HEINE QUALITY
MADE IN GERMANY

HEINE Dermatoscopes

CE

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med 0415 2015-03-25

V-200.00.036

HEINE Dermatoscopes

These instructions apply to the following products of the HEINE Dermatoscope series: HEINE® NC1 Dermatoscope, HEINE DELTA® 20 **P**lus Dermatoscope, HEINE DELTA® 20**T** Dermatoscope, HEINE mini3000® LED Dermatoscope, HEINE mini3000® Dermatoscope.

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

Intended Use

The HEINE dermatoscopes are battery-powered medical examination lights.These devices are intended for medical purposes to illuminate body surfaces during a medical examination. So are epiluminescence microscopes (dermatoscope) with a polarizing filter and a magnification used by a medical professional for non-invasive visual examination of intact skin.
This can be performed on every kind of patient.

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

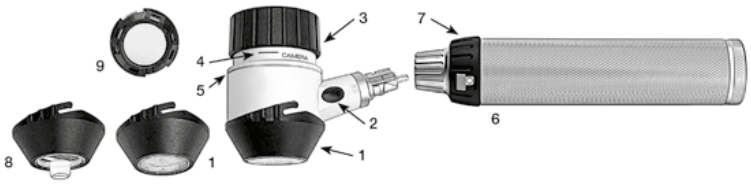
Warnings and Safety Information

Caution! Indicates potential hazardous situations. Ignoring the corresponding instructions may lead to dangerous situations of mild to moderate extent. (Background color yellow, foreground color black.)

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

Product overview

HEINE DELTA® 20 Plus and HEINE DELTA® 20T Dermatoscope



1 Contact plate
- 1a Contact plate immersion (N) with scale
- 1b Contact plate immersion (N) without scale
- 1c Contact plate polarisation (P) with scale
- 1d Contact plate polarisation (P) without scale
- 1e Contact plate DELTA 20**T** with scale
- 1f Contact plate DELTA 20**T** without scale

2 Changeover to 2 LEDs
3 Focus ring
4 Camera indicator
5 Fixation groove
6 BETA handle (optional)
7 Dimmer
8 Contact plate small
9 Filter insert
- 9a Polarizing insert
- 9b Neutral density insert
- 9c DELTA 20**T** filter insert

HEINE® NC1 Dermatoscope

10 Focusing ring
11 Contact plate

HEINE mini3000® LED/XHL Dermatoscope

12 Contact plate
13 Contact plate small
14 Ocular
15 Focusing ring
16 Light port
17 Handle head
18 Slide switch 1/0
19 End cap
20 LED or XHL light source integrated in instrument head

Setting up

To set up the instrument, screw the instrument head into the HEINE battery handle or plug it on the HEINE rechargeable handle.

HEINE DELTA® 20 Plus and HEINE DELTA® 20T Dermatoscope

Assembly of filter insert and contact plate:
Attach the insert (9) to the contact plate (1) and rotate the insert to lock the bayonet connection. To disassemble the filter (9) from the contact plate, please reverse the procedure.

Attachment of contact plate:
The contact plates (1 and 8) are attached by a bayonet connection. To remove the contact plate turn it counterclockwise and pull it away from the dermatoscope. To attach, reverse the procedure. Always check whether the bayonet is safely locked.

Operation

HEINE DELTA® 20 Plus Dermatoscope

For examination of hard to reach lesions use the small contact plate (8) in place of the standard contact plate (1).

Use DELTA 20 Plus with immersion contact plate (1a, 1b, 8):
Prepare the skin by moistening with HEINE dermatoscopy-oil (use a cotton swab) or disinfectant spray.
Turn the dermatoscope on by rotating the on/off ring (7) at the handle. Gently place the instrument so that the lesion is in the center of the contact plate. The examiner's eye should be as close to the eye-piece (3) as possible. Adjust the focus ring until a crisp, clearly-focused-image is obtained.

Always use the device in combination with one of the filter inserts (polarizing filter or neutral density filter).
Only use contact plates from HEINE.

Using the DELTA 20 Plus with polarizing contact plate (1c, 1d):
When using the polarizing contact plate, DO NOT prepare the skin with liquid like dermatoscopy-oil or disinfectants.
Apart from that the general operation is the same as the procedure above.

Brightness control:
The voltage regulation electronics of the HEINE DELTA® 20 **P**lus Dermatoscope guarantee constant brightness.

Pressing one of the two buttons on the instrument (2) will reduce the brightness by 50% and will turn off 2 of the 4 LED's resulting in lateral illumination for improved contrast when viewing the pigmented structure.

An electrical conducting connection between camera, PC and a mains power source is not permissible.

For documentation with a digital camera only, use the HEINE photo adaptor and our recommend adaptor from the digital camera adaptor range.

HEINE DELTA® 20T Dermatoscope

The DELTA 20**T** allows for a rapid change from polarized to non-polarized examination mode over a side switch. Application remains the same as the DELTA 20 **P**lus with the immersion contact plate (see above). A difference is that no immersion fluid is required in the polarized examination mode.

