

Operating Instructions

# ATMOS HL 21 LED

English



**CE**

GA1GB.150303.0

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# 1 Introduction

## 1.1 Notes on the operating instructions



This operating information contains important notes on how to operate your product safely, appropriately and effectively.

This manual is used to train and instruct operating personnel and is also intended as a reference manual. It may be reprinted, either in part or in whole, only with the written permission of ATMOS.

**These operating instructions must always be kept available near the product.**



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

Maintenance, repairs and period tests may be carried out only 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.



Read chapter “2 Notes on your safety” on page 8 before putting the product into service 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 the directive 2011/65/EU on the restriction of the use of certain dangerous 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 applied at ATMOS has been certified according to the international standard EN ISO 13485.

These operating instructions apply to 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

 <b>DANGER</b>	Warning of a danger resulting directly in fatal or serious injury. Observe the necessary measures.
 <b>WARNING</b>	Warning of a danger of fatal or serious injuries. Observe the necessary measures.
 <b>CAUTION</b>	Warning of a danger of minor injury. Observe the necessary measures.
<b>ATTENTION</b>	Notice of a danger of damage to the product or other objects. Observe the necessary measures.
	Warning of a danger of serious or fatal injury.
	Notice of potential material damage that can be caused.
	Useful information on handling the device.
1.	Call for action. Proceed step by step.
»	Result of an action.
	Move/plug in this direction.
	Engage and check for tight fitting.

### On the device, type plate and packaging

	Follow the operating instructions (blue)
	Observe the operating instructions
	Warning! Pay special attention.
	This product meets the relevant requirements of EU statutory ordinances.
	This product meets the relevant requirements of the Eurasian Economic Union.
	Manufacturer
	Date of manufacture
	Date of manufacture Country of manufacture: Germany

	Item number
	Unique identifier of a medical product
	Medical product
	Serial number
IPX0	Specification of the degree of protection against the ingress of solids and moisture
	No domestic waste
	Recyclable
	Do not look directly into the light source
	Connection for headlamp to LED battery
	Connection for recharging unit 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
	Off
	Handle with care
	Fragile, handle with care
	Store in a dry place
	Protect from sunlight
	Temperature limit
	Humidity limitation
	Atmospheric pressure, limit

## UDI application identifier

(1)	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 function:</b>	Medical LED cold light source with headband for fixation on the head of examiner
<b>Intended use / purpose:</b>	Illumination of orifices for (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 condition to be diagnosed, treated or monitored:</b>	Diagnostic examinations 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>	Out-patient medical facilities, e.g. ENT practices, hospital out-patient 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. Re-sterilization 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 delivery

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
Recharging unit (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, please compare the contents of the shipment for completeness immediately upon receipt (see scope of supply).

Please immediately document and report any damage in transit. Please use the supplied form VT-0184 **Delivery Complaint / Return Shipment** in the event of complaints or when sending back the device.

## 2 Notes on your safety

Please read the safety instructions thoroughly and pay attention to them before using the product.

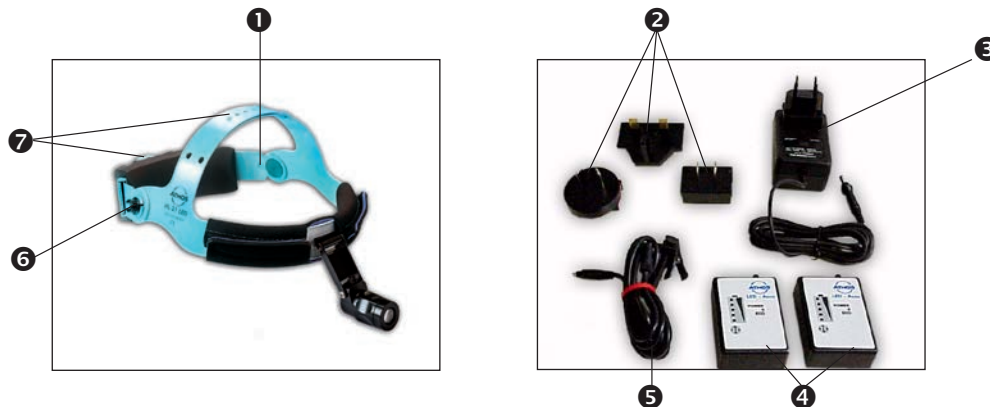
The product will meet the safety requirements of users, patients and third parties only if fully functional. Therefore, please observe the following instructions on your product:

