# HEINE mini 3000® LED Dermatoscope

ENGLISH

Please read and follow these instructions for use carefully and keep them for future reference.

**General Conditions of Warranty**

Instead of the statutory warranty time period of 2 years, HEINE will grant a guarantee of 5 years from the date of the consignment of the goods ex works, concerning its equipment (excluding disposables, e.g. bulbs, single-use articles, and rechargeable batteries). Date of consignment means that HEINE hands the goods over to the transport carrier, freight forwarder or any other person designated by the Customer for the transport of the goods without loading the collecting vehicle.

The guarantee covers irreproachable workmanship, on condition of the proper use of the equipment and the observation of the operating instructions. During the warranty- and guarantee time period, errors and deficiencies arising on the equipment will be rectified free of charge, in so far as such are evidenced by defective materials, processing and/or constructional errors. Should buyer complain of a material deficiency during the warranty time period, then the onus of proof is always to be on the orderer, that the product was defective already upon receipt of the goods. The statutory warranty and the guarantee do not apply to loss or damage caused by wear and tear, negligent use, the non-employment of original HEINE components and/or spares (in particular bulbs, as these have been especially developed for HEINE instruments in accordance with the following criterions: colour temperature, useful service life, safety, optical quality and performance. The statutory warranty and the guarantee do not apply to interventions by persons not authorised by HEINE or when the operating instructions are not observed by the customer. Any modification of a HEINE product with parts or additional parts which do not conform to the original HEINE specification will invalidate the warranty for the correct function of the product and further invalidate any warranty claims which result from such a change or modification. Further claims, in particular claims for replacement of loss or damage, which are experienced otherwise than directly on the HEINE product itself, are hereby excluded.

**For U.S. only:**
**Caution: Federal law restricts this device to sale by or on the order of a Physician or Practitioner!**

**Intended Use**

The HEINE mini 3000® LED Dermatoscope is a epiluminescence microscope (dermatoscope) for non-invasive visual examination of intact skin (dermatoscopy) by medical professionals.

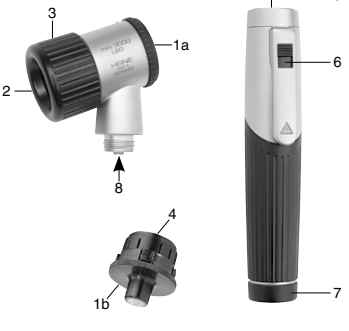
**Warnings and Safety Information**

**CAUTION!** Indicates potentially hazardous situations. Ignoring the corresponding instructions may lead to dangerous situations of mild to moderate extent. (Background: yellow; Foreground: black)

**NOTE!** Indicates valuable advice in terms of installation, operation, maintenance or repair. Notes are important, but not related to hazardous situations.

**Product overview**

1a Contact Plate
1b Small contact plate
2 Ocular
3 Focusing ring
4 Light port
5 Handle head
6 Slide switch 1/0
7 End cap
8 LED light source integrated in instrument thread



**Setting up the HEINE mini 3000® LED Dermatoscope**
To setup the HEINE mini 3000® LED Dermatoskope, please screw the instrument thread (8) onto the handle head (5) (exclusively of the mini 3000 product line). To insert fresh batteries, unscrew the end cap (7) of the handle and insert 2 new batteries (alkaline cells, size LR6/AA) with the plus contact facing the handle head (see picture).


To switch on the light source please slide the switch (6) down into position "1". To switch off the light source slide the switch up to position "0" or clip it firmly over your coat pocket. The handle is then automatically switched off.

- Performance Indicator: When turning on the device the brightness will increase softly to 100% and will then adjust to the brightness corresponding to the actual charge condition of the battery.
- If you realize a significant drop of brightness or a flashing of the lightning immediately after switching on the device, please change the batteries.

**Operation of the HEINE mini 3000® LED Dermatoscope**
Moisten the affected skin with HEINE dermatoscopy oil or comparable, e.g. with a cotton wool swab. Switch on the device and place it gently over the lesion, so that it is in the center of the contact plate (1a).

The examiner's eyes should be as close as possible to the ocular (2). With the free hand adjust the focusing ring (3) until a clearly-focused image is obtained. Using the scale on top of the dermatoscope you can control the adjustment of the focusing ring. In most cases it is only necessary to set up the focus once.

*Removing the contact plate:*
The contact plate (1a) is attached by a bayonet fitting. To remove, simply rotate the knurled ring counter-clockwise and detach from the dermatoscope. The small contact plate (1b) can be used instead of the contact plate (1a) for the examination of inaccessible lesions. It is a simple push-fit in the head. To remove it, simply hold the knurled housing and pull off without twisting. When replacing, make sure that the light-port (4) faces the bulb/LED.

⚠ The HEINE mini 3000® LED Dermatoscope is not allowed to be used for eye examinations!

