



LUXAMED GmbH & Co. KG

Daniel-Weil-Str.3 * 89143 Blaubeuren * Germany

Tel: +49(0)7344 92905 0 * Fax: +49(0)7344 92905 10

Email: info@luxamed.de * Internet: www.luxamed.de



Please read the instruction manual carefully before using the LUXAMED® medical device and its accessories, and keep this manual for future reference.

LUXAMED® LuxaScope Auris LED Otoscope

Product contents

- 1 Otoscope
- Single-use ear specula, grey, 10 pcs each: 2.5 mm and 4.0 mm
- 1 Instruction manual
- 1 Mains adapter for power supply, Type GTM46101-1005-USB (only 3.7 V USB variant)
- 1 plug EU / UK / US for mains adapter GTM46101-1005-USB (only 3.7 V USB variant)
- 1 Lithium-ion battery (10440, 320mAh) located in the handle (only 3.7 V USB variant)
- 2 Alkaline batteries (AAA/LR03) (only 2.5 V variant)
- 1 USB cable (only 3.7 V USB variant)

Intended purpose

LUXAMED® LuxaScope Auris LED otoscopes are intended to be used for examining the external auditory canal. The instrument can also be used for other lighting purposes during non-invasive examinations.

Contraindications

- Avoid direct contact with mucous membranes or injured skin.
- Do not shine the light in the eyes.

LUXAMED® LuxaScope Dermatoscope LED

Product contents

- 1 Dermatoscope
- 1 Instruction manual
- 1 Mains adapter for power supply, Type GTM46101-1005-USB (only 3.7 V USB variant)
- 1 Plug EU / UK / US for mains adapter GTM46101-1005-USB (only 3.7 V USB variant)
- 1 Lithium-ion battery (10440, 320mAh) located in the handle (only 3.7 V USB variant)
- 2 Alkaline batteries (AAA/LR03) (only 2.5 V variant)
- 1 USB cable (only 3.7 V USB variant)

Intended purpose

The LUXAMED® dermatoscope LED is intended for the examination of the epidermis in humans and animals and for lighting during non-invasive examinations. It should only come into contact with intact skin to diagnose potential skin changes.

Contraindications

- Avoid direct contact with mucous membranes or injured skin.
- Do not shine the light in the eyes.

LUXAMED® LuxaScope Oculus LED Ophthalmoscope

Product contents

- 1 Ophthalmoscope
- 1 Instruction manual
- 1 Mains adapter for power supply, Type GTM46101-1005-USB (only 3.7 V USB variant)
- 1 Plug EU / UK / US for mains adapter GTM46101-1005-USB (only 3.7 V USB variant)
- 1 Lithium-ion battery (10440, 320mAh) located in the handle (only 3.7 V USB variant)
- 2 Alkaline batteries (AAA/LR03) (only 2.5 V variant)
- 1 USB cable (only 3.7 V USB variant)

Intended purpose

The LuxaScope Ophthalmoscope is intended for examination of the ocular fundus.

Contraindications

- No known side-effects or contraindications.

General warnings



Make sure that there is sufficient contact between the LUXAMED® medical products and the charging plug while charging the device.



Do not use the device while you are charging it and do not charge it unattended.



When cleaning/disinfecting devices that come into contact with patients, make sure that appropriate cleaning agents/disinfectants are used.



Make sure to use personal protective equipment and follow all safety instructions / warnings.



Always remove the batteries (not rechargeable batteries) prior to cleaning/disinfection.



Make sure that no liquid enters the unit.



Only use LUXAMED® medical devices with LUXAMED® replacement parts and accessories. The use of replacement parts and accessories that are not listed in the instruction manual can reduce safety.



During use, metal components near the instrument head can become warm. This is especially the case when the device has been turned on for a long period of time. Do not leave the device turned on if it is not being used.



During normal use of the device, the temperature of touchable parts can reach temperatures up to 48°C.



Do not service LUXAMED® medical devices while using them on patients. Be mindful of all significant risks of reciprocal interference, which may occur when LUXAMED® medical devices are used during special examinations or treatments.



To prevent and minimise electromagnetic disturbances between the LUXAMED® medical device and other devices, please follow the EMC Guidelines for this device and the instructions of other devices.