### 2.1 General safety instructions

- Report any serious incidents that occur in connection with this product to the manufacturer and the national authority responsible for you.
- ATMOS can neither guarantee fault-free operation nor assume the liability for any personal injury and damage to property if no original ATMOS parts are used, the instructions for use in these operating instructions are disregarded or the installation, new settings, modifications, extensions and repairs are performed by persons not authorized by ATMOS.
- No warranty claims can be made in the event of damage or malfunctions caused by using non-ATMOS accessories or consumables.
- Please make sure the ATMOS HL 21 LED is used in the described EMC environment.
- Use only the recharging unit supplied by ATMOS.
- Use the ATMOS HL 21 LED headlamp only in connection with the LED battery or current sources from ATMOS.
- The disconnection of the recharging unit from the power supply can be ensured only if the recharging unit is unplugged from the power socket.
- Make sure the device is in safe technical and orderly condition each time before using it. Immediately replace any damaged cables!
- During each application, pay attention to proper fit of the headlamp ATMOS HL 21 LED.
- Please observe that the ATMOS HL 21 LED headlamp is not sterile during surgery.
- Make sure you never blind patients with the light source! Watch out that patients do not look directly into the light source!
- **Danger of eye injury**
- The charging of the LED battery must be checked regularly, because the light will go out very quickly when the battery goes flat.
- If the headlamp ATMOS HL 21 LED is used by several users, regular cleaning and disinfection must be carried out.
- 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. Please make sure the patients do not touch the light source during the examination.

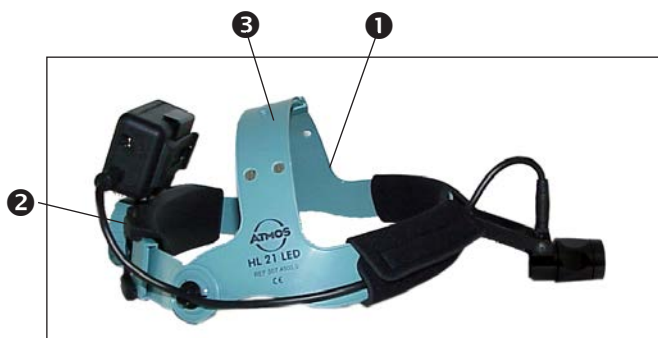
## 3 Setting up the device and putting it into service

### 3.1 Device overview



### 3.2 Individual components of the headlamp

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



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

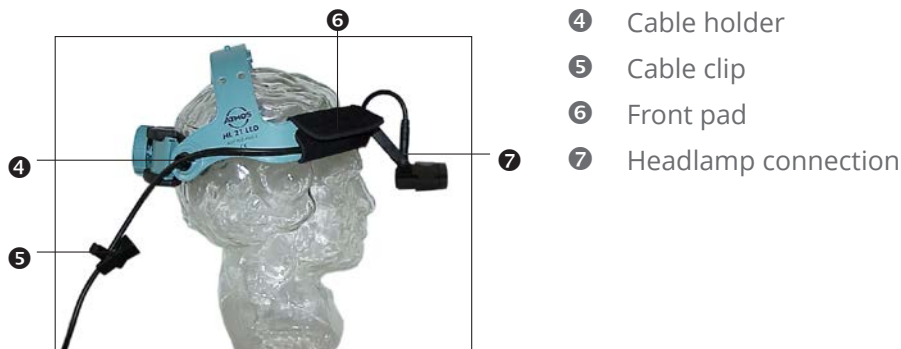
- ⓘ Make sure you observe the safety instructions in "2 Notes on your safety" on page 8 before putting the device into service.
- ⓘ Charge the LED battery with the supplied recharging unit before using the headlamp for the first time.

