

The new HEINE visionPRO video laryngoscope.

With very, very, very good image quality.

For fast and reliable intubation, nothing is more important than the best view of the glottis. The new HEINE visionPRO video laryngoscope provides just that with the new and one of a kind HEINE allBRIGHT display – even in very bright ambient light.

At the same time, the new HEINE visionPRO is extremely robust, reliable and durable. To be as environmentally friendly as possible, we chose a rechargeable lithium battery and are the first to provide a blade made from upcycled material. More on heine.com



DATA	
Product components description	Display unit: visionPRO DS1 Handle Mac: visionPRO HR1 Mac Charging station: visionPRO CS1
Catalogue numbers	visionPRO Set Mac: F-270.95.862 visionPRO DS1: F-007.22.350 visionPRO HR1 Mac: F-008.22.360 visionPRO CS1: X-002.99.214
Consumables	Single-use blades: visionPRO Mac 3, visionPRO Mac 4
Consumables catalogue number	visionPRO Mac 3 (10x): F-000.22.243, visionPRO Mac 3 (50x): F-000.22.253 visionPRO Mac 4 (10x): F-000.22.244, visionPRO Mac 4 (50x): F-000.22.254
Date	September, 2022

WEIGHT / DIMENSION	
Weight product	visionPRO video laryngoscope: 495 g (without blade) visionPRO DS1: ca. 220 g visionPRO HR1 Mac: ca. 275 g visionPRO CS1: ca. 630 g
Dimensions product	visionPRO video laryngoscope: 240 x 120 x 105 mm visionPRO DS1: 185 x 105 x 50 mm visionPRO HR1 Mac: 135 x 120 x 45 mm visionPRO CS1: ca. 270 x 80 x 73 mm
Weight packaging (including product)	visionPRO Set Mac: 1.6 kg visionPRO DS1: ca. 675 g visionPRO HR1 Mac: ca. 730 g visionPRO CS1: ca. 1,090 g
Dimensions packaging	visionPRO Set Mac: 350 x 180 x 120 mm visionPRO DS1: 350 x 180 x 120 mm visionPRO HR1 Mac: 350 x 180 x 120 mm visionPRO CS1: 350 x 180 x 120 mm
Imprints	visionPRO DS1: (front): visionPRO, HEINE logo, HEINE made in Germany, On-Off symbol. (inside): visionPRO DS1, production date, MD, CE, datamatrix code, serial number, www.heine.com , refers to instruction manual visionPRO HR1 Mac: visionPRO HR1 Mac, HEINE logo, production date, CE, datamatrix code, serial number, www.heine.com visionPRO CS1: visionPRO, HEINE logo

ELECTRICAL	
	visionPRO video laryngoscope
Power supply	Li-Ion cell (internal battery)
Power consumption	Max. 2.7 W (use), max. 7.2 W (charging)
Operating time	Typ. 4 h continuous operation, corresponds to typ. 50 intubations incl. preparation (à 5 min)
Charging time	Typ. 3 h
	visionPRO CS1 (charging station)
Power supply	External power supply
Input charging station	100-240 V~/50-60 Hz / 300-150 mA
Power consumption charging station	<15 W
Protection class	Charging station: II; Operating: interally powered

IMAGE PROCESSING	
Display type	TFT LCD
Display technology	Transflective
Display size	3.2 inch
Display dimensions (active area)	41.4 x 69.0 (L x H)
Display rotation	Portrait
Display resolution	480 x 800 (WVGA)
Video resolution	480 x 640 (VGA)
Illumination type	HEINE LED HQ, shadow-free image thanks to 4 x LED ring
Illuminance	Typ. 900 lx with Mac 3 blade
Colour temperature	Typ. 5,300 K cool white
Camera field of view	70°
Camera technology	CMOS

GENERAL	
Material	Plastic (PC/ABS, PEEK), elastomer (TPS), metal (stainless steel, aluminum), glass (float glass, alumino silicate glass), epoxy
Surface	Plastic, metal, glass
REACH / RoHS	REACH: conform RoHS: conform
Phthalate	Contains no phthalates
Latex	Contains no latex
Biocompatibility	Conform
Environmental conditions operation	+5 °C bis +35 °C, 10 % to 80 % rel. humidity, 700 hPa to 1,060 hPa
Environmental conditions storage / transport*	-20 °C to +50 °C, 0 % to 95 % rel. humidity, 700 hPa to 1,060 hPa*
Instructions for use **	Deutsch, English, Francais, Espanol, Italiano, Svenska, Nederlands, Dansk, Norsk, Suomi, Portugues **
Operating elements	On/Off Button
Maintenance	Maintenance-free