**Cleaning and disinfection**
The contact plate (1a) can be removed and sterilized or disinfected by any routine method e.g. in disinfectant solution, by washing, boiling or autoclaving (up to 134 degree Celsius for 5min). Sterilization should be used only after the examination of risk patients, because the durability of the contact plate will be reduced by sterilization.

The small contact plate (1b) and the dermatoscope can be cleaned by wiping with a damp cloth soaked in alkaline or pH-neutral cleaning agents.

For disinfection of the outer surface of the instrument we recommend wipe disinfection using detergents, which are released for medical devices.

*Battery handle:*
The handle can be cleaned with a damp cloth (e.g. alkaline or pH- neutral detergent). For disinfection of the outer surface we recommend wipe disinfection by using detergents, which are released for medical devices made out of plastic.

⚠ Disinfection by spraying or immersion as well as sterilization is not allowed and will damage the instrument!

**Maintenance**
The device does not require any regular maintenance.

*Changing the light source:*
With the HEINE mini 3000® LED Dermatoscope the LED cannot be changed.

**Service**
The device does not require regular service.

⚠ Do not open or modify the device. Repairs are only to be performed by qualified personnel.

**Disposal**
The product must be recycled as separated electrical and electronic devices. Please observe the relevant state-specific disposal regulations.

**Technical Specifications**

| | |
|---|---|
| Nominal voltage | 3V DC |
| Nominal current | typ. 220mA |
| Protection class | Internal power supply |
| Application part | Type BF |
| Device classification according to IEC 62471:2006 | Exempt |
| Battery Typ | 2 Alkaline (1.5 V), size AA/LR6 or 1 HEINE mini 2Z (rechargeable with HEINE® mini NT) |
| Magnification | approx. 10x (depending on distance) |
| Focal Range (correction) | approx. +/- 4dpt |
| Contact plates | Silica glass, multi-coated |
| Environmental conditions for operation | 10°C to 35°C<br>30% to 90% rel. humidity<br>800hPa to 1060hPa |
| Environmental conditions for storage and transport | -20°C to 50°C<br>10% to 95% rel. humidity<br>500hPa to 1060hPa |
| Dimensions (L x B x H) for head and handle | 165 x 52 x 35 $mm^3$ |
| Weight | ca. 195g (incl. 2 batteries) |

**General Notes and Warnings**

⚠ Check the correct operation of the device before use! Do not use the device if there are visible signs of damage.

⚠ Do not use the device in hyperbaric chambers, in explosive or oxygen loaded environments!

⚠ Do not use the device near strong magnetic fields like MRI scanners!

⚠ Do not look into bright light sources by means of loupes. Hazard of glare!

⚠ The performance and safety of the device can only be guaranteed when fitted with original HEINE accessories and HEINE spare parts. Otherwise the warranty is terminated.

⚠ Don't modify the device! If the device is modified despite that, take care that use of the device is safe by performing investigations and tests.

Your HEINE mini 3000® LED F.O. Dermatoscope is a precise optical instrument. Please handle the device with care and clean it at regular intervals.

Store and use the device in dry and dust-free environments only! If you don't use the device for a longer period of time, please remove the batteries in advance.

**Electromagnetic Compatibility**

Medical electric devices are subject to special precautionary measures with regard to electromagnetic compatibility (EMC). Portable and mobile high frequency communication equipment can affect medical electric devices.

⚠ This device is intended for use by medical professionals in the electromagnetic environment specified below. The user of this device should assure that it is used in such an environment.

⚠ The use of accessories, converters or cables other than the ones specified by HEINE might lead to increased emission reduced electrical immunity of the medical equipment.

⚠ The device may not be stacked directly near or used directly beside other devices. If the device is to be operated in a stack or with other devices, the device should be watched to ensure it operates properly in this location.

| Guidance and manufacturer's declaration – electromagnetic emissions | | |
|---|---|---|
| The device is intended for use in the electromagnetic environment specified below.<br>The customer or the user of the device should assure that it is used in such environment. | | |
| **Emission test** | **Compliance** | **Electromagnetic environment – Guidelines** |
| RF emissions<br>CISPR11 | Group 1 | The device uses RF energy only for its internal function. Therefore, RF-emission is very low and it is unlikely that any interference in nearby electronic equipment. |
| RF emissions<br>CISPR 11 | Class B | The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.<br>**Warning:** This device is intended only for use by medical professionals. This is a device of class A CISPR 11 in the domestic environment, this device may cause radio interference, so that it may be necessary in this case, to take appropriate remedial measures, as e.g. orientation, new arrangement or shielding of the device or restrict the connection to the site. |
| Harmonic Emissions<br>IEC 61000-3-2 | Not applicable | |
| Voltage Fluctuations/<br>Flicker Emissions IEC 61000-3-3 | Passed | |

