

## HEINE DELTA® 30 dermatoscope

### Reliable diagnostics

1.P. Dermatoskopas rankinis, nešiojamas



Not only would the HEINE DELTA 30 win any beauty pageant, but stands out due to its very good imaging. Combined with a field of view measuring a veritable 30 millimetres and unprecedented colour rendering, in LED<sup>HQ</sup> of course. Polarisation provides glare-free and non-reflective working conditions. Above all else, it is comfortable to operate with its angled, ergonomic design and intuitive control.

HEINE diSTANCE working ring: The stable working ring enables the user to examine and manage a lesion under magnification by maintaining a constant distance between the skin and the dermatoscope without contact. (optional)



Digital documentation  
by HEINE

- ▶ **Large true field of view of 30mm** (lens 32mm) ← 3.P. Integruota matavimo skalė 30 mm
- ▶ **Crystal-clear image** with the achromatic HEINE optical system ← 6.P. Kontaktiniai ir nekontaktiniai matavimo režimai
- ▶ **Fast change from contact- to non-contact examination** ← 9.P. Ergonominė kampinė rankena
- ▶ **Ergonomic handling** thanks to the angled product design ← 7.P. Dioptrijų kompensavimas
- ▶ **Operate with just one hand:** individual focusing dioptre compensation approximately -4 to +4 dpt. ← 2.P. Integruota apšvietimo sistema LED
- ▶ **Excellent colour rendering** due to LED<sup>HQ</sup>
- ▶ **Digital documentation:** Image and data management convenient and intuitive. More information on our website: [www.heine.com/en/digital](http://www.heine.com/en/digital)
- ▶ **Glare-free and non-reflective working conditions** thanks to polarisation
- ▶ **Custom light intensity:** 3 degrees of luminous intensity ← 4.P. Keičiamas dermatoskopo vaizdo ryškumas, 3 laipsnių
- ▶ **10x magnification** ← 5.P. Vaizdo didinimas 10x
- ▶ **Switch between polarised and non-polarised light at the touch of a button** = toggle function. For more information, please visit [heine.com/en/Toggle](http://heine.com/en/Toggle) ← 6.P. Poliarizuoti ir nepoliarizuoti šviesos darbiniai režimai
- ▶ **No cross-contamination:** autoclavable contact plate with scale ← 10.P. Apsauga nuo dulkių
- ▶ **Maintenance-free** due to our dustproof design
- ▶ **Rechargeable battery with Li-ion technology:** no memory effect; you can safely recharge the battery regardless of its charge state

12.P. Integruota ličio jonų baterija kraunama per USB jungtį

14.P. Dermatoskopas



[01]

DELTA 30 dermatoscope	LED
DELTA 30 with contact plate with scale, USB cord with medical approved plug-in power supply, hard case [01] ← 14.P. USB pakrovimo laidas	K-230.28.305
Charger 30 table charging station	X-002.99.212
HEINE diSTANCE working ring [02]	K-000.34.103



[02]

14.P. Priedėlis pagerinantis dermatoskopo prigludimą prie tiriančiojo akies

▶ Accessories can be found on [page 102](#).

# HEINE DELTA<sup>®</sup>one

## HEINE DELTA<sup>®</sup> 30

## HEINE DELTA<sup>®</sup> 30 PRO

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

### Intended use

#### *DELTAone, DELTA 30 and DELTA 30 PRO Dermatoscope*

The dermatoscope is an internally powered medical examination light for non-invasive transient contact and non-contact examination of the skin.

In contact mode, skin showing a pathological change or a change due to a disease can be examined.

The small contact plate is not suitable for use on mucosa. The examination of wounds is only permitted in non-contact mode. The contact plate must be removed for non-contact mode. The working ring is intended for the examination and instrument access of a skin section that has a pathological or disease-related change. The contact surface of the working ring must not come into contact with this altered skin.

The product may only be used by qualified medical professionals and in professional healthcare facilities.

The application is not limited to any patient demography.

#### *DELTAone, DELTA 30 and DELTA 30 PRO Dermatoscope with "Smartphone Adapter" option*

The "Smartphone Adapter" option can be used to mechanically connect a smartphone with a respective app.