HEINE® NC1 Dermatoscope

The device can be used in non-contact modus. To do this, the contact plate, which is attached through magnets, must be removed.
Hold the device approximately 2cm above the skin area to be examined. Bring your eye towards the eye piece (10) as close as possible and adjust the eye piece focus until a sharp image is achieved.

Contact modus (with contact plate):
See HEINE DELTA® 20 **P**lus Dermatoscope with polarizing contact plate.

An extra lens is integrated in the contact plate (11) which provides a 9 x magnification when the contact plate is connected. Without the contact plate, a 6 x magnification is achieved.

HEINE mini3000® LED/XHL Dermatoscope

Moisten the affected skin with HEINE dermatoscopy oil or comparable 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 (12).

The examiner's eyes should be as close as possible to the ocular (14). With the free hand adjust the focusing ring (15) 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 (12) is attached by a bayonet fitting. To remove, simply rotate the knurled ring counterclockwise and detach from the dermatoscope. The small contact plate (13) can be used instead of the contact plate (12) for the examination of inaccessible lesions. To remove it, simply hold the knurled housing and pull off without twisting. When replacing, make sure that the light port (16) faces the bulb/LED.

HEINE dermatoscopes are intended for a brief examination of less than 10 minutes with a 20 minutes break until the next application.

The setup and operation of the HEINE handles are described in a separate instruction for use.

Hygienic Reprocessing

Instructions on hygienic reprocessing must be adhered to, based on national standards, laws and guidelines.
Classification according to KRINKO: non-critical
Spaulding Classification USA: non-critical

⚠ Allow the device to cool down before reprocessing.

In the event of suspected contamination, the instruments should be forwarded for reprocessing immediately.

The described cleaning and disinfection measures do not replace the specific rules applicable for the establishment.

HEINE Optotechnik only approves the agents and procedures mentioned below.

Cleaning and disinfection may only be carried out by personnel with sufficient hygienic knowledge.

Observe the instructions of the manufacturer of the reprocessing media.

Do not use spray or immersion disinfection, dripping wet or heavily foaming tissues. Do not use ultrasonic reprocessing. Do not use reprocessing media including alcohol.

The contact plates have to be cleaned and/or disinfected after each use.

They should only be sterilized after the treatment of high risk patients. The mini3000 contact plate up to 4 times max., the DELTA 20 **P**lus contact plate up to 25 times max.

Steam sterilization of the instrument heads, the filter inserts (9), the small contact plates of the DELTA 20 **P**lus and DELTA 20**T** (8), of the mini3000, mini3000 LED dermatoscope (13) and the contact plate of the NC1 dermatoscope (11) and the DELTA 20**T** (1e+1f) is not allowed.

Procedure

Instrument head:

Clean and disinfect the head of the dermatoscopes manually (clean and disinfect through wiping)

Recommended agents:
Cleaning agent: Neodisher® MediClean
Disinfectant agent: quaternary ammonium compounds (e.g. Microbac® Tissues)

Contact plates:

Clean and disinfect the contact plates manually after removing from the instrument head (clean and disinfect through wiping).

Before cleaning or disinfection you can remove the additional lens of the NC1 dermatoscope, but you must remove the filter insert of the DELTA 20 **P**lus and of the DELTA 20**T**.

Recommended agents:
Cleaning agent: Neodisher® MediClean
Disinfectant agent: quaternary ammonium compounds (e.g. Microbac® Tissues)

The contact plates can be reprocessed up to 1000 cycles (without autoclaving).

The contact plates of the DELTA 20 **P**lus (1a-1d) and of the mini3000, mini3000 LED dermatoscope (12) can be sterilized once they have been removed from the instrument head and the filter inserts have been removed.

Recommended programs of sterilization:
Steam sterilization: 132-134°C; 3 min
Fractional vacuum procedure (three-times) or gravitational procedure (three-times).

Changing the light source

⚠ Allow the device to cool down before changing the bulb.

HEINE DELTA® 20 Plus, HEINE DELTA® 20T, HEINE® NC1 and HEINE mini3000® LED Dermatoscope:

The LED cannot be changed.

HEINE mini3000® Dermatoscope:

Remove the instrument head from the handle and pull out the bulb.
Wipe down the head of the new bulb with a soft cloth Insert the new bulb as far as possible into the socket.

Maintenance and Service

The instruments do not require maintenance or service.

General Warnings

⚠ Check the correct operation of the device before use! Do not use the device if there are visible signs of damage or the light begins to flash.

Do not use the device in fire- or explosive risk area (e.g. oxygen saturated or anaesthetic environments)

Do not modify the device.

Use only original HEINE parts, spare parts, accessories and power sources.

Repairs shall only be carried out by qualified persons.

Do not look directly into the light source to avoid dazzle from the intense light. The dermatoscopes are not suitable for eye examination.

General Notes

The warranty for the entire product is invalidated if non-genuine HEINE products or non-original parts are used and if repairs or modifications are made to the device by persons not authorized by HEINE. For more information, please visit www.heine.com.

If you don't use the device for a longer period of time, please remove the batteries in advance.

Disposal

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

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 is a device 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.

The use of accessories, converters or cables other than the ones specified by HEINE might lead to increased emission and 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.

