battery (please also see HL 21 LED headlight).

The light source has a fix connecting cable with a plug, which fits both to the rechargeable battery or to the power supply of the unit.

The light of the 2 Watt LED is beamed into the optical instrument with a launching lens.

The electrical components (connecting lead and LED) are installed in the housing and are isolated (4kV). Therefore, the light source fulfils the requirements for endoscopes respectively its light sources in accordance with DIN EN 60601-2-18 (labelling as an application part type BF).



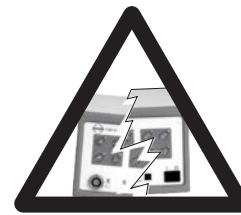
General safety information

- Please make sure that the ATMOS® LS 21 LED is used in an EMC area described in the appendix.
 - Please use the light source ATMOS® LS 21 LED only in connection with the rechargeable ATMOS LED battery or ATMOS current sources.
 - Pay also attention to the safety information of the attached devices / parts as well as to the safety informations 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.
- Make sure prior to every application of the equipment that it is technically safe and in proper condition. Damaged cables must be replaced immediately!
 - Pay attention to the correct fit of the light source in the holders.
 - Only use power sources manufactured by ATMOS.
 - Prior to starting up the light source ATMOS LS 21 LED, read these operating instructions carefully.
 - Attention: The light handle gets warmer during application.
 - ATMOS is not liable for personal injury and damage to property or malfunctions 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 been carried out by personnel not authorised by ATMOS.



Risk of injury!

- Always make sure that you do not blind patients with the light source! Watch out that patients do not look directly into the light source! Never look directly into the light source!
> EYE INJURY



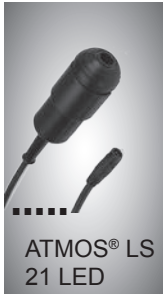
Danger to the device!

- There are no warranty claims whatsoever on defects which arise from the use of third party accessories or consumables.
- For cleaning, never use alcohol or alcoholic cleaning agents. Avoid any contact of the lens with alcohol!

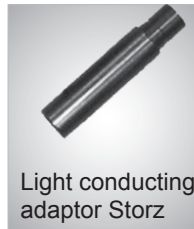
3.0 Scope of supply and connection



3.1 Scope of delivery



Optional:



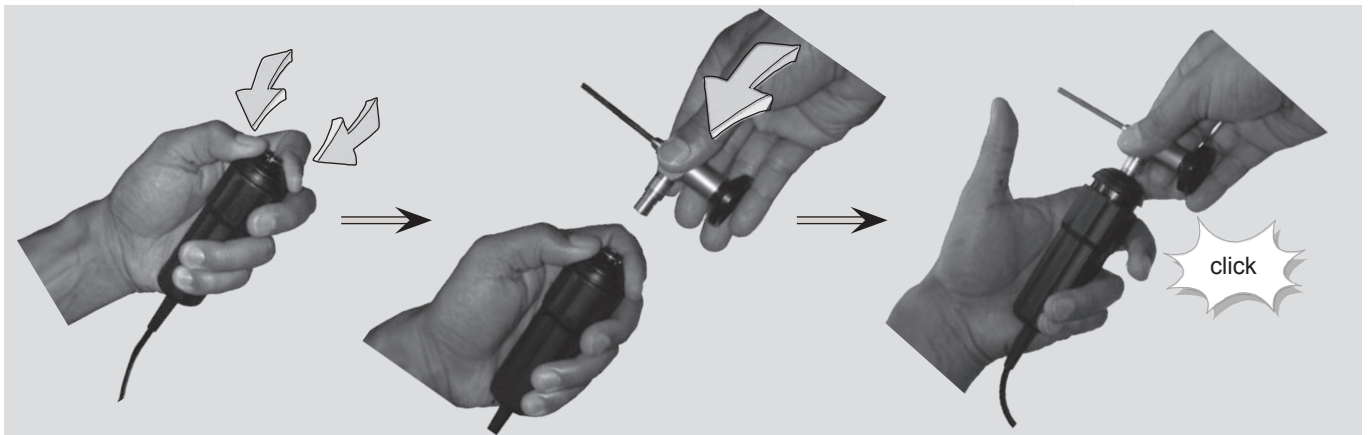
3.2 Connection



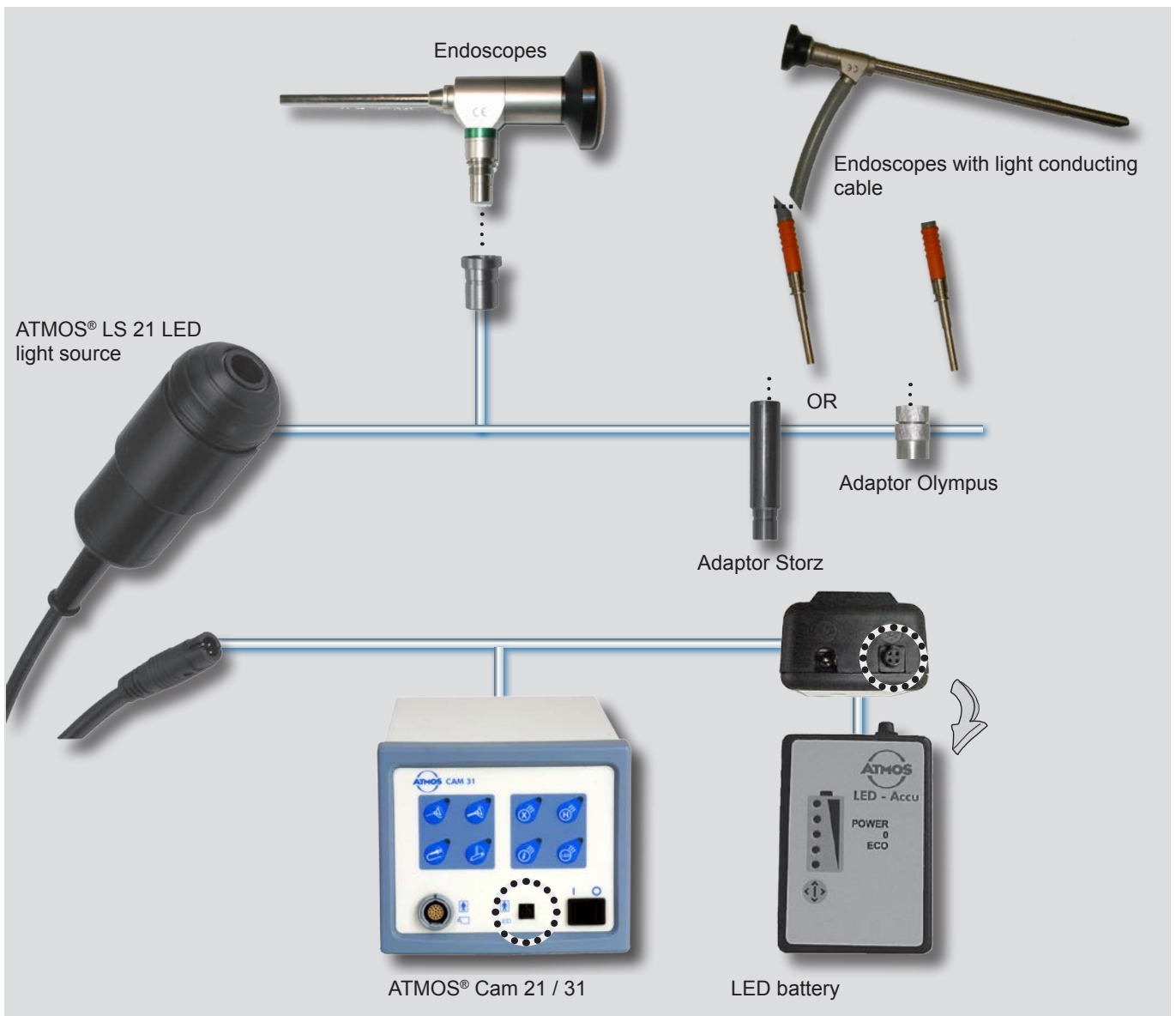
* Not contained in scope of delivery. Optionally available.

