



MedizinTechnik

English

Operating Instructions

ATMOS[®] LED Light Cube



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1.1 Notes on Operating Instructions



These operating instructions contain important notes on how to operate the ATMOS® LED Light Cube 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® LED Light Cube 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® LED Light Cube 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® LED Light Cube
Main function:	LED light source for optical instruments used for the illumination of natural orifices (throat / nose / ears) in ENT medicine.
Medical indications / application:	Standard ENT examination
Specification of the main function:	Light source - high performance LED daylight quality with a light output of min. 195 klux and 5.500 K ± 10 % (comparable to 250 W of a halogen light source)
Patient groups:	Patients of all ages - no restrictions - who require a standard ENT examination.
Application organ:	Throat / nose / ear
Application time:	For temporary application - the operation and application of the LED Light Cube may only be executed by trained personnel.
Application site:	Application sites are clinics and practices for ENT doctors and phoniatrists
Contraindications:	None
The product is	active
Sterility	Not sterile
Single-use product / reprocessing	No single-use product - cleaning of the device by wipe disinfection

1.3 Function

The ATMOS® LED Light Cube is a self-sufficient light source in form of a tabletop device with two light channels and an integrated automatic control with latest LED power technology (comparable to 250 W of a halogen light source). Due to an ingenious, passive cooling system noiseless working is guaranteed.

- ATMOS® LED Light Cube - comparable to 250 W of a halogen light source
- High Power LED: Daylight quality with outstanding light output of min. 195 kLux and 5.500 K ± 10 % due to our own development of an optimised illumination path - patent pending
- Energy efficient: More light output than a 150 W halogen with a minimal electrical power of 9 Watts
- No exchange of light bulbs due to the extremely long life cycle of the LEDs (50.000 h)
- Automatic control of the light channels: When removing the light conductor the light source is switched on automatically. Alternatively it is possible to control the device via 2 buttons on the frontside of the device.
- No disturbance through cooling noises due to passive cooling
- Flexible adapter system - applicable on all common makes (ATMOS/Storz, Wolf, Olympus, Pentax, ACMI)



1.4 Explanation of pictures and symbols

Symbols within these operating instructions

Follow the arrows

Check

Replace

Please read, important information

Warning, special diligent notice

Engage, check correct fit

Symbols of the ATMOS® LED Light Cube

Application part type BF

Manufacturing date

Fuse

The CE sign shows that this product meets the appropriate requirements of the EC Directives.

Professional disposal

Alternating current

Follow operating instructions (blue)

2.0 For your safety



General safety information

- Please make sure that the ATMOS® LED Light Cube is used in an EMC area described in the appendix.
- Please use the light source ATMOS® LED Light Cube only in connection with the rechargeable ATMOS LED battery or ATMOS current sources.
- Prior to starting up the light source ATMOS® LED Light Cube, read these operating instructions carefully.
- Make sure prior to every application of the equipment that it is technically safe and in proper condition. Damaged cables must be replaced immediately!
- In case that there is no adapter attached to the light conductor, touching the light source with either a finger or any tool should be avoided. On the one hand this may damage the lens and on the other hand there is a risk of injury.
- With every light source a warming of tissue due to radiation and absorption could occur. This could result in damage to the biological tissue. Please make sure to switch off the light source when not in use and to check heat development if necessary.
- The ATMOS® LED Light Cube may be operated only in rooms used for medical purposes, but not in areas subject to explosion hazards and in oxygen rich environments.
- 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!

- Do not direct the light source to the eyes!
 - Danger of severe damages to the eyes!



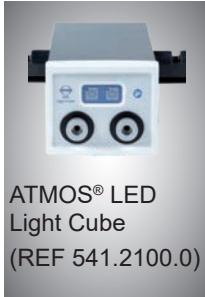
Danger to the device!

