

English

Operating Instructions

# ATMOS HL 21 LED



**CE**

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## 1.1 Notes on operating instructions

These operating instructions apply to the following devices:

- ATMOS HL 21 LED (examination set) 507.4505.0
- ATMOS HL 21 LED (OT set) 507.4506.0
- ATMOS HL 21 LED 507.4500.0
- ATMOS HL 21 LED 530.4020.0
- ATMOS HL 21 LED 506.7551.0

in connection with the accessories mentioned in chapter 8.0.

- These operating instructions contain important information on how to operate the ATMOS HL 21 LED headlamp safely, correctly and effectively.
  - **Always keep these operating instructions close to the device!**
- The device's operating safety and its readiness for use depend not only on your expertise, but also on the care and maintenance of the ATMOS HL 21 LED headlamp. Regular cleaning and preventive maintenance work are therefore essential.
- Maintenance and repairs may be carried out only by a skilled person authorized by ATMOS.
- In case of repairs you should insist that only original spare parts are used. This will guarantee that the safety, readiness for operation, and value of your device will be maintained.
- This device bears the CE marking CE in accordance with the European Medical Device Regulation (MDR) 2017/745.
- The product ATMOS HL 21 LED complies with all applicable requirements of the directive 2011/65/EU restricting the use of certain hazardous substances in electrical and electronic equipment ("RoHS").
- The declarations of conformity and our general terms and conditions can be viewed on our website at [www.atmosmed.com](http://www.atmosmed.com).
- The quality management system used at ATMOS has been certified for quality management in accordance with the relevant international standards.
- Reproduction of these operating instructions — even in part — only with the written permission of ATMOS.

## 1.2 Explanation of pictures and symbols

### In the operating instructions

#### Abbreviations/symbols in these operating instructions:

- Indicating a list
  - Subdivision of a list/activity

The recommended sequence must be followed in each case!

Important notes!

#### On the device, type plate and packaging



Consult the operating instructions



Medical device



Warning! Pay special attention



Serial number



This product meets the relevant requirements of EU statutory ordinances.

IPX0

Specification of the degree of protection against the ingress of solids and moisture



This product meets the relevant requirements of the Eurasian Economic Union.



Type B applied part



Manufacturer



Professional disposal



Date of manufacture



Recyclable



Date of manufacture  
Country of manufacture:  
Germany



Do not look directly into the light source



Article number



Connection for lamp to LED battery



Unique identifier of a medical device



Connection for charging power pack with polarity marking



Test button for battery test

ECO Half performance

O Lamp is switched off

POWER Full performance



Handle with care



Fragile, handle with care



Store in a dry place



Protect from sunlight



Temperature limit



Humidity limitation



Atmospheric pressure limitation

## UDI application identifier

(01) UDI-DI: Identification of the manufacturer and the device

(11) Date of manufacture

(21) Serial number



## 1.3 Intended use

<b>Product name:</b>	ATMOS HL 21 LED
<b>Main functions:</b>	Medical LED cold light source with headband for fixation on the head of the examiner
<b>Intended use / purpose:</b>	Illumination of orifices (e.g. ear/nose/throat) for visual diagnostics
<b>Intended users / user profile:</b>	Physicians and medical specialists
<b>Intended patient group:</b>	All patients without any restrictions
<b>Medical conditions to be diagnosed, treated, or monitored:</b>	Diagnostic examination of anatomy of all kinds
<b>Application organ:</b>	Without restrictions (mainly ear/nose, throat)
<b>Application time:</b>	< 60 min.
<b>Application site:</b>	Outpatient medical facilities, e.g. ENT practices, hospital outpatient departments, medical care centres
<b>Patient selection criteria:</b>	None
<b>Indications:</b>	Whenever visual examination is indicated
<b>Medical contraindications:</b>	None
<b>Other contraindications:</b>	None
<b>Warnings:</b>	None
<b>The product is:</b>	Active
<b>Sterility / specific microbial condition:</b>	Non-sterile
<b>Single-use product / re-sterilization:</b>	Not a disposable product. Reprocessing according to operating instructions.