	Danger to the device!
CAUTION!	<ul style="list-style-type: none"> • If the light source is used with unsuitable adaptors, the lens could be badly damaged! <ul style="list-style-type: none"> - Use optics only with the supplied and/or optional adaptors! - Make sure, the endoscopes with adaptor engage in the light source!

4.1 Attaching the application part

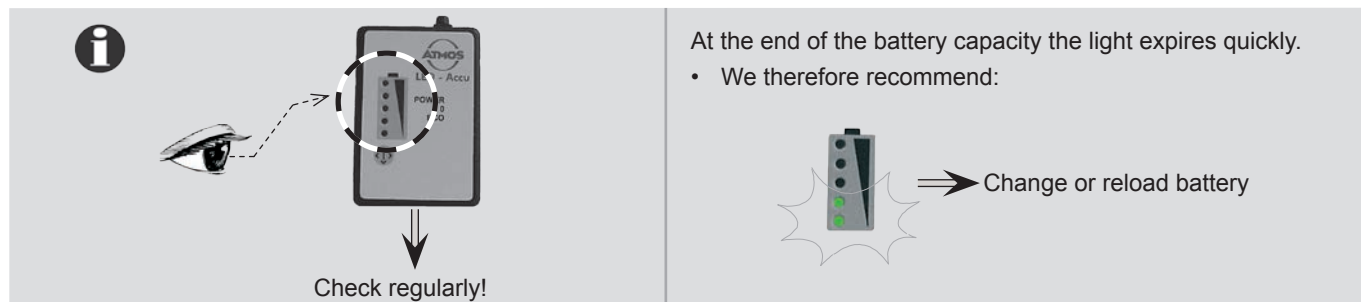


4.2 Connection possibilities of the light source



4.3 Operation of the optional LED battery

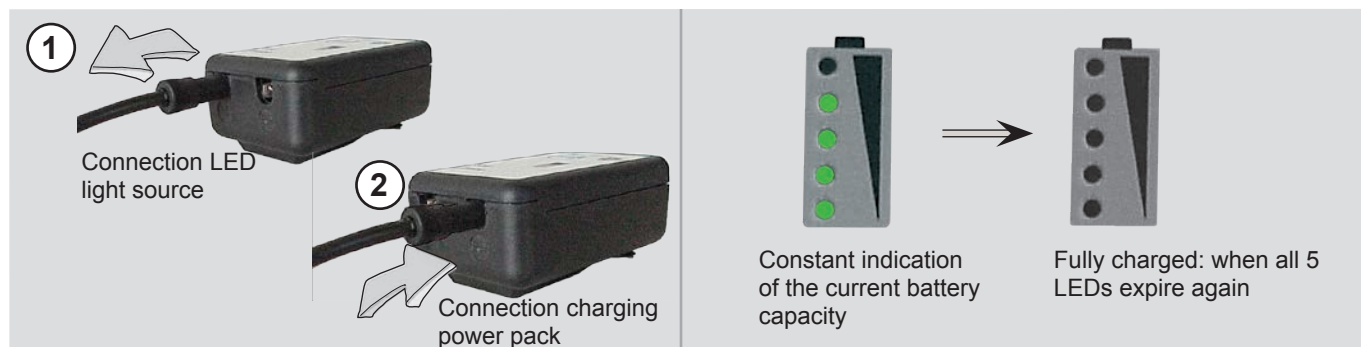
4.3.1 Indication of capacity



4.3.2 Reloading the LED battery

- i** • Use the primary adaptor fitting your power supply (Euro/US/UK/Aus).
- During charging, operation of the headlight is not possible!