### 3.3 Adjustment to the head circumference

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

#### Adjusting the headlamp frame:

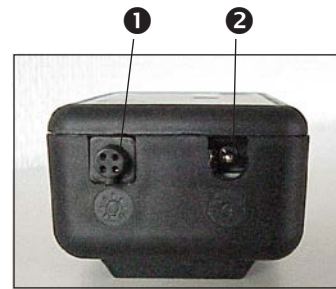
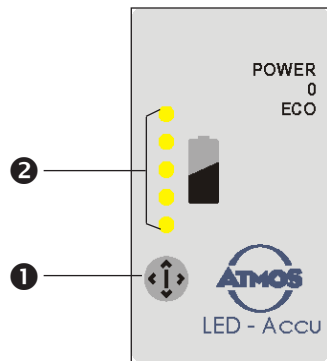
1. Use the locking screw to set the headlamp frame gradually to a comfortable and correct fit, according to the circumference of the head. The height of the headlamp frame is set by means of a strap.
- ☞ The lower edge of the headlamp frame should be positioned directly above the ears.



#### LED battery connection



- Take one of the enclosed connecting cables and connect one end of it to the ATMOS HL 21 LED headlamp connector (7).
  - 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 or trouser pocket or on your belt or if it is to be supplied by an ATMOS power source. If necessary, lay 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) to fix the long cable to your clothes.
  - Now connect the other end of the connecting cable to the socket of the LED battery or the power source in your ATMOS treatment unit.
- ☞ You can mount the LED battery with its rear cable clip to the coat pocket, belt or battery holder of the ATMOS HL 21 LED headlamp.



- 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

- ❶ The charging of the LED battery must be checked regularly, because the light will go out very quickly when the battery goes flat. We recommend exchanging or charging the battery when the capacity is below 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 suitable for your recharging unit (Euro/US/UK/Aus). See information enclosed with the recharging unit.
- To charge the LED battery, disconnect it from the ATMOS HL 21 LED headlamp.
- Connect 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.
- ❶ Charging not possible during operation!



Headlamp without battery holder



Headlamp with battery holder

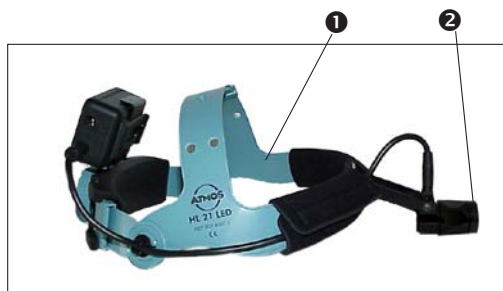
## 4 Operation

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

1. 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.
  - ❶ Also pay attention to the respective operating instructions of the ATMOS ENT treatment unit.
2. ATMOS HL 21 LED headlamp with short cable, LED battery in battery holder of the headlamp.

**To remove the battery holder, proceed as follows:**

1. Use the locking screw to adjust the headlamp frame quite tight.
2. Remove the middle cover in the locking screw and then use a cross-tip screwdriver to remove the screw.
3. Remove the locking screw and the battery holder.
4. Add the locking screw again. Make sure the tight adjustment of the headlamp frame has not changed. Otherwise, push the headlamp frame together again.
5. Screw in the screw and replace the cover cap.



- ❶ Headlamp frame
- ❷ Focusing ring

### 4.2 Switching on the device

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 set by turning the focusing ring.

## 5 Sterilization

### 5.1 Cleaning

The described measures relating to cleaning and disinfection are no replacement for the valid regulations for operation!

- ❶ Observe the operating instructions prescribed by the manufacturers of disinfectants. Pay particular attention to the concentration specifications and notes on material compatibility.
- ❷ Do **not** use any:
  - Disinfectants that contain concentrated organic or inorganic acids because they could cause corrosion damage.
  - Disinfectants containing chloramides, phenol derivatives, or anionic surfactants because they could cause stress cracks in the plastics used.
- ❸ If the ATMOS HL 21 LED headlamp is used by several users, it must be cleaned and disinfected regular.
- ❹ Do not touch the lens in the light fitting.

Fingerprints can be removed with a soft cloth, using ethanol if necessary.