## 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 supply

REF	507.4500.0	507.4505.0	507.4506.0	530.4020.0	506.7551.0
ATMOS HL 21 LED headlamp	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 has been carefully packed. Nevertheless, please compare the contents of the shipment on completeness immediately upon receipt (see scope of supply).
- Please document and report damages in transit immediately. For complaints or return deliveries, please use enclosed form QD 434 **Delivery complaint / return shipment**.



- Prior to starting up the headlamp ATMOS HL 21 LED, read these operating instructions carefully.
- ATMOS neither guarantees for fault-free operation nor for personal injuries and damage to property if
  - no original ATMOS parts are being used,
  - The instructions for use included in these operating instructions are disregarded.
  - Assembly work, new settings, alterations, extensions and repairs are carried out by personnel not authorized by ATMOS.
- No warranty rights shall exist in the event of damage or failure caused by the use of non-ATMOS accessories or non-ATMOS consumables.
- Please make sure that the ATMOS HL 21 LED is used in the described EMC environment.
- Only use the charging power pack supplied by ATMOS.
- Use the headlamp ATMOS HL 21 LED only in connection with the ATMOS LED battery or ATMOS current sources.
- The disconnection of the charging power pack from the power supply is only guaranteed when the charging power pack is unplugged from the power socket.
- Prior to each application, check the device's functions and its proper condition. Damaged cables must be replaced immediately!
- During each application, pay attention to proper fit of the ATMOS HL 21 LED headlamp.
- During surgery, please note that the ATMOS HL 21 LED headlamp is not sterile.
- 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!
  - **Danger of eye injury**
- Charging of the LED battery must be checked regularly, as the light goes out very quickly when the battery goes flat.
- If the ATMOS HL 21 LED headlamp is used by several users, regular cleaning and disinfection must be carried out.
- Switch off the ATMOS HL 21 LED headlamp when not in use.
- Report all serious incidents that have occurred in connection with this product to the manufacturer and your national competent authority.

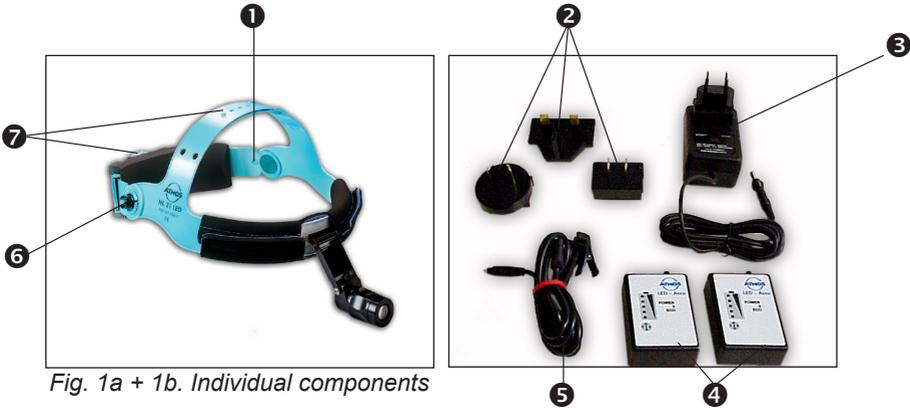


Fig. 1a + 1b. Individual components

### 3.1 Individual components of the headlamp

- ❶ ATMOS HL 21 LED headlamp
- ❷ Different power plugs for charging power pack (Euro/UK/US/Aus)
- ❸ Charging power pack, 12 V DC
- ❹ LED battery
- ❺ Connecting cables, 40 cm, 140 cm and 200 cm long
- ❻ Cable holder on the headlamp frame
- ❼ Adjusting instruments of the headlamp frame

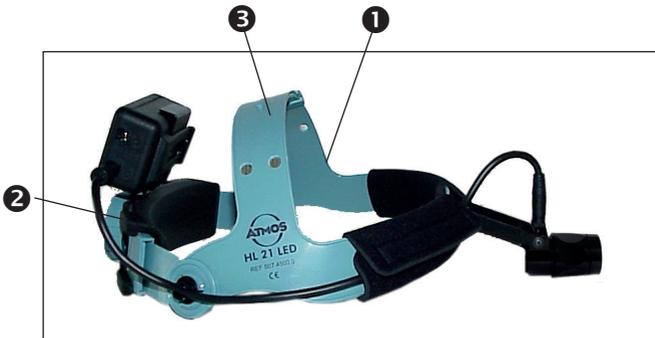


Fig. 2. ATMOS HL 21 LED headlamp

- ❶ Headlamp frame
- ❷ Locking screw for adjusting the circumference
- ❸ Strap for adjusting the height

- ⓘ Prior to the first operation, pay attention to the safety information in chapter 2.0.
- ⓘ Prior to using the headlamp for the first time, charge the LED battery with the supplied charging power pack.