During charging process



4.3.3 Maintenance of battery

During storage

Do not:	Always do:
<ul style="list-style-type: none"> • Store discharged over a longer period of time. • Do not continuously connect the light handle to the recharging unit. Overcharging will destroy the batteries. 	<ul style="list-style-type: none"> • Store in charged condition. • Charge at least all 3 months.
<p>i</p> <p>The cooler you store the LED battery, the longer it works.</p> <ul style="list-style-type: none"> • Store frost-free! • Store charged up and cool (e.g. in the fridge). 	

During usage

Do not:
<ul style="list-style-type: none"> • „Suck it out“! When the capacity indication shows „empty“ (all LEDs are out) do not use the battery any more. <ul style="list-style-type: none"> - Recharge immediately! For flawless operation the battery needs a residue capacity. • Expose the battery to solar radiation or put it close to heaters. <ul style="list-style-type: none"> - This will reduce the lifespan of the battery.
<p>i</p> <p>After approx. 500 charging cycles the battery is flat.</p> <ul style="list-style-type: none"> • Get a replacement in time.

- i** • For cleaning, never use alcohol or alcoholic cleaning agents. Avoid any contact of the lens with alcohol!
- Please observe the operating instructions for use prescribed by the manufacturers of disinfectants. Pay attention regarding concentration and material compatibility.
- Do not use:
 - disinfectants which contain concentrated organic or inorganic acids as they could cause corrosion damage.
 - Disinfectants containing chloramides, phenol derivatives or anionic tensides, as these may cause stress cracks in the material used for the housing of the unit.
- Do not moisten the lens in the light object with liquids.
- The surfaces can be cleaned with a moist cloth.
- The device has to be cleaned and disinfected regularly, if it is applied by several users.

Surface disinfectants

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

6.0 Repairs and servicing



Maintenance, repairs and period 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.

- Please comply with the country-specific guidelines regarding regular testing especially for the electrical safety. 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 authorised by ATMOS. At this pay attention to chapter 2.0 „For your safety“.
- There are no warranty claims whatsoever on defects or malfunctions which arise from the use of third party accessories or consumables.

6.1 Sending in the device

- Remove and properly dispose of consumables.
- Clean and disinfect the product and accessories according to the operating instructions.
- Place used accessories with the product.
- Fill in the form QD 434 „Delivery complaint / return shipment“ and the respective **decontamination certificate**.
☞ This form is enclosed to each delivery and can be found at www.atmosmed.com.
- The device must be well padded and packed in suitable packaging.
- Place the form QD 434 „Delivery complaint / return shipment“ and the respective **decontamination certificate** in an envelope.
- Affix the envelope to the outside of the package.
- Send the product to ATMOS or to your dealer.

7.0 Troubleshooting

The ATMOS® LS 21 LED was subjected to a thorough quality control in the factory. If however any problems should occur, you can possibly eliminate these personally, if observing the following notes.

Error indication	Cause of error	Troubleshooting
No light	<ul style="list-style-type: none">• LED battery is flat• Cable is not connected properly• Cable is defective	<ul style="list-style-type: none">• Charge LED battery• Connect cable• New cable
LED battery cannot be charged	<ul style="list-style-type: none">• LED battery is defective• Charging power pack is defective	<ul style="list-style-type: none">• New LED battery is required• New charging power pack is required