The app is designed for documentation by recording, storing and displaying images.

 **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!** This symbol 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!** This symbol indicates valuable advice. This notes are important, but no related to hazardous situations.

### Product overview

#### HEINE DELTAone

- 1 On/Off switch
- 2 Focusing ring
- 3 Contact plate
- 3a Contact plate small
- 4 Micro-USB connector
- 5 Charge indicator
- 6 Brightness control (right)
- 7 Polarisation button (left)
- 8 Polarisation indicator



#### HEINE DELTA 30

- 9 On/Off switch
- 10 Polarisation button
- 11 Brightness control
- 12 Contact plate
- 12a Contact plate small
- 13 Focusing ring
- 14 Polarisation indicator
- 15 Micro-USB connector
- 16 Charge indicator
- 20 HEINE diSTANCE working ring

11.P. Pakrovimo indikatorius



## HEINE DELTA 30 PRO

- 9 On/Off switch
- 10 Polarisation button
- 11 Brightness control
- 12 Contact plate
- 12a Contact plate small
- 13 Focusing ring
- 14 Polarisation indicator
- 16 Charge indicator
- 17 Colour temperature indicator
- 18 USB-C connector
- 19 Colour change button
- 20 HEINE diSTANCE working ring

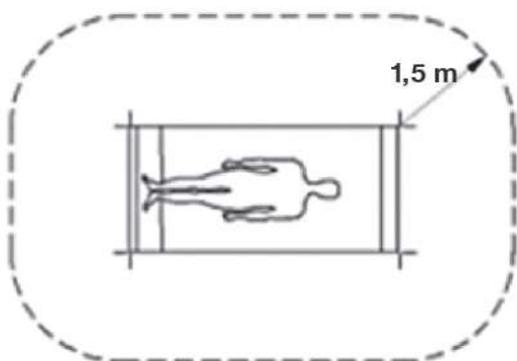


### Setting up

Charge the instrument fully before first use.

### Charging

Charge the device outside of the patient environment (1.5 m).



#### Charging via USB (DELTAone and DELTA 30)

Use a USB cable to connect the USB connector (4, 15) of the dermatoscope to a USB power supply (e.g. HEINE E4-USB).

#### Charging via USB-C (DELTA 30 PRO)

Use the USB-C cable delivered with the DELTA 30 PRO cable to connect the USB-C connector (18) of the dermatoscope to a USB power supply.

#### Using the charging station (DELTA 30 and DELTA 30 PRO)

Use the charging station to charge DELTA 30 and DELTA 30 PRO. The blue LED on the charging station indicates contact with the dermatoscope. The charge indicator is located on DELTA 30 and DELTA 30 PRO.

 Pay attention to the fact that no foreign objects are between the device and the charging station.

When using DELTA 30 or DELTA 30 PRO, make sure that the charging station and DELTA 30 or DELTA 30 PRO are not contaminated.

The setting up and operation of the charging station is described in a separate instruction of use.

#### Charge indicator

A charge indicator (5, 16) is located on the side or underside of the dermatoscope.

#### Colour temperature indicator

For the DELTA 30 PRO there is an indicator located on the left side of the dermatoscope, showing the selected colour temperature.

Indicator colour	Selected colour temperature
Orange	Neutral warm white
Purple	Neutral cold white
Light blue	Cold white
Deep blue	Blue cold white

## DELTAone

Instrument	Charger	Battery	Charge indicator
switched off	connected	charging	green, flashing
		full	green
switched on	not connected	full ( $\geq 25\%$ )	green
		empty ( $< 25\%$ )	orange
		residual capacity ( $< 10\%$ )	orange, flashing

## DELTA 30 and DELTA 30 PRO

Instrument	Charger	Battery	Charge indicator segments		
			Green - 1	Green - 2	Orange - 3
switched off	connected	100 %	on	on	on
		full (99 % – 66 %)	flashing	on	on
		sufficiently charged (66 % – 33 %)	off	flashing	on
		empty ( $\leq 33\%$ )	off	off	flashing
switched on	not connected	full ( $\geq 66\%$ )	on	on	on
		sufficiently charged (66 % – 33 %)	off	on	on
		empty (33 % – 10 %)	off	off	on
		residual capacity ( $< 10\%$ )	off	off	flashing

If the device is switched off, the charge indicator remains on for a further 3 seconds and then goes off.