It is possible for the product to switch on unintentionally when it is turned off as a result of an electrostatic malfunction. The product can be turned off at any time manually or it will turn off automatically after 3 minutes.



If a patient has a warm sensation in the areas of contact, the diagnostic examination must be temporarily stopped and the LUXAMED® device should be turned off to cool off.



All serious incidents that occur in connection with the product must be reported to the manufacturer and the competent authority of the member state in which the user and/or the patient is registered.

Additional warnings for the otoscope



Do not use LUXAMED® otoscopes to shine the light in a patient's eyes.



Ear canal examinations may only be carried out with an ear specula attached.



NEVER use the device without an ear specula. When in use, the ear specula may not be left inside the ear (skin contact) for longer than 1 minute.



The pressure build-up during a pneumatic test must be done carefully (excess pressure hazard and resulting damage).



Caution: The slit for attaching the ear specula has sharp edges, and there is risk of injury.

Additional warnings for the dermatoscope



Do not use LUXAMED® dermatoscopes to shine light in a patient's eyes.



The examination may only be carried out with a viewing window attached. NEVER use the device without a viewing window.



When the device is in use, the viewing window may not be kept on the skin (skin contact) for longer than 1 minute.

Additional warnings for the ophthalmoscope



Maximum duration of shining light in the eyes: 1 minute!

General instructions for use

The head of the medical device can be detached from the handle by pulling it vertically.

The head can be put back on the handle in reverse order by pushing the mounting adjustment vertically onto the handle with locking pins (5) until you can feel it lock into place.

Power supply

- 2 Alkaline cell batteries (AAA/LR03) for models without charging function
- LUXAMED® charging handle with built-in charging unit and LUXAMED® rechargeable battery for models with charging function.
- The LUXAMED® charging cover (3) indicates the correct charging process on the charging status display (orange LED light appears); once the rechargeable battery is fully charged, the orange LED light turns off.

CAUTION: Fully charge the battery before using it for the first time! Charging time: 4 hrs.

When the USB charging cable is connected to a computer, it must meet the requirements of IEC 60601-1.

Instructions for LUXAMED® instrument handle

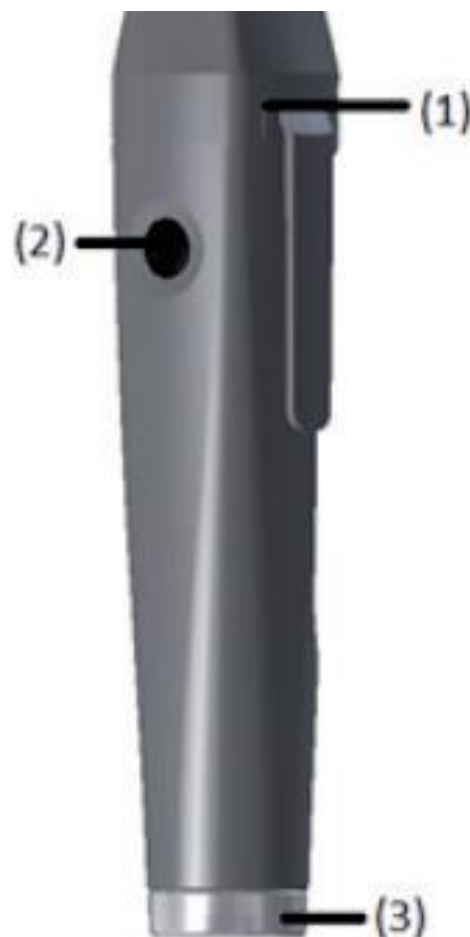
The LUXAMED® instrument handle is only intended for use with LUXAMED® instruments. The instruments may only be used by medically trained personnel.

Instrument connection

Mounting adjustment with locking grooves (1).

To turn on

Press the push-button switch (2) once.



To adjust the brightness

To make it brighter: Hold down the push-button switch (2) when the device is in switched-on mode. When the desired level of brightness has been reached, let go.
To make it less bright: Hold down the push-button switch (2) again. When the desired level of brightness has been reached, let go.

Changing the colour of the light

With the product variant CCT, the user can select the type of lighting they want instead of the function described previously for adjusting the brightness (not available with the ophthalmoscope):

The LUXAMED medical device has two different types of lighting.