### 3.2 Adjustment to head circumference

- First, take the headlamp frame incl. headlamp (❶, Fig. 2) and put it on a table in front of you.

#### Adjusting the headlamp frame:

- Depending on the head circumference, adjust the headlamp frame gradually to a comfortable and correct fit with the locking screw (❷, Fig. 2). The height of the headlamp frame is adjusted by means of a strap (❸, Fig. 2).
- ⓘ The lower edge of the headlamp frame is to be positioned directly above the ears.

## 3.0 Setting up and starting up

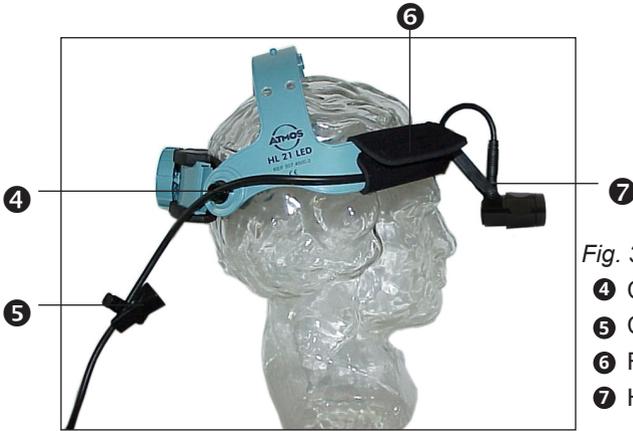


Fig. 3.

- ④ Cable holder
- ⑤ Cable clip
- ⑥ Front pad
- ⑦ Headlamp connection



Fig. 4. Connection of LED battery

- Take one of the enclosed connecting cables and join it to the ATMOS HL 21 LED headlamp connection (⑦, Fig. 3).
- Use the short connecting cable if you want to carry the LED battery on the headband (Fig. 8, page 13).
- 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. This cable is also to be used if the headlamp is to be supplied from an ATMOS power source. If necessary, lead the cable under the front pad and through the cable holders in the joint of the ATMOS HL 21 LED headlamp.
- Use the enclosed cable clip (⑤, Fig. 3) to fix the long cable to your clothes.
- Connect the other end of the connecting cable to the socket on the LED battery (Fig. 4) or the power source in your ATMOS ENT treatment unit.
- NOTE: With its rear cable clip, the rechargeable LED battery can be fixed to your coat pocket, to your belt or to the battery holder on the ATMOS HL 21 LED headlamp.

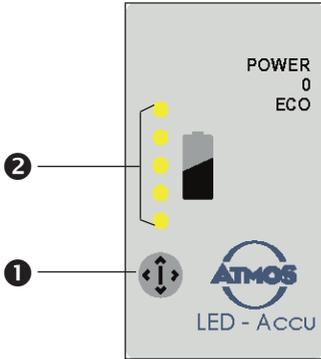


Fig. 5.

- ① Test button
- ② Indication of the battery capacity (green LED)

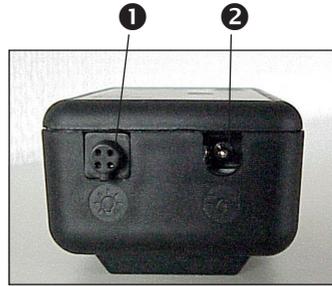


Fig. 6.

- ① Connecting socket for headlamp
- ② Charging socket of LED battery

## 3.3 Functionality of the LED battery

### 3.3.1 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 exchanging or charging the battery when the capacity is < 50%.
  - As long as the test button (①, Fig. 5) of the rechargeable LED battery is pressed, the battery capacity is shown for approx. 3 seconds (②, Fig. 5, green LEDs for levels 1...5).