The appendix contains following tables:
- Guidance and manufacturer's declaration – Electromagnetic immunity
- Technical specification
- Explanation of the used symbols

Guidance and manufacturer's declaration – electromagnetic emissions		
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.		
Emission test	**Compliance**	**Electromagnetic environment – Guidelines**
RF emissions 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 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.
Harmonic Emissions IEC 61000-3-2	Class A	Symmetrical three-phase devices and other devices.
Voltage Fluctuations/ 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. 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 IEC 61000-4-2	± 6 kV contact discharge ± 8 kV air discharge	± 6 kV contact discharge ± 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 IEC 61000-4-4	± 2 kV for mains cables ± 1 kV for input and output lines	± 2 kV for mains cables ± 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, ± 2 kV voltage phase – earth	± 1 kV voltage phase – phase ± 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 IEC 61000-4-11	< 5% U_T, (>95% dip in U_T) for 1/2 period 40% U_T, (60% dip in U_T) for 5 periods 70% U_T, (30% dip in U_T) for 25 periods <5% U_T, (>95% dip in U_T) for 5 seconds	< 5% U_T, (>95% dip in U_T) for 1/2 period 40% U_T, (60% dip in U_T) for 5 periods 70% U_T, (30% dip in U_T) for 25 periods <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 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 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 IEC 61000-4-6	3 Veff 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 IEC 61000-4-3	3 V/m 80MHz to 2,5GHz	3 V/m	**Recommended separation distance:** d = 3,5/3 * SQRT (P/W) d = 3,5/3 * SQRT (P/W) 80 MHz to 800 MHz d = 7/3 * SQRT (P/W) 800 MHz to 2,5 GHz 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). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey**a**, should be less than the compliance level in each frequency range.**b** Interference may occur in the vicinity of equipment marked with the following symbol: 

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 d = 3,5/3 * SQRT (P)	**80 MHz to 800 MHz** d = 3,5/3 * SQRT (P)	**800 MHz to 2,5 GHz** 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.			

Technical specification

Environmental conditions for operation	+10°C to +35°C 30% to 75% rel. humidity 700hPa to 1060hPa
Environmental conditions for storage	+5°C to +45°C 45% to 80% rel. humidity 500hPa to 1060hPa
Environmental conditions for transport	-20°C to +50°C 45% to 80% rel. humidity 500hPa to 1060hPa
Nominal voltage	3.0V – 3.7V
Nominal current	440 – 760mA
Protection class	internal power supply
IP-Code	IP20
Device classification according to IEC 6247	Group 2
Applied part	Type BF (for contact plate)
HEINE mini3000® Dermatoscope	#109 (2,5V)

Erläuterung der verwendeten Symbole
Auf dem Gerät bzw. der Verpackung finden sich folgende Symbole:

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

Explication des symboles utilisés
Les symboles suivants figurent sur l'appareil ou sur l'emballage :

Explicación de los símbolos utilizados
Sobre el aparato o sobre el embalaje se encuentran los siguientes símbolos:

Spiegazione dei simboli utilizzati
Sull'apparecchio e/o sulla confezione sono presenti i seguenti simboli:

Förklaring av symboler som används
På enheten eller på förpackningen hittar du följande symboler:

Verklaring van de gebruikte symbolen
Op het apparaat resp. op de verpakking staan de volgende symbolen:

Forklaring af de anvendte symboler
Følgende symboler findes på apparatet hhv. emballagen:

Käytettyjen symbolien selitys
Laitteesta ja pakkauksesta löytyvät seuraavat symbolit:

Explicação dos símbolos utilizados
Os símbolos seguintes são usados nos equipamentos ou nas suas embalagens:

CE	CE-Kennzeichnung kennzeichnet die Übereinstimmung mit der Europäischen Medizinprodukterichtlinie 93/42 EWG. The CE mark indicates that the product complies with the European medical device directive 93/42/EEC. Le marquage CE indique la conformité à la directive européenne 93/42/CEE relative aux dispositifs médicaux. El marcado CE indique la conformidad con la directiva europea 93/42 /CEE relativa a los productos sanitarios. Il marchio CE indica la conformità con la direttiva europea sui dispositivi medici 93/42 CEE. CE-märkning markerar en överensstämmelse med det europeiska direktivet för medicinska produkter 93/42 EEG. CE-markering duidt de overeenstemming aan met de Europese Richtlijn betreffende medische hulpmiddelen 93/42 EEG. CE-mærkningen angiver overensstemmelse med det europæiske direktiv 93/42/EØF om medicinsk udstyr. CE-merkintä tarkoittaa, että laite vastaa eurooppalaisen lääkinnällisiä laitteita koskevan standardin 93/42 ETY vaatimuksia. O símbolo CE identifica a concordância com a Diretriz Européia para Dispositivos Médicos 93/42/CEE.
REF	Katalog- oder Bestellnummer Catalogue- or order number Numéro de catalogue ou de commande Número de catálogo o de pedido Codice catalogo e di dell'ordine numero Katalog- eller Beställningsnummer Catalogus- of Bestelnummer Katalog- eller Ordrenummer Luettelo- tai viitenumero Número de catálogo ou pedido