HYGIENIC REPROCESSING	
Procedure	Please see detailed description for the reprocessing procedure online at www.HEINE.com

CODES	
Customs code (tariff number)	90189084
GTIN	visionPRO DS1: 4053755200030 visionPRO HR1 Mac: 4053755199976 visionPRO CS1: 4053755199914
Traceability	UDI Code
Country of origin	Germany (DE)

REGULATORY	
Product classification (EU / Canada)	Class I
Product classification (USA)	Class 1, 510(k) exempt
GMDNS code (video laryngoscope)	62761
GMDNS code (charging station)	17115
UMDNS code	visionPRO video laryngoscope: 15-076 visionPRO CS1: 17-115
Regulation number (FDA)	868,554
Product code (FDA)	CCW

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 60601-2-18	Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
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
DIN EN ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
IEC 62304	Medical device software - Software life-cycle processes
IEC 62133-2	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 - Part 2: Lithium systems
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
EN 1041	Information supplied by the manufacturer of medical devices
ISO 15223-1	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
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
Regulation (1907/2006/EC) REACH	Registration, evaluation, authorization and restriction of chemicals
Directive (2006/66/EC) Battery / Acc. Waste	Batteries and accumulators, and waste batteries and accumulators, German registration no. DE 48554371
Directive (2012/19/EU) WEEE	Waste of electrical and electronic equipment, German registration no. DE 87119271
Directive (94/62/EC) Packaging / Packaging Waste	Packaging and packaging waste, German registration no. DE 5329703000126

*) to ensure optimal product lifetime, please avoid high temperature conditions during extended storage periods

**) further languages on request

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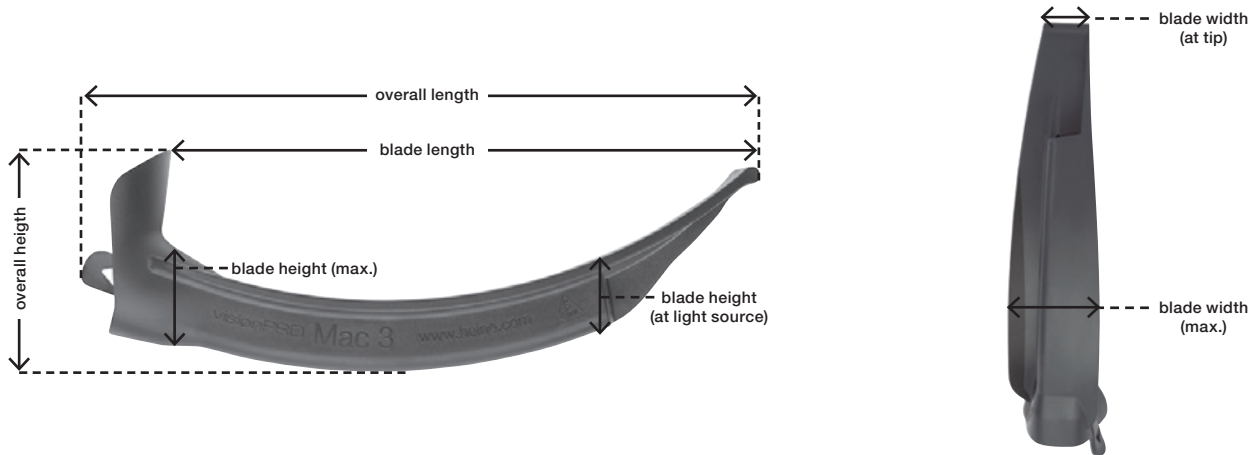
HEINE visionPRO single-use laryngoscope blades

Mac 3 and Mac 4

First blade made from upcycled material.

Our visionPRO blades are made of upcycled material from discarded refrigerators. By recycling these refrigerators in a controlled manner, we spare the environment around 200 metric tons of CO₂ annually already in the very first year. This is equivalent to 3.8 million miles of rail travel per person, or about 140 times around the world.

