

# HEINE® NC 2 DERMATOSCOPE



Contact plate with  
10x magnification and scale

**LED HQ**  
LED NOW IN HEINE QUALITY.

LED in HQ – twice as bright as the predecessor model NC 1. Completely homogeneous, bright light with true colour rendering for a precise diagnosis.

Especially large overview field. HEINE precision optics with 27 mm diameter for unmatched sharpness, high-resolution images.

Micro-USB connection for charging the integrated Li-ion battery.

Compact and ergonomic

DATA	
Description	HEINE NC 2 Dermatoscope
Catalogue Number	D-841.78.120, D-842.78.120
Version / Date	Rev.03 / 23.10.2017
GENERAL	
Weight	Instrument 180g, contact plate 20g
Dimensions product	170 x 60 x 57 mm (with contact plate), 170 x 60 x 35 mm (without contact plate)
Dimensions packaging	228 x 188 x 80 mm
Material	Metal, plastic, glas, magnets
REACH/RoHS	Conform
Phthalate	Product is Phthalate free
Latex	Product is Latex free
Biocompatibility	Conform
Surface	Metal, plastic, glas
Environmental conditions operation	Temperature: +10 °C to +35 °C, relative humidity: 30% to 75%, air pressure: 700hPa to 1060hPa
Environmental conditions storage	Temperature: +5 °C to +45 °C, relative humidity: 45% to 80%, air pressure: 500hPa to 1060hPa
Environmental conditions transport	Temperature: -20 °C to +50 °C, relative humidity: 45% to 80%, air pressure: 500hPa to 1060hPa
Instructions for use	Deutsch, English, Français, Español, Italiano, Svenska, Nederlands, Português, Dansk, Suomi
Operating elements	On/off switch, focussing, charging indicator
Removable parts / accessories	Contact plate with scale, adaptor for Apple iPhone, mobile phone case for Apple iPhone 7 / 6s / 5 / 5s / SE / iPod Touch (6th Generation), NC2 App
Maintenance	Device is maintenance-free
Service	Device is service-free
Patents	n/a
MECHANICAL	
Connections	Magnetic mount for contact plate, USB 2.0 Micro B
Imprints	Instrument: product name, HEINE made in Germany, CE, HEINE logo, serial number, data matrix code, www.heine.com Contact plate: product name, BF symbol, HEINE made in Germany
Protection class	IP20
ELECTRICAL	
Power supply	Li-ion cell 3.6V (changeable)
Input	5V, 500mA (USB)
Power consumption	Max. 1.2W
Operating time*	Typ. 90 min in continuous operation
Safety class	Charging: II, operating: interally powered

\*) using fully charged Li-ion cell



# HEINE® NC 2 DERMATOSCOPE

<b>OPTICAL</b>	
Type	LED Illumination (HQ)
Magnification	6-fold (without contact plate), 10-fold (with contact plate)
Dioppter	0 to -2.5 dpt
Illumination	Homogeneous, covers 100% of observation area in contact and non-contact mode
Illuminance	Typ. 20,000lx in 20mm distance without contact plate
Color temperature	5000K +/- 500K
Color rendering index	CRI min. 80 (typ. 82)
Lifetime	Typ. 100,000h
Working distance	Ca. 20mm distance in non-contact mode, contact to skin in contact mode
Classification according to IEC 62471	Groupe 2
<b>APP &amp; SOFTWARE</b>	
Operating system	Requires iOS 10 or later
Maintenance	Software updates are distributed via App Store® and must be installed as soon as they are available
Image Format	RAW, JPEG
Special Feature	Up to 30x digital magnification / up to 12 MP resolution (with iPhone 6s, SE and 7). Integrated patient management function, e-mail function, assignment of image information and patient details on a bodymap
<b>HYGIENIC REPROCESSING</b>	
Procedure	Wipe cleaning and wipe disinfection with agents recommended in the instructions for use. Please consider the detailed informations in the instructions for use!
<b>CODES</b>	
Customs Code (tariff number)	90189084
EAN/GTIN	4053755191611 (D-841.78.120), 4053755191628 (D-842.78.120)
Country of origin	Germany
<b>REGULATORY</b>	
Product classification (EU)	Class 1
Product classification (USA)	Class 1
Product classification (Canada)	Class 1
UMDNS Code	18-021
GMDNS Code	18021
Regulation Number (FDA)	880.6350
Product Code (FDA)	KYT
<b>FULFILLS THE REQUIREMENTS OF DIRECTIVES &amp; STANDARDS</b>	
ISO 13485	Medical devices – Quality management systems – Requirements for regulatory purposes
Directive 93/42/EEC	Concerning 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 60601-1-6	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
IEC 62366-1	Medical devices – Part 1: Application of usability engineering to medical devices
IEC 62471	Photobiological safety of lamps and lamp systems
IEC 62304	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	Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices
ISO 2248	Packaging; complete, filled transport packages; vertical impact test by dropping
ISO 19003-1	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management system
Directive (2011/65/EU) ROHS	On the restriction of the use of certain hazardous substances in electrical and electronic equipment
Directive (2012/19/EU) WEEE	On Waste Electrical and Electronic Equipment
Regulation (1907/2006) REACH	Registration, Evaluation, Authorization and Restriction of Chemicals