Do not look directly into the light source when checking the charge level.

## Operation

To switch on the illumination, press the button (1,9) on the instrument. The device starts with the last selected brightness level and in polarisation mode.

For DELTA 30 PRO: The device starts with the last selected colour temperature, last selected brightness level and in polarisation mode.

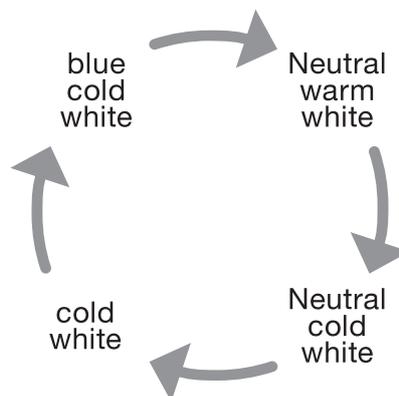
Press the button (6, 11) to adjust the brightness in three steps.

The device switches off automatically after 10 minutes if the polarisation buttons, the colour temperature buttons or the brightness control are not used.

13.P. Automatinis išsijungimas nenaudojant

### DELTA 30 PRO colour temperature change

By pressing the button (19) labelled as “C” on the front of the DELTA 30 PRO, the colour temperature is changed forward to a more bluish colour with a high CCT value. There are 4 colour temperatures to cycle through. If the highest value is reached, the cycle starts again with neutral warm white.



HEINE DELTA 30 PRO is intended for a transient examination of less than 20 minutes with a 10 minutes break until the next application.

### *Contact mode (with contact plate)*

Place the contact plate (3,3a,12,12a) on the instrument, making sure that it snaps into place.

The working ring (20) is used instead of the contact plate (3,3a,12,12a). Place the working ring on the instrument, making sure that it snaps into place. Place the instrument with the contact plate or the working ring onto the area of skin being examined.

With DELTAone, extend the contact plate (3,3a) over the focusing ring (2).

When carrying out examinations with polarised illumination, you do NOT need any contact liquid such as immersion oil or disinfection spray. In polarised mode, the polarisation indicator (8,14) lights up blue.

Use the polarisation button (7,10) to switch to non-polarised mode. In this case, use a contact fluid such as immersion oil. When using the small contact plate (3a,12a), examination is only possible in non-polarised mode.

### *Adjusting the focus in contact mode*

Your eye needs to be at a distance of approximately 2 cm from the focusing ring (2,13). Rotate the focusing ring until you see a sharp image. The image has 10-fold magnification.

### *Non-contact mode (without contact plate)*

Take off the contact plate (3,3a,12,12a) or the working ring (20) and hold the device at a distance of approximately 1 cm above the area of skin being examined. Use the polarisation button (7,10) to switch to non-polarised mode.

### *Adjusting the focus in non-contact mode*

Your eye needs to be at a distance of approximately 2 cm from the focusing ring (2,13).

With DELTA 30 and DELTA 30 PRO, rotate the focusing ring (13) until you see a sharp image.

With DELTAone, the focus is adjusted via the distance between the skin and the optics. There is no need to rotate the focusing ring (2).

The image has 10-fold magnification.

### *Reset of the device*

If the device cannot be operated even though the battery is sufficiently charged, press buttons 10 and 11 for 8 seconds on the DELTA 30 or buttons 10 and 19 for 8 seconds on the DELTA 30 PRO.

### *Smartphone Adapter*

To connect the dermatoscope to a smartphone, you need a suitable adapter for your smartphone.

Place the adapter onto the focusing ring (2,13). The adapter is held in place by magnetic force.

Install the corresponding app on your smartphone. The app is available in the App Store\*.

To avoid any possible malfunctions, please deactivate all other services (switch on flight mode).

\*App Store is a service mark of Apple Inc.

