

HEINE DELTA 20T

Dermatoscope



DATA

Description	DELTA 20T Dermatoscope
Catalogue number	see catalogue or price list
Document release date	June 13, 2025

MECHANICAL

Weight product	106 g AV version 110g TL version (instrument without handle)
Weight packaging (including product)	0,117 kg
Dimensions product	79 x 56 x 42 mm
Dimension packaging	235 x 149 x 55 mm
Connections	AV-lock
Imprints	instrument: DELTA 20T, HEINE made in Germany, HEINE logo, CE, BF sign, camera contact plate: DELTA 20T
Enclosure rating	IP20

ELECTRICAL

Power supply	battery handle, USB rechargeable handle, rechargeable handle with table charger, EN 200 EN 200-1
Input	3.0 V - 3.7 V nominal
Power consumption	typ. 440 mA - 760 mA
Operating time	battery handle dry cells 2x C: 100% typ. 2 h, 100 % - 50 %: typ. 450 min rechargeable battery handle NiMH: 100% typ. 2.5 h, 100 % - 50 %: typ. 120 min Li-Ion and Li-Ion L: typ. 5.5 h
Protection class	charging: II; operating: internally powered

OPTICAL

Type	HEINE LED illumination (HQ), 4 LEDs
Magnification	10 to 16 times (depending on the viewing distance)
Diopter	+/- 6 dpt (focusing range)
Optical system	4 lenses 2 achromats
Colour temperature	5 000 K +/- 1 000 K
Color rendering index (CRI)	typ. ≥ 80
Illuminated field	Ø 23 mm with contact plate, Ø 8 mm with small contact plate
Working distance	typ. 20 mm (distance examiner loupe surface)
Light controlling	rheostat (continuous brightness control)
Classification according to IEC 62471	group 2

GENERAL

Material	aluminium, synthetic material, brass, glass
REACH RoHS	conform
Phthalate	contains no phthalates that require declaration
Latex	contains no latex
Biocompatibility	conform
Surface	aluminium anodized, synthetic material matt black and anthracite grey, brass blackened
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	push button polarisation non-polarisation, diopter adjustment
Removable parts accessories	contact plate with without scale, small contact plate, SLR adapter
Maintenance	device is maintenance-free
Service	device is service-free
Patents	n/a

HYGIENIC REPROCESSING

Procedure	please see detailed description for the reprocessing procedure online at www.heine.com
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CODES

Customs code (tariff number)	90189084
GTIN	4053755181339
Traceability	UDI code
Country of origin	Germany

REGULATORY

Product classification (EU)	class I
Product classification (USA)	class 1, 510(k) exempt
Product classification (Canada)	class I
UMDNS code	18-021
GMDN code	18021
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
Regulation (EU) 2017/745	European regulation for medical devices (MDR)
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 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 10993-1	Biological evaluation of medical devices - part 1: evaluation and testing within a risk management process
ISO 17664-2	Processing of health care products - information to be provided by the medical device manufacturer for the processing of medical devices part 2: non-critical medical devices
IEC 62471	Photobiological safety of lamps and lamp systems
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