| Guidance and manufacturer declaration - Electromagnetic immunity | | | |
|---|---|---|---|
| The device is intended for use in the electromagnetic environment specified below.<br>The customer or the user of the device should assure that it is used in such environment. | | | |
| **Immunity test** | **IEC 60601 test level** | **Compliance level** | **Electromagnetic environment – Guideline** |
| Electrostatic discharge (ESD) acc. to<br>IEC 61000-4-2 | ± 6 kV contact discharge<br>± 8 kV air discharge | ± 6 kV contact discharge<br>± 8 kV air discharge | Floors should be wood, concrete or covered with ceramic tiles. If floors are covered with synthetic material, the relative humidity should be at least 30 %. |
| Electrical fast transient/ burst<br>IEC 61000-4-4 | ± 2 kV for mains cables<br>± 1 kV for input and output lines | ± 2 kV for mains cables<br>± 1 kV for input and output lines | The supply voltage quality should be that of a typical commercial or hospital environment. |
| Surge IEC 61000-4-5 | ± 1 kV voltage phase – phase,<br>± 2 kV voltage phase – earth | ± 1 kV voltage phase – phase<br>± 2 kV voltage phase – earth | Mains power quality should be that of a typical commercial or hospital environment. |
| Voltage dips, short interruptions and voltage variations on power supply input lines<br>IEC 61000-4-11 | < 5% $U_T$, (>95% dip in $U_T$) for 1/2 period<br>40% $U_T$, (60% dip in $U_T$) for 5 periods<br>70% $U_T$, (30% dip in $U_T$) for 25 periods<br><5% $U_T$, (>95% dip in $U_T$) for 5 seconds | < 5% $U_T$, (>95% dip in $U_T$) for 1/2 period<br>40% $U_T$, (60% dip in $U_T$) for 5 periods<br>70% $U_T$, (30% dip in $U_T$) for 25 periods<br><5% $U_T$, (>95% dip in $U_T$) for 5 seconds | Mains power quality should be that of a typical commercial or hospital environment. If the user of the device device requires continued operation during power mains interruptions, it is recommended that the device be powered by a UPS (uninterruptible power supply) or a battery. |
| Power frequency (50/60 Hz) magnetic field<br>IEC 61000-4-8 | 3 A/m | 3 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
| Comment: $U_T$ is the a.c. supply voltage prior to application of the test level. | | | |

| Guidance and manufacturer's declaration – electromagnetic immunity | | | |
|---|---|---|---|
| The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such environment. | | | |
| **Immunity test** | **IEC 60601 test level** | **Compliance level** | **Electromagnetic environment Guidelines** |
| Conducted RF<br>IEC 61000-4-6 | 3 Veff<br>150 kHz to 80 MHz | 3 V eff | Portable and mobile RF communication equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. |
| Radiated HF<br>IEC 61000-4-3 | 3 V/m<br>80MHz to 2,5GHz | 3 V/m | **Recommended separation distance:**<br>d = 3,5/3 * SQRT (P/W)<br>d = 3,5/3 * SQRT (P/W) 80 MHz to 800 MHz<br>d = 7/3 * SQRT (P/W) 800 MHz to 2,5 GHz<br>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).<br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site surveya, should be less than the compliance level in each frequency range.b<br>Interference may occur in the vicinity of equipment marked with the following symbol:<br>  |

Note 1: At 80Hz and 800MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

**a** Field strengths from fixed transmitters, such as base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

**b** Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V / m.

| Recommended separation distances for portable and mobile RF communication equipment and the device | | | |
|---|---|---|---|
| The device is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment. | | | |
| **Rated maximum output power of transmitter (W)** | **Separation distance according to frequency of transmitter (m)** | | |
| | **150 kHz to 80 MHz**<br>d = 3,5/3 * SQRT (P) | **80 MHz to 800 MHz**<br>d = 3,5/3 * SQRT (P) | **800 MHz to 2,5 GHz**<br>d = 7/3 * SQRT (P) |
| 0.01 | 0.1 | 0.1 | 0.2 |
| 0.1 | 0.4 | 0.4 | 0.7 |
| 1 | 1.2 | 1.2 | 2.3 |
| 10 | 3.7 | 3.7 | 7.4 |
| 100 | 11.7 | 11.7 | 23.3 |

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

**Explanation of utilized symbols**
The following symbols are used on the device or on the packaging:

| | |
|---|---|
| CE | The CE marking indicates that the product conforms to the provisions of European Medical Device Directive (93/42/EEC). |
| REF | Catalogue number |
|  | Manufacturer |
|  | Date of manufacture |
|  | Product bearing this symbol may not be disposed of together with general household waste, but instead requires separate disposal. |
|  | Temperature limits in °C for storage and transport |
|  | Temperature limits in °F for storage and transport |
|  | Humidity limitation for storage and transport |
|  | Pressure limitation for storage and transport |
|  | Interference may occur in the vicinity of equipment marked with the following symbol. |
|  | Fragile, handle with care! |
|  | Keep dry! |
|  | "Grüner Punkt" (country-specific) |
|  | Please read and follow the instructions for use and keep them for future reference (Background: blue; Foreground: white) |
|  | Type BF applied part |