 Protecting patient data is users' sole responsibility (e. g. protection of the smartphone with a pin, data transmission via a secure connection). Ensure that your smartphone is adequately protected against access by third parties.

An electrical conducting connection between smartphone, PC and a mains power source is not permissible during the recording of the picture.

 All images are saved exclusively on the smartphone in the app's sandbox. The user is responsible for the regular creation of a data backup to prevent data loss, which can happen for example through deleting the app or losing the smartphone. A data backup can be made via cable to another computer or via the network to the iCloud.

### **Hygienic reprocessing**

The instruction is available:

- at [www.heine.com](http://www.heine.com)

- in a paper version which you can request from the address listed

### **Maintenance**

The device is maintenance free.

## Service

The device has no components serviceable by the end-user.

## 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](http://www.heine.com).

The expected life cycle amounts with designated use and the observation of warning and safety information as well as the maintenance instructions up to 7 years. Beyond this period, the product may continue to be used if it is in a safe and good condition.

Note to the user and/or patient:

All serious incidents that occur in connection with the product must be reported to HEINE Optotechnik GmbH & Co. KG and the member state's competent authority.

Charge your device during longer storage periods to protect the battery from deep discharge.

Store and use the device only in a dry and dust-free environment.

To reduce the contact temperatures in high ambient conditions, the DELTA 30 and DELTA 30 PRO have a brightness reduction feature.

## General warnings

 Use only CE marked USB power supplies (5 V) from reputable manufacturers that conform with the safety requirements from the IEC 60601-1 Medical electrical equipment.

Do not use power supplies where damage has been detected.

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).

This product is not allowed to be entered or used in strong magnetic fields like MRI scanners.

Do not modify the device.

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

Do not look directly into the light source to avoid dazzle from the intense light.

The dermatoscope is not suitable for eye examination.

## Disposal

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

The appendix contains following tables

- Electromagnetic disturbances – Requirements and tests
- Technical specification
- Explanation of the used symbols

# We invented the dermatoscope 30 years ago. Now we've done it again.

The new Dermatoscopes: DELTA 30 and DELTAone.



**30**  
YEARS  
1st DERMATOSCOPE



# THE NEW HEINE DELTA 30 DERMATOSCOPE.

## If there's something to discover, you'll be sure to see it.

Not only would our new high-end dermatoscope win any beauty pageant; it stands out due to the best imaging we've ever developed. Combined with a field of view measuring a veritable 30 millimetres and unprecedented colour rendering, in LED<sup>HQ</sup> of course.

Polarisation provides glare-free and non-reflective working conditions. Above all else, it is comfortable to operate with its angled, ergonomic design and intuitive control. Feel free to take a look – you're in for a real discovery.

Crystal-clear image with the new achromatic HEINE optical system

Largest field of view of real 30mm (lens 32mm)

**LED<sup>HQ</sup>**  
LED NOW IN HEINE QUALITY.

Excellent colour rendering due to LED<sup>HQ</sup>

Ergonomic handling thanks to angled product design



Digital documentation with the exclusive HEINE DERM app or the HEINE Cube System\*



Table charger for DELTA 30

THE NEW DERMATOSCOPES: DELTA 30 AND DELTAone.

## Simply digital. Digitally simple.

Both of the new dermatoscopes can also be combined with an iPhone\* from version 6 upwards using the (also new) adapter. Our exclusive HEINE DERM App lets you create patient files, manage and archive pictures,

and save the serial documentation of progression over time. The HEINE DERM App is easy to install and the software is simple and intuitive to use.