### 3.3.2 Charging the LED battery

- Use the primary adapter suitable for your power supply (Euro/US/UK/Aus). See information enclosed with the charging power pack.
  - To charge the LED battery, disconnect it from the ATMOS HL 21 LED headlamp.
  - Connect the round connector of the power pack cable to the socket (②, Fig. 6) of the LED battery.
  - During the charging process, the current battery capacity is indicated (②, Fig. 5, green LEDs for levels 1...5). The battery is fully charged when all five LEDs go out again.
- ❗ During charging, operation of the headlamp is impossible!



Fig. 7. Headlamp without battery holder



Fig. 8. Headlamp with battery holder

#### 4.1 Different variants of the ATMOS HL 21 LED headlamp

- Fig. 7: ATMOS HL 21 LED headlamp 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 operating instructions of the ATMOS ENT treatment unit.

- Fig. 8: ATMOS HL 21 LED headlamp with short cable, LED battery in battery holder of the headlamp.
- To remove the battery holder, proceed as follows:
  - Use the locking screw to adjust the headlamp frame quite tight.
  - Remove the central cover in the locking screw and then take a Phillips-head screwdriver to remove the screw.
  - Remove the locking screw and remove the battery holder.
  - 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.
  - Insert the screw and replace the cover cap.

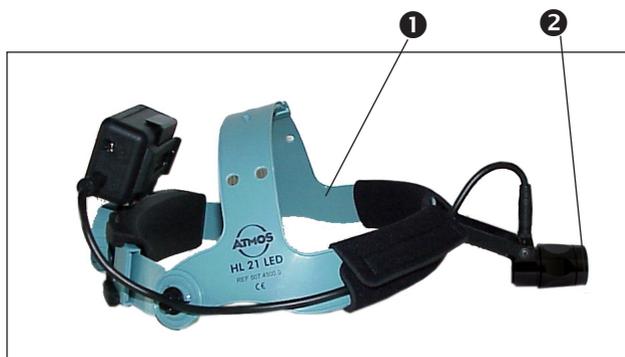


Fig. 9. Focusing

- ① Headlamp frame
- ② Focusing ring

### 4.2 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.

### 4.3 Focusing the headlamp

- The size of the light spot can be adjusted by turning the focusing ring (②, Fig. 9).

The described measures relating to cleaning and disinfection do not replace the valid regulations for operation!

- i** Always comply on principle with the operating instructions of the manufacturer regarding concentration and material compatibility.
- i** Do **not** use any:
  - disinfectants containing concentrated organic or inorganic acids or bases since they may cause corrosion damage.
  - Disinfectants containing chloramines, phenol derivatives, or anionic surfactants since these may cause stress cracks in the plastics used.
- i** If the ATMOS HL 21 LED headlamp is used by several users, regular cleaning and disinfection must be carried out.
- i** Do not touch the lens in the light object.

Fingerprints can be removed 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 ATMOS HL 21 LED headlamp cannot be sterilised.
- The light body and the rigid headlamp frame can be wiped 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 must not be spin-dried or be put in the tumble dryer.

### 5.1 Recommended surface disinfectants

Disinfectant	Ingredients	(in 100 g)	Manufacturer
Incidin® Plus (Application concentrate)	Glucoprotamin Non-ionic surfactants Solvents, complexing agents	26.0 g	Henkel, Düsseldorf
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)



- Prior to each application, check the device's functions and its proper condition. Damaged cables must be replaced immediately!
- The ATMOS HL 21 LED headlamp is low-maintenance. The instructions and regulations for the respective field of application should be observed.
- Maintenance, repairs and period tests may be carried out only by persons who have the appropriate technical knowledge and are familiar with the product. The person in question must possess the test devices and original spare parts required to take the mentioned measures.  
ATMOS recommend commissioning an authorized ATMOS service partner. This will ensure that the repairs and tests are carried out appropriately, original spare parts are used and any warranty claims remain unaffected.
- Please comply with the country-specific guidelines regarding regular testing, especially with regard to electrical safety. ATMOS recommend a test every 24 months.
- This device can be returned directly to ATMOS for repairs.
- ATMOS neither guarantee fault-free operation nor assume any liability for personal injuries and damage to property if:
  - No original ATMOS parts are used.
  - The instructions for use included in these operating instructions are disregarded.
  - Assembly, new settings, alterations, extensions and repairs are carried out by ATMOS authorised personnel.
- No warranty rights shall exist in the event of damage or failure caused by the use of non-ATMOS accessories or non-ATMOS consumables.
- Batteries are wearing parts and therefore excluded from the general two-year product liability!

