# The 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 HEINE visionPRO video laryngoscope provides just that with the one of a kind HEINE allBRIGHT display – even in very bright ambient light. At the same time, the 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  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			
Catalogue numbers				
Consumables	single-use blades: visionPRO Mac 2, visionPRO Mac 3, visionPRO Mac 4, visionPRO HyMac 3			
Consumables catalogue number	visionPRO Mac 2 (10x): F-000.22.242, visionPRO Mac 2 (50x): F-000.22.252, 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, visionPRO HyMac 3 (10x): F-000.22.246, visionPRO HyMac 3 (50x): F-000.22.256			
Date	August, 2024			

	visionPRO HyMac 3 (10x): F-000.22.246, visionPRO HyMac 3 (50x): F-000.22.256		
Date	August, 2024		
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		

DATA

### 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 (á 5 mi			
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: internally powered			

### IMAGE PROCESSING

TFT LCD	
transflective	
3.2 inch	
41.4 mm x 69.0 mm (L x H)	
portrait	
480 x 800 (WVGA)	
480 x 640 (VGA)	
HEINE LED HQ, shadow-free image thanks to 4 x LED ring	
typ. 900 lx with Mac 3 blade	
typ. 5,300 K cool white	
70° (diagonal)	
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		
Ingress protection code (IP code)	IP68 (handle), IP6X (display unit)		
Guarantee	for more information, please visit www.heine.com		
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
	visionPRO DS1: 4053755200030
GTIN	visionPRO HR1 Mac: 4053755199976
	visionPRO CS1: 4053755199914
Traceability	UDI-code
Country of origin	Germany (DE)

### REGULATORY

Product classification (EU)	class I
Product classification (USA)	class I, 510(k) exempt
Product classification (Canada)	class II
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  IEC 60601-1	european regulation for medical devices (MDR)  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 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			

 $<sup>^{\</sup>star}$ ) to ensure optimal product lifetime, please avoid high temperature conditions during extended storage periods

You can find ordering information and other products at www.heine.com/laryngoscopes

<sup>\*\*)</sup> further languages on request

# HEINE visionPRO single-use laryngoscope blades Mac 2, Mac 3, Mac 4 and HyMac 3.

## 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 CO<sub>2</sub> 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	visionPRO	visionPRO	visionPRO	visionPRO
	Mac 2	Mac 3	Mac 4	HyMac 3
Catalogue number	visionPRO Mac 2	visionPRO Mac 3	visionPRO Mac 4	visionPRO HyMac 3
	(10x): F-000.22.242	(10x): F-000.22.243	(10x): F-000.22.244	(10x): F-000.22.246
	visionPRO Mac 2	visionPRO Mac 3	visionPRO Mac 4	visionPRO HyMac 3
	(50x): F-000.22.252	(50x): F-000.22.253	(50x): F-000.22.254	(50x): F-000.22.256
Document release date	August, 2024			

### MECHANICAL

Weight product	13 g	14.5 g	16 g	15 g
Weight packaging (including product)	pack of 10 pcs: 0.265 kg pack of 50 pcs: 1.215 kg	pack of 10 pcs: 0.280 kg pack of 50 pcs: 1.165 kg	pack of 10 pcs: 0.320 kg pack of 50 pcs: 1.365 kg	pack of 10 pcs: 0.305 kg pack of 50 pcs: 1.315 kg
Blade length (overall   packaging   bounding box)	119 mm	135 mm	151 mm	134 mm
Blade length (insertion)	101 mm	117 mm	132 mm	115 mm
Blade width (overall   packaging   bounding box)	30 mm	32 mm	33 mm	32 mm
Blade width (insertion max.   medial)	26 mm	30 mm	31.5 mm	30 mm
Blade width (tip)	14.5 mm	14.5 mm	15.5 mm	15 mm
Blade height (overall   packaging   bounding box)	40 mm	43.5 mm	48.5 mm	46 mm
Blade height (insertion max.   proximal)	18.5 mm	18.5 mm	18.5 mm	18.5 mm
Blade height (middle   medial)	15 mm	15 mm	15 mm	14 mm
Blade height (at light source)	14 mm	14.5 mm	15 mm	13 mm
Dimension packaging	visionPRO Mac 2 (10x): 250x165x110 mm visionPRO Mac 2 (50x): 340x250x267.5 mm	visionPRO Mac 3 (10x): 250x165x110 mm visionPRO Mac 3 (50x): 340x250x267.5 mm	visionPRO Mac 4 (10x): 250x165x110 mm visionPRO Mac 4 (50x): 340x250x267.5 mm	visionPRO HyMac 3 (10x): 250x165x110 mm visionPRO HyMac 3 (50x): 340x250x267.5 mm
Connections	fits HEINE visionPRO	HR1 Mac	,	
Imprints	HEINE logo, product LOT, manufacturing of		v.heine.com, CE, single	-use, BF-symbol,

GENERAL
---------

GENERAL			
Material	plastic, blade made of 93% recycled material		
Coating	anti-fog coating (transparent cap)		
REACH   RoHS	conform		
Phthalate	contains no phthalates that require declaration		
Latex	contains no latex		
Biocompatibility	conform		
Environmental conditions operation	temperature: +5 °C to +35 °C, relative humidity: 10 % to 80 % (n. c.), air pressure: 700 hPa to 1,060 hPa		
Environmental conditions storage	temperature: -20 °C to +50 °C, relative humidity: 0 % to 95 % (n. c.), air pressure: 700 hPa to 1,060 hPa		
Environmental conditions transport	temperature: -20 °C to +50 °C, relative humidity: 0 % to 95 % (n. c.), air pressure: 500 hPa to 1,060 hPa		
Instructions for use*	Deutsch, English, Francais, Espanol, Italiano, Svenska, Nederlands, Dansk, Norsk, Suomi, Portugues		
Operating elements	none		
Removable parts   accessories	HEINE visionPRO HR1 Mac		
Maintenance	the device is maintenance-free		
Service	the device is service-free		
Shelf Life	3 years +/- 1 month		
Patents	patent pending, registered design		

# HYGIENIC REPROCESSING

Procedure	n/a blade will not be reprocessed

### CODES

Customs code (tariff number)	90189084			
GTIN	visionPRO	visionPRO	visionPRO	visionPRO
	Mac 2 (10x):	Mac 3 (10x):	Mac 4 (10x):	HyMac 3 (10x):
	04053755201846	04053755200047	04053755200054	04053755200900
	visionPRO	visionPRO	visionPRO	visionPRO
	Mac 2 (50x):	Mac 3 (50x):	Mac 4 (50x):	HyMac 3 (50x):
	04053755202065	04053755200061	04053755200078	04053755202072
Country of origin	Germany (DE)			

### REGULATORY

Product classification (EU)	class I
Product classification (USA)	class I, 510(k) exempt
Product classification (Canada)	class II
UMDNS code	15-076
GMDNS code	46828
Regulation number (FDA)	868.5540
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		
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 a 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 performance - collateral standard: requirements for environmentally conscious design
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

 $<sup>\</sup>ensuremath{^*}\xspace$  ) further languages on request

You can find ordering information and other products at www.heine.com/laryngoscopes

**HEINE Optotechnik GmbH & Co. KG** 

Dornierstr. 6, 82205 Gilching, Germany www.heine.com