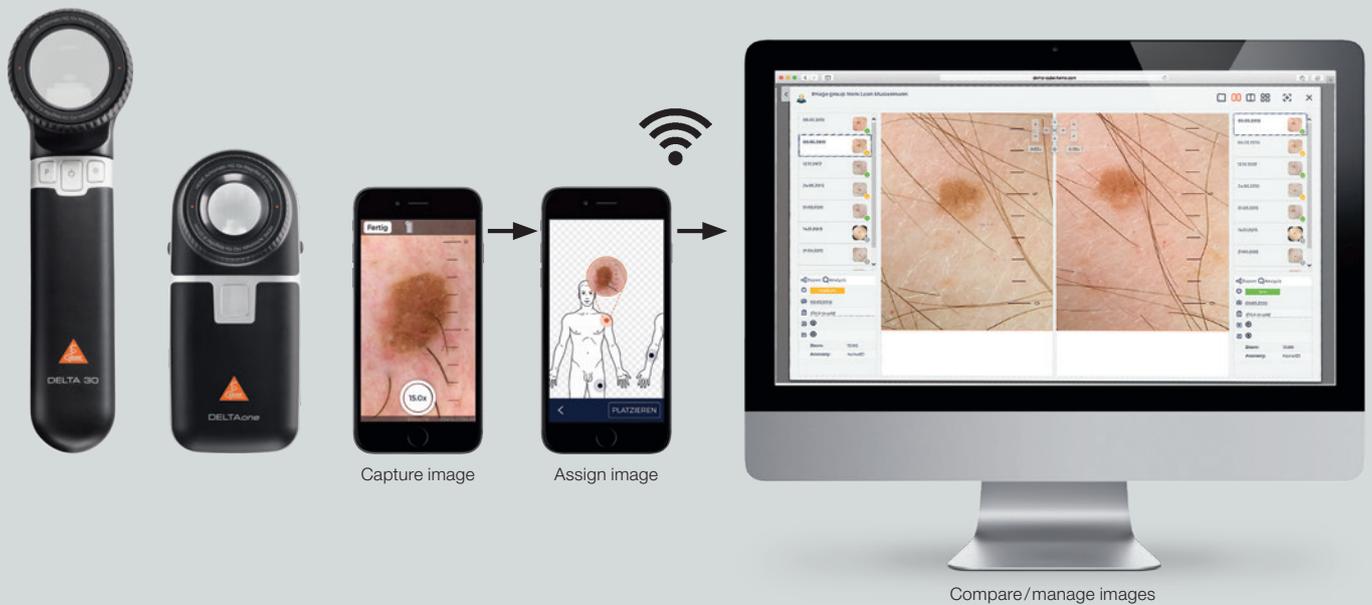
**Alternatively, you can choose the HEINE Cube System\*\* for image and data management.** It manages images in chronological order, using many smart ideas and

partly exclusive functions. The highlight: the convenient WLAN. One Cube System is enough for up to 10 mobile HEINE dermatoscopes.

\*The Apple iPhone is not included in the scope of delivery. Apple, the Apple logo and iPhone are trademarks of Apple Inc., registered in the U.S. and other countries. App Store is a service mark of Apple Inc. \*\*Not available in all countries.

HEINE CUBE SYSTEM.

**Quick, flexible and intuitive.**



**Our developers have worked particularly hard, to make your work particularly easy.**

**The day is off to a good start:  
Handy daily list.**

The Cube System will transfer all the patient data from your patient management system into a daily or task list at the touch of a button. In order of appointment, the doctor can now access the digital patient file from any computer. Daily lists can be created for different examination rooms and different doctors.

**Simple is the way to go:  
Easy picture management.**

It's up to you whether you prefer full-body, individual, serial images or to comment on any of your images immediately or at a later time; the overview feature is unique. For example, when you photograph a patient's entire torso, detailed images can easily be placed on this overview photograph.

**Identifying suspects immediately:  
Clear and insightful.**

The exclusive 'comparison wizard' function shows the series of pictures taken during previous appointments and helps to make differences far clearer.

**Impressive: Wireless picture transfer in real time.**

When you take a picture, it is instantly transferred to the HEINE Cube over a wireless network and then deleted from the memory. So it's available on the computer or tablet straight after being taken – and is even accessible to other users too.

**Maintaining an overview:  
Smart ideas for serial documentation.**

You can directly compare current pictures with previous ones during the examination. Or to show four photos side by side to assist with illustrating progression over time. Or to create a slide-over solution, by placing one image on top of another. Or to perform a contour comparison, where you put a previous picture's contours over the current shot.