What's more, we manufacture the blades for the visionPRO video laryngoscope on a machine that runs on green-sourced electricity. Learn more about sustainability at heine.com. Various national and international industrial property rights have been registered and granted for the smart design of our blades.



DATA		
Description	HEINE visionPRO Mac 3	HEINE visionPRO Mac 4
Catalogue numbers	visionPRO Mac 3 (10x): F-000.22.243 visionPRO Mac 3 (50x): F-000.22.253	visionPRO Mac 4 (10x): F-000.22.244 visionPRO Mac 4 (50x): F-000.22.254
Date	September, 2022	
WEIGHT / DIMENSION		
Weight product	ca. 14 g	ca. 18 g
Overall length	135 mm	151 mm
Blade length	117 mm	132 mm
Blade width (max.)	30 mm	31.5 mm
Blade width (at tip)	14.5 mm	15.5 mm
Overall height	43.5 mm	48.5 mm
Blade height (max.)	18.5 mm	18.5 mm
Blade height (at light source)	14.5 mm	15 mm
Weight packaging (including product)	visionPRO Mac 3 (10x): ca. 280 g visionPRO Mac 3 (50x): ca. 1.17 kg	visionPRO Mac 4 (10x): ca. 320 g visionPRO Mac 4 (50x): ca. 1.37 kg
Dimensions packaging	visionPRO Mac 3 (10x): 225 x 160 x 100 mm visionPRO Mac 3 (50x): 330 x 250 x 220 mm	visionPRO Mac 4 (10x): 250 x 165 x 110 mm visionPRO Mac 4 (50x): 330 x 250 x 220 mm
Connections	Fits HEINE visionPRO HR1 Mac	
Imprints	HEINE logo, product name, blade size, www.heine.com , CE, single-use, BF-symbol, LOT, manufacturing date	
GENERAL		
Material	Blade made of 93% recycled material. Transparent camera protection made of plastic	
REACH / RoHS	REACH: conform	
Phthalate	Contains no phthalates	
Latex	Contains no latex	
Biocompatibility	Conform	
Environmental conditions operation	+5 °C to +35 °C, 10 % to 80 % rel. humidity, 700 hPa to 1060 hPa	
Environmental conditions storage	-20 °C to +50 °C, 0 % to 95 % rel. humidity, 700 hPa to 1060 hPa	
Environmental conditions transport	-20 °C to +50 °C, 0 % to 95 % rel. humidity, 500 hPa to 1060 hPa	
Shelf life	3 years	
Instructions for use*	Deutsch, English, Francais, Espanol, Italiano, Svenska, Nederlands, Dansk, Norsk, Suomi, Portugues*	
Operating elements	None	
Maintenance	Maintenance-free	
Service	Service-free	
Patents	Patent pending, registered design	
HYGIENIC REPROCESSING		
Procedure	No reprocessing of single-use blades	
CODES		
Customs code (tariff number)	90189084	
GTIN	visionPRO Mac 3 (10x): 4053755200047 visionPRO Mac 3 (50x): 4053755200061	visionPRO Mac 4 (10x): 4053755200054 visionPRO Mac 4 (50x): 4053755200078
Country of origin	Germany (DE)	

REGULATORY	
Product classification (EU)	Class I
Product classification (USA)	Class 1, 510(k) exempt
Product classification (Canada)	Class I
GMDNS code	46828
UMDNS code	15-076
Regulation number (FDA)	868.554
Product code (FDA)	CCW
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)
DIN EN ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management system
DIN EN ISO 7376	Anaesthetic and respiratory equipment - Laryngoscopes for tracheal intubation
ISO 18190	Anaesthetic and respiratory equipment - General requirements for airways and related equipment
DIN EN 60601-1	Medical electrical equipment: General requirements for basic safety and essential performance
DIN EN 60601-2-18	Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
DIN EN 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
DIN EN 60601-1-6	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
DIN EN 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
ISO 2248	Packaging; complete, filled transport packages; vertical impact test by dropping
Directive (94/62/EC) Packaging / Packaging waste	Packaging and packaging waste, German registration no. DE 5329703000126
Regulation (1907/2006) REACH	Registration, Evaluation, Authorization and Restriction of Chemicals

*) further languages on request

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