8.1 Accessories	REF
LED battery	507.4510.0
Battery recharging unit	011.1199.0
Endoscope adaptor Wolf	507.4657.0
Adaptor for light conducting cables with detent	507.4611.0
Adaptor Storz for light conducting cables for screwing	507.4612.0
Adaptor Olympus for flexible endoscopes	507.0949.0
Laryngoscopes	REF
Laryngoscope 70° Ø 10 mm, working length 176 mm, autoclavable, without light guide	950.0209.0
Laryngoscope 70°, Ø 8 mm, working length 166 mm, autoclavable, without light guide	950.0246.0
Laryngoscope 90°, Ø 10 mm, working length 174 mm, autoclavable, without light guide	950.0210.0
Tele-magnifying laryngoscope 70° Ø 10 mm, working length 147.5 mm, can be immersed, without light guide	950.0211.0
Tele-magnifying laryngoscope 90° Ø 10 mm, working length 145 mm, can be immersed, without light guide	950.0212.0
Ear endoscopes	
Wide-angle optic, 0° Working length: 50 mm, Ø 4 mm, autoclavable	950.0213.0
Wide-angle optic, 30° Working length: 50 mm, Ø 4 mm, autoclavable	950.0214.0
Wide-angle optic, 0° Working length: 34 mm, Ø 2.7 mm, can be immersed Incl. adapter for ear-speculum	950.0215.0
Nose / Pharynx endoscopes Ø 4 mm	
Wide-angle optic, 0° Working length: 180 mm, Ø 4 mm, autoclavable	950.0216.0
Wide-angle optic, 30° Working length: 180 mm, Ø 4 mm, autoclavable	950.0217.0
Wide-angle optic, 45° Working length: 180 mm, Ø 4 mm, autoclavable	950.0218.0
Wide-angle optic, 70° Working length: 180 mm, Ø 4 mm, autoclavable	950.0219.0
Nose/Pharynx endoscopes wide angle Ø 2.7 mm	
Wide-angle optic, 0° Working length: 110 mm, Ø 2.7 mm, autoclavable	950.0220.0
Wide-angle optic, 30° Working length: 110 mm, Ø 2.7 mm, autoclavable	950.0221.0
Flexible endoscopes	
High-resolution Naso-Pharyngoscope Ø 3.8 mm, Working length 300 mm, 0°, angle of field of view 80° Depth of focus: 5 mm – infinite Angle 125° / 125° Supplied incl. aluminium carrying case, leakage tester	950.0222.0

8.2 Spare parts

Operating Instructions

9.0 Technical data



Charger	100...240 V~ 50/60 Hz; exchangeable primary adapters (Euro/UK/US/Aus); secondary 12 V DC; max. 0.8 A via 1.8 m cable with DC plug 5.5 x 2.5 mm; protection class II; only for dry rooms
LED battery	Charging with 12V DC; max. 0.8 A, max. charging time 1h 50min after complete discharge; automatic switchover to compensation charging; capacity indication by 5 LEDs at the touch of a button and during the charging process; Lithium-ion battery with 3.7 V nominal voltage and a 1800 mAh capacity; at least 500 charging cycles possible; switch with 2 operating modes (Power and ECO): 240 min operation with full light performance and at least 330 min with reduced light performance; weight approx. 80 g
Light emitter white high-performance LED	
Electricity	700 mA
Performance	2 W
Light intensity	Min. 220 klx
Light flux	Min. 175 lm
Colour temperature	Type 6000 K
Light emitter warm white high-performance LED	
Electricity	700 mA
Performance	2 W
Light intensity	Min. 150 klx
Light flux	Min. 120 lm
Colour temperature	Type 3900 K
Ambient conditions transport / storage	
• Temperature	-20...+50 °C
• Humidity without condensation	5...90 %
• Air pressure	700...1060 hPa
Ambient conditions for operation	
• Temperature	+10...+35 °C
• Humidity without condensation	20...80 %
• Air pressure	700...1060 hPa
Period tests	Recommended: Testing every 24 months.
Protection class (EN60601-1)	II (Charging power pack)
Degree of protection	Application part type BF 
Type of protection	IP X0
Classification according to Appendix IX EC Directive 93/42/EEC	Class 1
CE marking	CE
GMDN code	12340
UMDNS code	12-340
ID No. (REF)	507.4600.0 white light 507.4602.0 warm white

10.0 Disposal

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



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

11.1 Guidelines and Manufacturer's Declaration - Emissions

The ATMOS® LS 21 LED light source is intended for use in the electromagnetic environment specified below. The customer or user of the ATMOS® LS 21 LED should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions acc.to CISPR 11	Group 1	The ATMOS® LS 21 LED uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions acc. to CISPR 11	Class B	The ATMOS® LS 21 LED is suitable for use in all establishments, including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions according to IEC 61000-3-2	Inapplicable	
Voltage fluctuations/flicker acc. to IEC 61000-3-3	Inapplicable	

11.2 Guidelines and Manufacturer's Declaration - Immunity

The ATMOS® LS 21 LED is intended for use in the electromagnetic environment specified below. The customer or user of the ATMOS® LS 21 LED should ensure that it is used in such an environment.