## ORDER OVERVIEW

# Let's get numerical.

<b>DELTA 30</b> with contact plate with scale, USB cord with medical approved plug-in power supply, case	K-230.28.305
<b>DELTAone Standard Edition</b> (black-silver) with contact plate with scale, USB cord with medical approved plug-in power supply, case	K-210.28.305
<b>DELTAone White Edition</b> (white-silver) with contact plate with scale, USB cord with medical approved plug-in power supply, case	K-211.28.305
<b>Contact plate</b> with scale for DELTA 30	K-000.34.220
<b>Small contact plate</b> for DELTA 30. For the examination of difficult-to-access pigmented lesions.	K-000.34.206
<b>Contact plate</b> with scale for DELTAone	K-000.34.222
<b>Small contact plate</b> for DELTAone. For the examination of difficult-to-access pigmented lesions.	K-000.24.207
<b>Table charger</b> for DELTA 30	X-002.99.212
<b>Mounting case smartphone</b> for Apple iPhone 6/6s* suitable for DELTA 30/DELTAone	K-000.34.260
<b>Mounting case smartphone</b> for Apple iPhone 7/8* suitable for DELTA 30/DELTAone	K-000.34.261
<b>Mounting case smartphone</b> for Apple iPhone X/XS* suitable for DELTA 30/DELTAone	K-000.34.262
<b>Mounting case smartphone</b> for Apple iPhone XR* suitable for DELTA 30/DELTAone	K-000.34.263
<b>Universal Smartphone Connector.</b> Suitable for many common smartphone mounting cases. Connector suitable for mobile phone cases with a smooth surface where the camera mustn't protrude from the case.	K-000.34.270
<b>14.P. Universal adapteris dermatoskopo sujungimui su išmaniasiais telefonais</b>	
<b>HEINE Cube System**</b> , consists of: HEINE Cube hardware, HEINE Cube software, 3 hours remote support within the first week after the initial installation, software updates for a period of 2 years, 2 years hardware guarantee on the HEINE Cube (up to 10 clients)	O-160.00.002

\*The Apple iPhone is not included in the scope of delivery. Apple, the Apple logo and iPhone are trademarks of Apple Inc., registered in the U.S. and other countries. App Store is a service mark of Apple Inc. \*\*Not available in all countries.

# HEINE DELTA 30 Dermatoscope



DATA	
Description	DELTA 30
Item included in following catalogue numbers	K-230.28.305 - DELTA 30
Date	November 01, 2019

MECHANICAL	
Dimensions product	LxWxH 195x55x70 mm
Connections	Micro USB port, mounting for mounting case smartphone Connection to Charger 30 table charging station
Imprints	Instrument: product name, HEINE logo, CE, production date, serial number, www.heine.com, datamatrix code, symbols, power supply, optics specification
Protection class	IP20

ELECTRICAL	
Power supply	Li-ion Cell (internal battery)
Input	USB 2.0 Micro B: 5 V DC, 1.2 A Charger 30 table charging station: See datasheet of charger
Power consumption	Max. 6 W
Operating time with max energy consumption	Typ. 160 min.
Operating time with min energy consumption	Typ. 640 min.
Avg. working time before charging*	6 days
Charging time	USB: typ. 120 min. Charger 30 table charging station: typ. 120 min.
Safety class	Charging: II; Operating: internally powered

OPTICAL	
Type	HEINE LED illumination (HQ)
Magnification	10-fold
Diopter	-4 to +4 dpt
Optical system	Achromatic System, 3 Elements
Illuminance	Typ. > 25,000 lx in 15 mm distance without contact plate
Colour temperature	Typ. 5,700 K
Color rendering index (CRI)	Typ. ≥ 90
Medium life expectancy (LED)	Typ. > 50,000 h
Lense diameter	32 mm
Antireflection coating	Loupe optics multilayer coating R < 0.5% per optical surface Contact plate inside surface multilayer coating R < 0.5%, outside surface no coating Polarisation plate inner / outer side no coating
Working distance	15 mm distance in non-contact mode, contact to skin in contact mode
Contact / non-contact mode	Can be used in contact and non-contact mode
Resolution	40 LP/mm in image center with 80% contrast at 50 mm observation distance
Classification according to IEC 62471	Group 1

\*) based on average energy consumption and based on average daily use in a clinical practice.