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

3.0 Scope of supply and connection



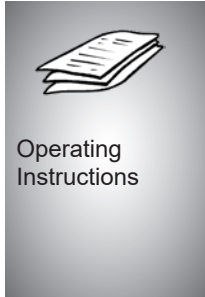
3.1 Scope of delivery



ATMOS® LED
Light Cube
(REF 541.2100.0)



Adapter for light
conductor with
ATMOS/Storz
connection (2
pieces)
(REF 530.6100.0)



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Optional:

Adapter for light conductor with Olympus connection (REF 530.6101.0)

Adapter for light conductor with Pentax connection (REF 530.6102.0)

Adapter for light conductor with Wolf connection (REF 530.6103.0)

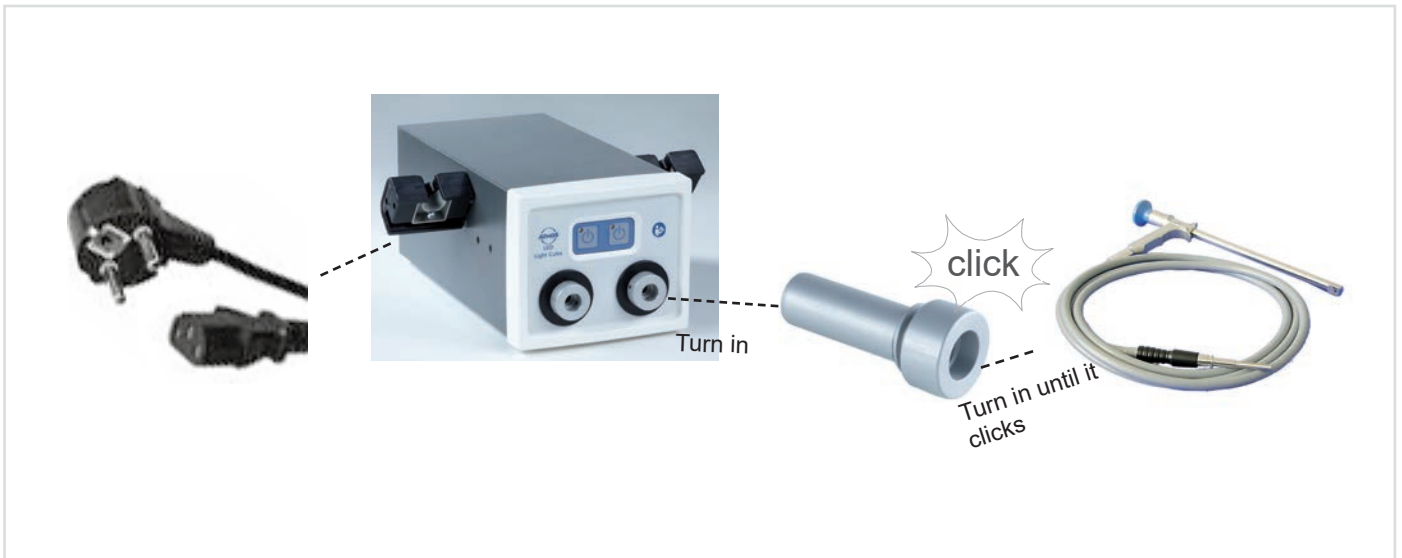
Adapter for light conductor with ACMI connection (REF 530.6104.0)

High performance light cable (REF 950.0152.0)

Light conducting cable, Ø 3.5 mm, L = 1.7m, Storz, straight (REF 508.0663.0)

Light conducting cable, Ø 3.5 mm, L = 1.8 m, Storz angled, 90° (REF 508.0664.0)

3.2 Connection



	Danger to the device!
<p>CAUTION!</p>	<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 endoscope with adaptor engages in the light source!

4.1 Starting up

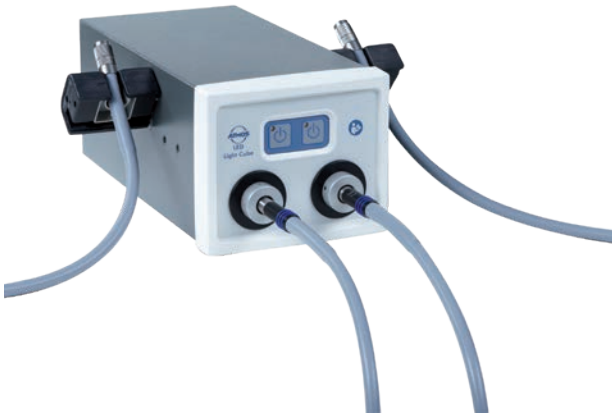
Switch on the device by pressing the on /off switch at the rear side of the device.