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



Immunity Test	IEC 60601- Test Level	Compliance Level	Electromagnetic Environment - Guidance
Voltage Dips / Dropout IEC 61000-4-11	$< 5\% U_T$ (> 95 % Dip of the U_T) for 0.5 Cycle $40\% U_T$ (60% Dip of the U_T) For 5 cycles $70\% U_T$ (30 % Dip of the U_T) For 25 cycles $< 5\% U_T$ (> 95 % Dip of the U_T) for 5 s	$< 5\% U_T$ (> 95 % Dip of the U_T) for 0.5 Cycle $40\% U_T$ (60% Dip of the U_T) For 5 cycles $70\% U_T$ (30 % Dip of the U_T) For 25 cycles $< 5\% U_T$ (> 95 % Dip of the U_T) for 5 s	The quality of the supply voltage should correspond to a typical commercial or hospital environment. If the user of the ATMOS® LS 21 LED requires continued function during interruptions of the energy supply, it is recommended to supply the ATMOS® LS 21 LED from an uninterruptible power supply or a battery.
NOTE U_T is the mains alternating current prior to application of the test levels.			

11.3 Guidelines and Manufacturer's Declaration - Immunity

The ATMOS® LS 21 LED is intended for use in the electromagnetic environment specified below. The customer or user of the ATMOS® LS 21 LED should ensure that it is used in such an environment.

Immunity Test	IEC 60601- Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 V _{eff} 150 kHz to 80 MHz	10V	Portable and mobile communications equipment should be separated from the ATMOS® LS 21 LED including the cables by no less than the distances calculated/listed below. Recommended distances: $d = 0.35\sqrt{P}$ $d = 0.35\sqrt{P}$ 80 MHz to 800 MHz $d = 0.7\sqrt{P}$ 800 MHz to 2.5 GHz where „P“ is the max. power in watts (W) and d is the recommended separation distance in meters (m). Field strengths from fixed transmitters, as determined by an electromagnetic site (a) survey, should be less than the compliance level (b). Interference may occur in the vicinity of equipment containing following symbol:
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	10V/m	



NOTE 1

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

NOTE 2

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

a

The field strength of stationary transmitters, such as base stations of cellular phones and mobile terrain radio equipment, amateur radio transmitters, cbm broadcast and TV stations cannot be predestined exactly. To determine the electromagnetic environment in regard to stationary transmitters, a study of the location is to be considered. If the measured field strength at the location where the ATMOS® LS 21 LED is used exceeds the above compliance level, the ATMOS® LS 21 LED is to be observed to verify the intended use. If abnormal performance characteristics are noted, additional measures might be necessary, e. g. a changed arrangement or another location for the ATMOS® LS 21 LED

b

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

11.4 Recommended safety distance between portable and mobile RF Communications equipment and the ATMOS® LS 21 LED

The ATMOS® LS 21 LED is intended for use in electromagnetic environment in which radiated disturbances are controlled. The customer or user of the ATMOS® LS 21 LED can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications equipment and the ATMOS® LS 21 LED as recommended below, according to the maximum output power of the communications equipment

Power of transmitter W	Safety distance, depending on transmit-frequency m		
	150 kHz to 80 MHz $d = 0.35\sqrt{P}$	80 MHz to 800 MHz $d = 0.35\sqrt{P}$	800 MHz to 2.5 GHz $d = 0.7\sqrt{P}$
0.01	0.035	0.035	0.07
0.1	0.11	0.11	0.22
1	0.35	0.35	0.70
10	1.11	1.11	2.22
100	3.5	3.5	7.0

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

NOTE 1

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

NOTE 2

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



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