# HEINE DELTA 30 Dermatoscope

## DATA

<table>
<thead>
<tr>
<th>Description</th>
<th>DELTA 30</th>
</tr>
</thead>
<tbody>
<tr>
<td>Item included in following catalogue numbers</td>
<td>K-230.28.305 - DELTA 30</td>
</tr>
<tr>
<td>Date</td>
<td>November 01, 2019</td>
</tr>
</tbody>
</table>

## MECHANICAL

<table>
<thead>
<tr>
<th>Dimensions product</th>
<th>LxWxH 195x55x70 mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Connections</td>
<td>Micro USB port, mounting for mounting case smartphone</td>
</tr>
<tr>
<td>Imprints</td>
<td>instrument: product name, HEINE logo, CE, production date, serial number, <a href="http://www.heine.com">www.heine.com</a>, datamatrix code, symbols, power supply, optics specification</td>
</tr>
<tr>
<td>Protection class</td>
<td>IP20</td>
</tr>
</tbody>
</table>

## ELECTRICAL

<table>
<thead>
<tr>
<th>Power supply</th>
<th>Li-ion Cell (internal battery)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Input</td>
<td>USB 2.0 Micro B: 5 V DC, 1.2 A</td>
</tr>
<tr>
<td>Power consumption</td>
<td>Max. 6 W</td>
</tr>
<tr>
<td>Operating time with max energy consumption</td>
<td>Typ. 160 min.</td>
</tr>
<tr>
<td>Operating time with min energy consumption</td>
<td>Typ. 640 min.</td>
</tr>
<tr>
<td>Avg. working time before charging*</td>
<td>6 days</td>
</tr>
<tr>
<td>Charging time</td>
<td>USB: typ. 120 min.</td>
</tr>
<tr>
<td>Safety class</td>
<td>Charging: II: Operating: internally powered</td>
</tr>
</tbody>
</table>

## OPTICAL

<table>
<thead>
<tr>
<th>Type</th>
<th>HEINE LED illumination (HQ)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnification</td>
<td>10-fold</td>
</tr>
<tr>
<td>Diopter</td>
<td>-4 to +4 dpt</td>
</tr>
<tr>
<td>Optical system</td>
<td>Achromatic System, 3 Elements</td>
</tr>
<tr>
<td>Illuminance</td>
<td>Typ. ≥ 25,000 lx in 15 mm distance without contact plate</td>
</tr>
<tr>
<td>Colour temperature</td>
<td>Typ. 5,700 K</td>
</tr>
<tr>
<td>Color rendering index (CRI)</td>
<td>Typ. ≥ 90</td>
</tr>
<tr>
<td>Medium life expectancy (LED)</td>
<td>Typ. &gt; 50,000 h</td>
</tr>
<tr>
<td>Lense diameter</td>
<td>32 mm</td>
</tr>
<tr>
<td>Antirefection coating</td>
<td>Loupe optics multilayer coating R &lt; 0.5% per optical surface</td>
</tr>
<tr>
<td></td>
<td>Contact plate inside surface multilayer coating R &lt; 0.5%, outside surface no coating</td>
</tr>
<tr>
<td>Working distance</td>
<td>15 mm distance in non-contact mode, contact to skin in contact mode</td>
</tr>
<tr>
<td>Contact / non-contact mode</td>
<td>Can be used in contact and non-contact mode</td>
</tr>
<tr>
<td>Resolution</td>
<td>40 LP/imm in image center with 85% contrast at 50 mm observation distance</td>
</tr>
<tr>
<td>Classification according to IEC 62471</td>
<td>Group 1</td>
</tr>
</tbody>
</table>

*) based on average energy consumption and based on average daily use in a clinical practice.
**APP & SOFTWARE**

Operating system  
Requires iOS 12 or later

Updates  
Software updates are distributed via App Store and must be installed as soon as they are available

Image format  
PNG, JPEG

Special features  
eCapture, management and classification of dermatoscopic images, patient management, skin cancer screening assistant, image

**GENERAL**

Material  
Plastic, metal, glass

REACH/RoHS  
Conform

Phthalate  
Contains no phthalate

Latex  
Contains no latex

Biocompatibility  
Conform

Surface  
Plastic, metal, glass

Environmental conditions operation  
+10 °C to +35 °C, 30 % to 75 % rel. humidity, 700 hPa to 1060 hPa

Environmental conditions storage  
+5 °C to +45 °C, 45 % to 80 % rel. humidity, 500 hPa to 1060 hPa

Environmental conditions transport  
-20 °C to +50 °C, 45 % to 80 % rel. humidity, 500 hPa to 1060 hPa

Instructions for use  
Deutsch, English, Français, Español, Italiano, Svenska, Nederlands, Dansk, Norsk, Suomi, Português. **

Operating elements  
Power switch, brightness control in 3 stages, polarisation switch, diopter adjustment wheel, charging indicator, polarisation indicator

Removable parts / accessories  
Contact plate with scale, mobile phone covers for Apple® iPhone XR, XS ***

Maintenance  
Device is maintenance-free

Service  
Device is service-free

Patents  
Wa

**HYGIENIC REPROCESSING**

Procedure  
Housing can be cleaned and disinfected manually (wipe clean and wipe disinfect). Please see detailed description in the accompanying documents.

**CODES**

Customs code (tariff number)  
86199084

Country of origin  
DE

**REGULATORY**

Product classification (EU)  
Class I

Product classification (USA)  
Class I, 510(k) exempt

Product classification (Canada)  
Class I

UMDNS code  
18-021

UMDNS code  
18-021

Regulation number (FDA)  
880.6350

Product code (FDA)  
KYT

Fulfills the Requirements of Directives & Standards

ISO 13485  
Medical devices - Quality management systems - Requirements for regulatory purposes

Directive 93/42/EEC  
European directive for medical devices

IEC 60601-1  
Medical electrical equipment: General requirements for basic safety and essential performance

IEC 60601-1-2  
Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests

ISO 14971  
Medical devices - Application of risk management to medical devices

IEC 62366-1  
Medical devices - Part 1: Application of usability engineering to medical devices

IEC 62471  
Photo biological safety of lamps and lamp systems

IEC 62594  
Medical device software - Software life-cycle processes

IEC 62133  
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

UN Transport Test  
UN Transport Test, Section 38.3 lithium ion batteries / Part III

IEC 60601-1-9  
Medical electrical equipment - Part 1-9: General requirements for basic safety and essential performance - Collateral Standard: Requirements for environmentally conscious design

ISO 17664  
Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices

ISO 2248  
Packaging: complete, filled transport packages; vertical impact test by dropping

Directive (2011/65/EU) ROHS  
Restriction of the use of certain hazardous substances in electrical and electronic equipment

Directive (2012/19/EU) WEEE  
Waste of electrical and electronic equipment

Regulation (1907/2006) REACH  
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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