With a simple rotary motion the adapters are screwed in up to the stop position and fixed in the LED Light Cube. The light conductors can be plugged into the connection.

4.2 Selecting the light outlet


The selected light channel is automatically activated when the light conductor is removed from the support. Manual on and off switching of the light channels by means of the control panel is also possible. The glowing LED on the control panel displays which light channel is active at the moment.

Both light channels can be operated independently from one another.



5.1 General information on cleaning and disinfection

Prior to cleaning



- If required, wipe the camera with a cloth moistened with a cleaning solution and disinfect the application parts which come into contact with the patient. Do not spray the liquid directly on the camera.
- For cleaning / disinfecting the optics please pay attention to the respective cleaning instructions.
- For disinfection, you may use all surface disinfectants listed on the bottom of this page.
- Always observe the concentration specifications and instructions by the respective manufacturer!



- **Do not use disinfectants which contain organic or inorganic acids or bases as they could cause corrosion damage.**
- **Do not use disinfectants containing chloramides, phenol derivatives or anionic tensides, as these may cause stress cracks in the plastic material used.**

5.2 Cleaning of the ATMOS® LED Light Cube

- If necessary clean the LED Light Cube with a wet cloth. All disinfectants mentioned under „surface disinfectants“ are suitable for disinfection. Always observe the concentration specifications and instructions by the respective manufacturer!
- For cleaning, never use alcohol or alcoholic cleaning agents. Avoid any contact to the lens in the light channel with alcohol.
- Avoid moistening the lens in the light channel with any liquid.
- The device has to be cleaned and disinfected regularly, if it is used by several users.
- For cleaning / disinfecting the optics please pay attention to the respective cleaning instructions.

Surface disinfectants

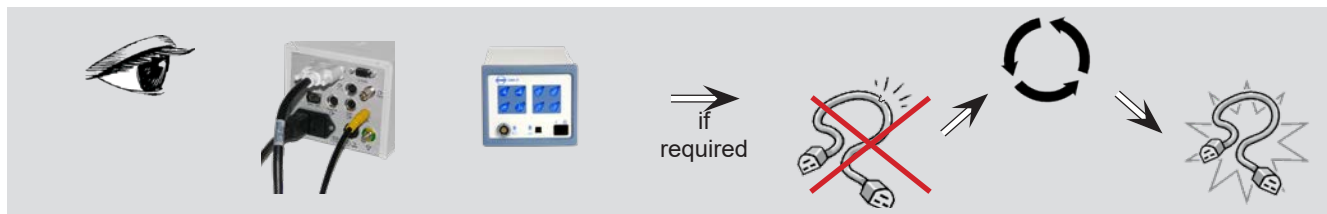
For disinfecting the surface the following disinfectants have been tested:

Disinfectant	Ingredients	(in 100g)	Manufacturer
Dismozon® pur (Application concentrate) End of product 12/2014	Magnesium monoperoxyphthalate Hexahydrate	80 g	Bode Chemie, Hamburg
Dismozon® plus (Application concentrate)	Magnesium monoperoxyphthalate Hexahydrate	95.8 g	Bode Chemie, Hamburg
Green & Clean SK (Application concentrate)	Alkyl dimethyl benzyl ammonium chloride Dialkyl-dimethyl-ammonium chloride	< 1 g	Metasys, Rum (Austria)
Incidin® Plus (Application concentrate)	Glucoprotamin Nonionic tensides Solvents, complexing agents	26.0 g	Ecolab, Düsseldorf

When disinfectants containing aldehyde and amine are used on the same object colour changes may occur.

6.1 General checks

Medical devices like the ATMOS® LED Light Cube must be fail safe at all times. Therefore we recommend prior to every use:



Further regular maintenance work is not required.

6.2 Period tests

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. 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.

6.3 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 with 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.