- A moist cloth will do to clean the surfaces, using ethanol if necessary.
- The ATMOS HL 21 LED headlamp cannot be sterilized.
- The light fitting and the rigid headlamp frame can be cleaned on the outside by wiping them with a cloth moistened with a surface disinfectant (see chapter 5.1).
- The front pad can be cleaned with a brush, clear water, and soap, using 70% ethanol solution if necessary. The cleaning agent must not contain any 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 a 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)	Alkyl dimethyl benzyl ammonium chloride Dialkyl-dimethyl-ammonium chloride	< 1 g	Metasys, Rum (Austria)

## 6 Maintenance and service

- Make sure the device is in safe technical and orderly condition each time before using it. Immediately replace any damaged cables!
- The ATMOS HL 21 LED headlamp is low-maintenance. However, the regulations and instructions that apply to the respective field of application must 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. To carry out these measures, the person must have the necessary test devices and original spare parts.  
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 can neither guarantee fault-free operation nor assume any liability for personal injury and damage to property if:
  - No original ATMOS parts are used.
  - The instructions for use included in these operating instructions are disregarded.
  - Assembly work, new settings, alterations, extensions or repairs are carried out by persons not authorized by ATMOS.
- No warranty claims can be made in the event of damage or malfunctions caused by using non-ATMOS accessories or consumables.
- Batteries are wearing parts and therefore excluded from the general two-year product liability!

### 6.1 Sending in the device

1. Clean and disinfect the product and accessories in accordance with the operating instructions.
2. Enclose any accessories used with the product.
3. Fill in the form VT-0184 "Delivery Complaint / Return Shipment" and the corresponding **decontamination certificate**.  
☞ This form is enclosed with the product and can be found at [www.atmosmed.com](http://www.atmosmed.com).
4. The product 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 packaging.
7. Send the product to ATMOS or your dealer.

## 7 Troubleshooting

The ATMOS HL 21 LED has been subjected to thorough quality control at the factory. If, however, a malfunction occurs, you may be able to eliminate it yourself by observing the following notes.

Error symptom	Cause of error	Troubleshooting
No light	LED battery is flat	Charge the 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
	Recharging unit defective	New recharging unit

## 8 Accessories


Accessories	REF
Lithium-ion battery	507.4510.0

## 9 Disposal

- 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.

## 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
Colour temperature:	Typ. 5500 K
Service life of the LED:	Max. 50,000 h
Illumination diameter:	25–55 mm (focused on 17 cm)
Operating mode:	Continuous operation
Maximum operating altitude:	3000 m
Contamination level:	2
Overvoltage category:	II
Dimensions:	Headlamp frame: circumference: adjustable 50 – 64 cm; height: 92 – 115 mm Connecting cable: 40 cm, 140 cm and 200 cm in length
Weight:	Approx. 200 g
Type of protection:	IPX0
CE marking:	
Electric shock protection class (in acc. with 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:	Lithium-ion battery 1S1P
Battery voltage:	Nominal: 3.6 V DC
Capacity:	2200 mAh
Energy:	7.92 Wh
Output current:	Power mode: 700 mA DC ± 10% ECO mode: 400 mA DC ± 10%
Operating time:	Power mode: min. 120 min ECO mode: 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

Type of protection:	IPX0
Reference number (REF):	507.4510.0

### Recharging unit

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 (according to EN 60601-1):	II
CE marking:	
Reference number (REF):	011.1199.0

### General data

Ambient conditions: Transport/storage	
- Temperature:	-20...+50 °C
- Humidity without condensation:	5...90%
- Air pressure:	700...1060 hPa
Ambient conditions: Operation	
- Temperature:	+10...+35 °C
- Humidity without condensation:	20...80 %
- Air pressure:	700...1060 hPa
Period tests	Recommended: testing every 24 months

Updated: 19/8/2024

## 11 Notes on EMC

- Medical electrical devices are subject to special precautions with regard to EMC and must be installed according to the EMC instructions described in the following.

### Guidelines and manufacturer's declaration – Ambient conditions

The ATMOS HL 21 LED is suitable for operation 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 operated in a prescribed environment.

### Guidelines and manufacturer's declaration – Key features

- Please note the technical data in this manual. The essential 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
Recharging unit	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 HF communications equipment (e.g. radios, antenna cables) should be used no closer than 30 cm\* to any part of the ATMOS HL 21 LED specified by the manufacturer, including cables. Otherwise, this could result in degradation of the key features of the device.

- \*The distance may be reduced at higher immunity test levels.

#### **⚠ WARNING**

Avoid placing the device on top of or next to another device. This could result in incorrect operation. If this is unavoidable, the proper functioning of the device must be monitored regularly. Please switch off any nearby devices not in use, if possible.

## 12 Notes



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