1. Warm white light with 3000 K
2. Cold white light with 6000 K

The push-button switch (2) must be pushed to change the colour. To change it again, repeat the process.

To turn off the device

If the medical device is on, push the switch (2) once.

The medical device also has an automatic shut-off function. It will turn off the device after 3 minutes.

To change the batteries (for the 2.5 V variant)

To change the battery, open the battery compartment lid (3) by turning it to the left. **CAUTION:** Make sure to put the poles of the new batteries in the correct position (the plus pole of the battery faces the head of the medical device and the minus pole faces the battery compartment lid). Batteries placed incorrectly can damage the LUXAMED® medical device and lead to expiry of warranty claims.

Put the battery compartment lid (3) back on and close it by turning it to the right. Do not change the batteries when in the vicinity of patients.

Troubleshooting

If the light of the device flickers during operation, please replace the batteries contained in the device.

To change rechargeable batteries (for the 3.7 V variant)

Rechargeable batteries may only be changed by authorised personnel. In the event of a defective rechargeable battery, please send the entire instrument

handle to LUXAMED® or an authorised dealer. If inadequately trained personnel change the rechargeable battery, it could lead to hazards such as high temperatures, fire or explosion.

Cleaning

Clean the device with a soft, lint-free towel; if needed, moistened with a little alcohol. The LUXAMED medical device may not be submerged in liquid.

Disinfection

Use a disinfectant wipe to disinfect or hygienically clean the external surfaces of device. Disinfectants can be used that have been approved for medical devices made of metal, plastic and glass. Follow the information provided by the manufacturer of the cleaning agent.

In accordance with RKI recommendations (Robert Koch Institute, Germany), the disinfectant must fall under the AB classification range (verifiably bactericide, fungicide and virucide) in the RKI definition list.

Sterilisation

No sterilisation is permitted.

Disposal

The product must be taken to a separate waste collection site for electrical and electronic equipment.

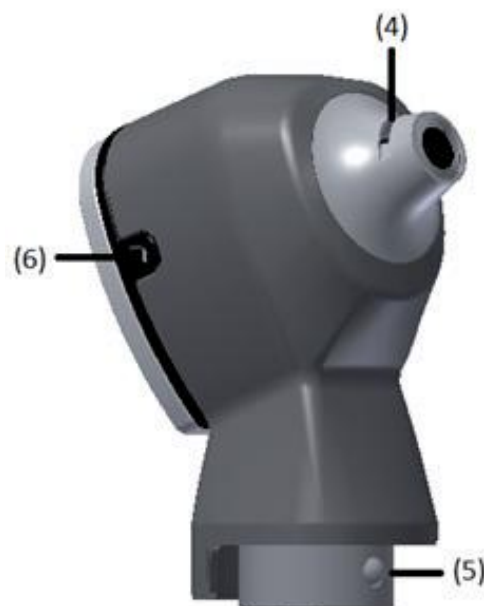
Additional instructions for using the otoscope

Attachment of the ear specula:

LUXAMED® LuxaScope Auris LED otoscopes may only be placed in the ear canal with an ear specula attached.

The ear specula should be attached to the tip of the otoscope (4) with the locking pin by turning it slightly clockwise.

An ear specula does not have to be placed on the otoscope if it is being used as a light for another purpose, as long as it does not come into direct contact with the skin or mucous membranes.



Magnifying function:


The magnifying glass in the field of view provides 3x object magnification. The magnifying glass can be turned clockwise until the end stop for instrumentation.

Use for a pneumatic otoscopy test:

The LUXAMED® LuxaScope Auris LED otoscope can be connected to a pneumatic head with a rubber bulb and tubing for conducting a pneumatic test (6).

NE

Cleaning

 Ear speculas may only be used once. Treatment can lead to damage on the ear specula.

The magnifying glass must not be cleaned/disinfected with cleaning agents containing alcohol as there is a risk of clouding. Only use products that are suitable for plastic lenses.

Additional instructions for using the dermatoscope

Viewing window:

The viewing window (3) has a right-hand screw thread so it can be detached from the dermatoscope head when necessary.