<b>APP &amp; SOFTWARE</b>	
<b>Operating system</b>	Requires iOS 12 or later
<b>Updates</b>	Software updates are distributed via App Store and must be installed as soon as they are available
<b>Image format</b>	PNG, JPEG
<b>Special features</b>	aCapture, management and classification of dermatoscopic images, patient management, skin cancer screening assistant, image

<b>GENERAL</b>	
<b>Material</b>	Plastic, metal, glass
<b>REACH/RoHS</b>	Conform
<b>Phthalate</b>	Contains no phthalate
<b>Latex</b>	Contains no latex
<b>Biocompatibility</b>	Conform
<b>Surface</b>	Plastic, metal, glass
<b>Environmental conditions operation</b>	+10 °C to +35 °C, 30 % to 75 % rel. humidity, 700 hPa to 1060 hPa
<b>Environmental conditions storage</b>	+5 °C to +45 °C, 45 % to 80 % rel. humidity, 500 hPa to 1060 hPa
<b>Environmental conditions transport</b>	-20 °C to +50 °C, 45 % to 80 % rel. humidity, 500 hPa to 1060 hPa
<b>Instructions for use</b>	Deutsch, English, Francais, Espanol, Italiano, Svenska, Nederlands, Dansk, Norsk, Suomi, Portugues **
<b>Operating elements</b>	Power switch, brightness control in 3 stages, polarisation switch, diopter adjustment wheel, charging indicator, polarisation indicator
<b>Removable parts / accessories</b>	Contact plate with scale, mobile phone covers for Apple® iPhone XR, XS ***
<b>Maintenance</b>	Device is maintenance-free
<b>Service</b>	Device is service-free
<b>Patents</b>	N/a

<b>HYGIENIC REPROCESSING</b>	
<b>Procedure</b>	Housing can be cleaned and disinfected manually (wipe clean and wipe disinfect). Please see detailed description in the accompanying documents.

<b>CODES</b>	
<b>Customs code (tariff number)</b>	90189084
<b>Country of origin</b>	DE

<b>REGULATORY</b>	
<b>Product classification (EU)</b>	Class I
<b>Product classification (USA)</b>	Class I, 510(k) exempt
<b>Product classification (Canada)</b>	Class I
<b>UMDNS code</b>	18-021
<b>GMDNS code</b>	18021
<b>Regulation number (FDA)</b>	880.6350
<b>Product code (FDA)</b>	KYT

<b>Fulfills the Requirements of Directives &amp; Standards</b>	
<b>ISO 13485</b>	Medical devices - Quality management systems - Requirements for regulatory purposes
<b>Directive 93/42/EEC</b>	European directive for medical devices
<b>IEC 60601-1</b>	Medical electrical equipment: General requirements for basic safety and essential performance
<b>IEC 60601-1-2</b>	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests
<b>ISO 14971</b>	Medical devices - Application of risk management to medical devices
<b>IEC 60601-1-6</b>	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
<b>IEC 62366-1</b>	Medical devices - Part 1: Application of usability engineering to medical devices
<b>IEC 62471</b>	Photobiological safety of lamps and lamp systems
<b>IEC 62304</b>	Medical device software - Software life-cycle processes
<b>IEC 62133</b>	Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications
<b>UN Transport Test</b>	UN Transport Test, Section 38.3 lithium ion batteries / Part III
<b>IEC 60601-1-9</b>	Medical electrical equipment - Part 1-9: General requirements for basic safety and essential performance - Collateral Standard: Requirements for environmentally conscious design
<b>ISO 17664</b>	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices
<b>ISO 2248</b>	Packaging; complete, filled transport packages; vertical impact test by dropping
<b>Directive (2011/65/EU) ROHS</b>	Restriction of the use of certain hazardous substances in electrical and electronic equipment
<b>Directive (2012/19/EU) WEEE</b>	Waste of electrical and electronic equipment
<b>Regulation (1907/2006) REACH</b>	Registration, evaluation, authorization and restriction of chemicals

\*\*\*) further languages on request

\*\*\*) The Apple iPhone is not included in the scope of delivery.

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