Error description	Possible cause	Remedy
No function	Power line not connected	Check power line and connect if necessary
	Device is not switched on	Check switch on the rear side of the device; switch the device on if necessary
	Fuses are defective	Check the fine fuses in the fuse drawer; exchange if necessary
	Power supply unit is defective	Contact the service; have the power supply unit replaced
	Control electronics are defective	Contact the service; have the control electronics replaced
Light channel cannot be switched on via the button (green LED on the display is not alight)	Button / control panel is defective or the connection lines do not contact	Contact the service; have the control panel checked and replaced if necessary
Light channel cannot be switched on via the button (green LED on the display is alight but the illumination LED does not work)	Illumination LED or their control is defective	Contact service; have illumination LED and its control checked and replaced if necessary
Light channel cannot be switched on via the light barrier (green LED on the display is not alight)	Light barrier is defective or the connection lines have no contact	Contact the service; have the light barrier checked and replaced if necessary
Light channel cannot be switched on via the light barrier (green LED on the display is alight but the illumination LED does not work)	Illumination LED or their control is defective	Contact service; have illumination LED and its control checked and replaced if necessary
Colour temperature of the lighting changes	Adjustment of the internal optics is no longer optimal	Contact the service; have the optics re-adjusted
	Control of the LED is defective	Contact the service; have the control checked and replaced if necessary
	LED is defective	Contact the service; have the LED checked and replaced if necessary
Light conductor falls from the connection adapter	Wrong adapter in use	Check whether the fitting light conductor has been chosen for the adapter (Wolf, Storz, Olympus, etc.)
When removing the light conductor from the support, the wrong light outlet is activated	Light conductors placed on the wrong support (left outlet placed on the right hand side support and the other way round)	Untangle the light conductors and replace onto the correct support



Adapter for light conductor with ATMOS/Storz connection	530.6100.0
Adapter for light conductor with Olympus connection	530.6101.0
Adapter for light conductor with Pentax connection	530.6102.0
Adapter for light conductor with Wolf connection	530.6103.0
Adapter for light conductor with ACMI connection	530.6104.0
High performance light cable	950.0152.0
Light conducting cable, Ø 3.5mm, L = 1.7m, Storz straight	508.0663.0
Light conducting cable, Ø 3.5mm, L = 1.8m, Storz angled, 90°	508.0664.0
Laryngoscopes	
Laryngoscope HD 70°, Ø 8 mm, L = 190 mm	950.0254.0
Laryngoscope HD 70°, Ø 10 mm, L = 190 mm	950.0255.0
Laryngoscope HD 90°, Ø 10 mm, L = 190 mm	950.0256.0
Ear endoscopes	
Otoscope HD 0°, Ø 4 mm, L = 50 mm	950.0257.0
Otoscope HD 30°, Ø 4 mm, L = 50 mm	950.0258.0
Otoscope HD 0°, Ø 2,7 mm, L = 50 mm	950.0259.0
Sinus-/ Laryngoscopes Ø 4 mm	
Sinuscope HD 0°, Ø 4 mm, L = 175 mm	950.0260.0
Sinuscope HD 30°, Ø 4 mm, L = 175 mm	950.0261.0
Sinuscope HD 45°, Ø 4 mm, L = 175 mm	950.0262.0
Sinuscope HD 70°, Ø 4 mm, L = 175 mm	950.0263.0
Sinus-/ Laryngoscopes Ø 2.7 mm	
Sinuscope HD 70°, Ø 2,7 mm, L = 110 mm	950.0264.0
Sinuscope HD 30°, Ø 2,7 mm, L = 110 mm	950.0265.0
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



9.0 Technical data



Voltage	100-240 V~ ± 10 %; 50 / 60 Hz
Power consumption	Max. 20 VA
Fuses	T 6,3 A (f. 230 V~, 50 / 60 Hz) T 12 A (f. 110 V~, 127 V~, 50 / 60 Hz)
Light intensity	Min. 200 klx
Colour temperature	5.500 K ± 10 %
Operating time	Continuous operation
Cooling	Fanless / Passive
Protective earth conductor resistance	Max. 0.5 Ω
Earth leakage current	Max. 0.5 mA
Housing leakage current	Max. 0.1 mA
Patient leakage current	Max. 0.1 mA
Ambient conditions transport / storage	
• Temperature	-10...+50 °C
• Humidity without condensation	30...95 %
• Air pressure	500...1060 hPa
Ambient conditions for operation	
• Temperature	+10...+35 °C
• Humidity without condensation	30...95 %
• Air pressure	700...1060 hPa
Maximum operational altitude	≤ 3000 m
Contamination level	Class 2
Overvoltage category	II
Dimensions H x W x D	116 x 138 x 265 mm
Weight	3.0 kg
Period tests	Repeat test of the electrical safety every 24 months. Recommended: inspection according to the manufacturer's specifications.
Protection class (EN 60601-1)	I
Degree of protection	Application parts type BF
Type of protection	IP X0
Classification according to Appendix IX EC Directive 93/42/EEC	Class I acc. to rule 12
CE marking	CE
GMDN code	12340
UMDNS code	12-340
ID No. (REF)	541.2100.0