Zoom function:

The magnifying glass in the field of view can magnify an area from 1 to 10 times and features a zoom function. The user can zoom in on an area by turning the black ring (4).

If necessary, apply transparent ultrasound gel or a similar product to the area to be examined. Turn on the light and place the viewing window in the middle of the examination area. Do not apply any pressure when doing so. You can then get closer with your eyes and use the zoom ring to bring the image into focus.



Additional instructions for using the ophthalmoscope

Correction values of the lens wheel

+ | 1 | 2 | 3 | 4 | 6 | 8 | 10 | 15 | 20 D

- | 1 | 2 | 3 | 4 | 6 | 8 | 10 | 15 | 20 D

Hold the handle of the ophthalmoscope and place your index finger on the edge of the lens.

This can be turned again during the examination to get the best dioptre setting. Negative dioptre values of the corrective lens are shown in red and positive values in black. The setting without any corrections ("0") is green. Hold the ophthalmoscope approximately 15 cm away from patients.

Use your index finger to adjust the available aperture settings for the lens. To do this, turn the horizontal aperture dial on the front of the device until the desired aperture is locked in place. The following aperture settings are available: cross-hairs, large spot, small spot, half-spot and green filter.



General technical specifications

Nominal voltage	2.5 V or 3.7 V
Ampacity	23mA
Applied part	BF
Protection class	Class II
Protection rating	IP20
Ambient conditions	5° C – 40° C 10-90% rel. humidity 700-1070 hPa atmospheric pressure
Warehouse/ transport conditions	-10° and +45°C. 10% - 90% rel. humidity
Supply voltage	2 AAA Alkaline Batteries (2.5 V variant) 1 3.7 V lithium rechargeable battery (3.7 V variant)














Applicable standards

Otoscope	Dermatoscope	Ophthalmoscope
IEC 60601-1	IEC 60601-1	DIN EN 60601-1
IEC 60601-1-2	IEC 60601-1-2	DIN EN 60601-1-2
IEC 60601-1-6	IEC 60601-1-6	DIN EN 60601-1-6
IEC 60601-1-9	IEC 60601-1-9	DIN EN 60601-1-9
DIN EN ISO 10993-1	DIN EN ISO 10993-1	DIN EN ISO 10993-1
IEC 62471	IEC 62471	DIN EN ISO 15004 DIN EN ISO 10942

Products covered by these instructions for use

See table overleaf for product numbers.

Explanation of symbols

	Applied part type BF
	Protection class II
	Follow the instruction manual
	Stand-by (on/off button)
	Do not reuse
	Manufacturer
	Production date
	Caution
	The product must be taken to a separate waste collection site for electrical and electronic equipment.
	Conforms with EU regulations
	This instrument is a medical device
	Conforms with UK regulations
	Authorised agent for medical products in Switzerland: Inspera GmbH Thunstrasse 64 CH-3110 Münsingen, Switzerland

Warranty conditions

We grant a warranty period of 2 years for this product starting from the date of purchase. The purchase date must be proved with a receipt. Defects due to material or production flaws will be remedied within the warranty period free of charge. The warranty period is not extended for the entire product as a result of service provided under the warranty, but rather only for the replaced parts.

Deterioration through wear and tear, transport damage and any damage caused by improper handling (e.g. not following the instruction manual) or due to interference by unauthorised persons are excluded from the warranty. The warranty does not give rise to any claims for damages against us.

The statutory claims for defects of the buyer pursuant to Section 437 of the German Civil Code (BGB) are not restricted.

In case of a claim under the warranty, the device must be sent to the manufacturer together with the original receipt:

LUXAMED GmbH & Co. KG
Daniel-Weil-Straße 3
89143 Blaubeuren
GERMANY

Customer service

Warranty and repair work must be carried out by trained and authorised personnel. The device may not be modified without the manufacturer's permission. Send the device carefully packed and with sufficient postage to your authorised dealer or directly to:

LUXAMED GmbH & Co. KG
Abteilung Service
Daniel-Weil-Straße 3
89143 Blaubeuren
GERMANY
Tel: + 49 (0) 7344 92905-0

UK Responsible Person

Advena Ltd
Pure Offices
Plato Close
Warwick
CV34 6WE
England, United Kingdom