## 6.0 Maintenance and service

### 6.1 Sending in the device

- Clean and disinfect the product and accessories in accordance with the operating instructions.
- Enclose any used accessories with the product.
- Fill in the QD 434 form “Delivery Complaint / Return Shipment” and the corresponding **decontamination certificate**.
- ☞ This form is enclosed with each delivery and can be found at [www.atmosmed.com](http://www.atmosmed.com) .
- The device must be well padded and packed in suitable packaging.
- Place the QD 434 form “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 your dealer.

## 7.0 Troubleshooting

The ATMOS HL 21 LED was subjected to thorough quality control at the factory. If, however, any problems should occur, you may be able to eliminate them yourself by observing the following notes.

<b>Error symptom</b>	<b>Cause of error</b>	<b>Troubleshooting</b>
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

## 8.0 Accessories



<b>Description .....</b>	<b>REF</b>
Lithium-ion battery.....	507.4510.0

Voltage	Battery recharging unit: 100-240 V~ 50/60 HZ; secondary, 12 VDC LED battery Charge with 12 V DC lithium-ion battery with 3.7 V nominal voltage and a 2200 mAh capacity
Current consumption	Battery recharging unit: 0.8 A via non-medical 1.8 m cable with 5.5 x 2.5 mm DC plug Headlamp: max. 700 mA DC
Power consumption	Light emitter 3 watts
Light intensity	100,000 lux
Lifespan, LED	Max 50,000 h
Light emitter:	White high-performance LED, type 5500 K, light spot focusing with a diameter of 25 to 55 mm in at a distance of 25 cm to the eye.
LED battery	Approx. 120 min charging time after complete discharge; automatic switchover battery to compensation; capacity indication by five LEDs at the touch of a button and during the charging process, at least 500 charging cycles possible.
Operating time	LED battery switch with two operating modes (Power and ECO); 120 minutes of operation with full light performance and at 240 min. with reduced light performance.
Ambient conditions for transport/storage	
<ul style="list-style-type: none"> <li>• Temperature</li> <li>• Air humidity</li> <li>• Pressure</li> </ul>	<p>-30 to +50°C</p> <p>5...90% air humidity without condensation</p> <p>At air pressure of 700...1060 hPa</p>
Environmental conditions for operation	
<ul style="list-style-type: none"> <li>• Temperature</li> <li>• Air humidity</li> <li>• Pressure</li> </ul>	<p>+10 to 35°C</p> <p>20...80% air humidity without condensation</p> <p>At air pressure of 700...1060 hPa</p>
Maximum operational altitude	3000 m (NN)
Contamination level	2
Overvoltage category	I
Dimensions (H x W x D)	Headlamp frame: Circumference: Adjustable from 50 – 64 cm; height 92 – 115 mm Connecting cable: 40 cm, 140 cm and 200 cm in length
Weight	With emitter: approx. 200g
Period tests	Recommended: Test every 24 months / 2 years.

## 9.0 Technical data



Protection class (EN60601-1)	II (charging power pack)
Type of protection	IP X0
CE mark	<b>CE</b>
ID no. (REF)	530.4020.0 ATMOS HL 21 LED 506.7551.0 ATMOS HL 21 LED 507.4505.0 ATMOS HL 21 LED (examination set) 507.4506.0 ATMOS HL 21 LED (OT set) 507.4500.0 ATMOS HL 21 LED



- The ATMOS HL 21 LED headlamp does not contain any hazardous goods.
- The LED battery (lithium-ion) must be disposed of correctly.
- The device and accessories must be decontaminated prior to disposal.
- Pay attention to careful separation of the different materials.
- Please observe the national disposal regulations.



☞ Medical electrical devices are 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.
- At professional healthcare facilities, such as: Medical practices, clinics, first aid facilities and operating theatres.

The following environments are not suitable:

- Within 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 observe the technical data in this manual. The key features are fully usable even in the presence of electromagnetic disturbances.

### Guidelines 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

### Guidelines 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, this could result in degradation of the performance of this equipment.

☞ \*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 incorrect operation. If this is unavoidable, the proper functioning of the device must be monitored regularly. Please switch off any nearby devices that are not in use, if possible.



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