- The ATMOS® LED Light Cube does not contain any hazardous materials.
- The housing material is fully recyclable.
- Device and accessories must be decontaminated prior to disposal.
- Pay attention to a careful separation of the different materials.
- Please observe national disposal regulations (e.g. waste incineration).



Disposal within the EC

The device described above is a high-quality medical product with a long service life. After its life cycle it must be disposed of professionally. According to the EC directives (WEEE and RoHS) the device may not be disposed of in domestic waste. Please observe existing national laws and rules for disposal of old devices in the respective country.

Disposal within the Federal Republic of Germany

In the Federal Republic of Germany the law for electrical devices (ElektroG) regulates the disposal of electrical devices. In order to guarantee a proper disposal of your old device, please either pass on your old device to your specialised dealer or send it directly to ATMOS MedizinTechnik for a professional disposal.

Before disposal respectively before transport, all parts, which came into contact with the patient must be thoroughly cleaned, disinfected. The device surface must be disinfected.



- 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® LED Light Cube light source is intended for use in the electromagnetic environment specified below. The customer or user of the ATMOS® LED Light Cube 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® LED Light Cube 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 according to CISPR 11	Class B	The ATMOS® LED Light Cube 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 according to IEC 61000-3-3	Inapplicable	

11.2 Guidelines and Manufacturer's Declaration - Immunity

The ATMOS® LED Light Cube is intended for use in the electromagnetic environment specified below. The customer or user of the ATMOS® LED Light Cube 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	± 6 kV Contact	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 %.
	± 8 kV Air	± 8 kV Air	
Fast electrical transient/ burst IEC 61000-4-4	± 2 kV Mains	± 2 kV Mains	The quality of the supply voltage should correspond to a typical commercial or hospital environment.
	± 1 kV I/Os	Inapplicable	
Surges IEC 61000-4-5	1 kV Common	1 kV symmetric	The quality of the supply voltage should correspond to a typical commercial or hospital environment.
	2 kV Differential	Inapplicable	
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	<p>< 5 % U_T (> 95 % Dip of the U_T) for 0.5 Cycle</p> <p>40 % U_T (60% Dip of the U_T) For 5 cycles</p> <p>70% U_T (30 % Dip of the U_T) For 25 cycles</p> <p>< 5 % U_T (>95 % Dip of the U_T) for 5 s</p>	<p>< 5 % U_T (> 95 % Dip of the U_T) for 0.5 Cycle</p> <p>40 % U_T (60% Dip of the U_T) For 5 cycles</p> <p>70% U_T (30 % Dip of the U_T) For 25 cycles</p> <p>< 5 % U_T (>95 % Dip of the U_T) for 5 s</p>	The quality of the supply voltage should correspond to a typical commercial or hospital environment. If the user of the ATMOS® LED Light Cube demands continued function even in case of interruptions of the energy supply, it is recommended to supply the ATMOS® LED Light Cube from an uninterruptible current 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® LED Light Cube is intended for use in the electromagnetic environment specified below. The customer or user of the ATMOS® LED Light Cube 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	<p>Portable and mobile communications equipment should be separated from the ATMOS® LED Light Cube including the cables by no less than the distances calculated/listed below.</p> <p>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</p> <p>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:</p>
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® LED Light Cube is used exceeds the above compliance level, the ATMOS LED Light Cube is to be observed to verify the intended use. If abnormal performance characteristics are noted, additional measures may be necessary, e.g. a changed arrangement or another location for the ATMOS® LED Light Cube.

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® LED Light Cube

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

Nominal output of the 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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