

INSTRUCTIONS FOR USE



CLEAR GUIDE Optical Head

- CG-OH
- CG-OH-M



Customer Support
support@clearguidemedical.com
www.clearguidemedical.com/support
+1 (443) 267-7661

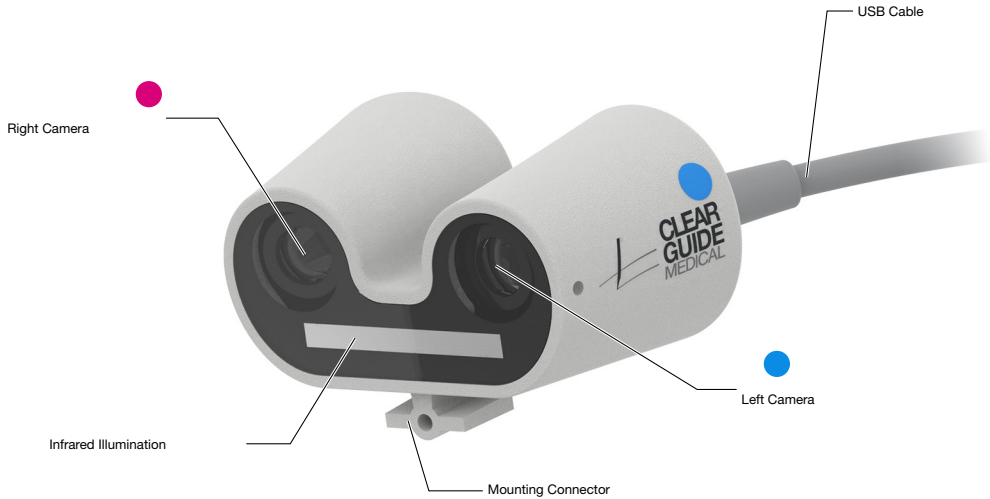


30007R03 EN

2026-02-16

Optical Head

REF CG-OH



PC

Enclosure Material

185g

Max Weight



USB 2.0

12-bit ×2

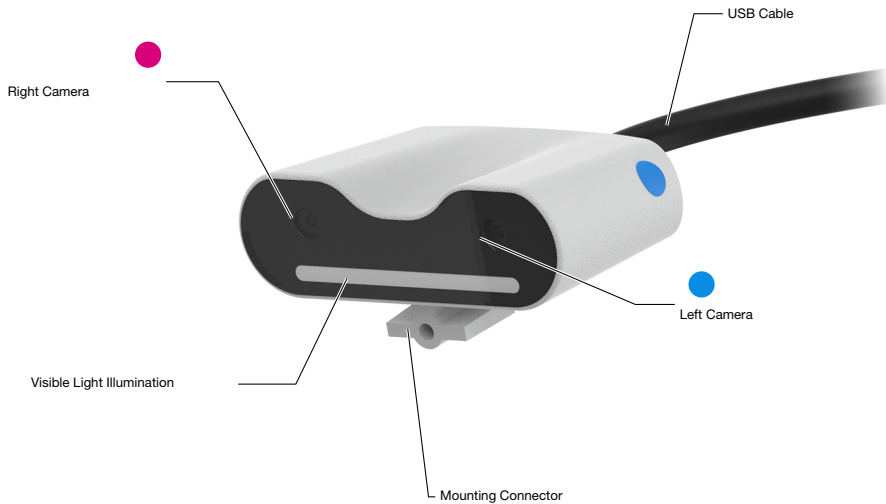
480p @ 30 fps



LED 850nm

Optical Head

REF CG-OH-M



PA12+PMMA

Enclosure Material

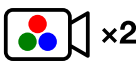


160g

Max Weight



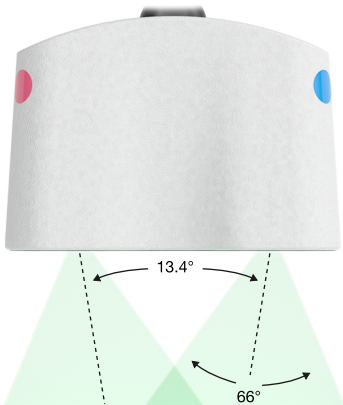
USB 3.0



1080p @ 30fps



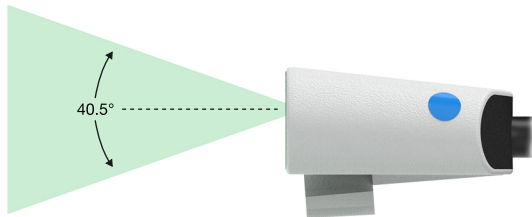
LED 460nm



43 mm



62 mm



23 mm

29 mm



IP53





WARNING: This device must be installed by trained personnel authorized by the system manufacturer.

WARNING: No modifications to the **CLEAR GUIDE** Optical Head are allowed.

CLEAR GUIDE Optical Head is not a stand-alone medical device. It is intended for use only with compatible computer-assisted instrument or image guidance (CAIG®) systems.



For additional information, refer to the system user manual.

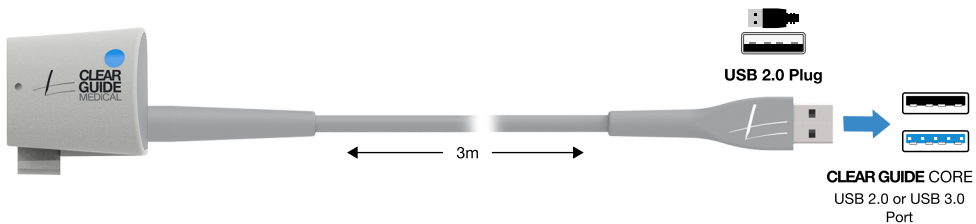
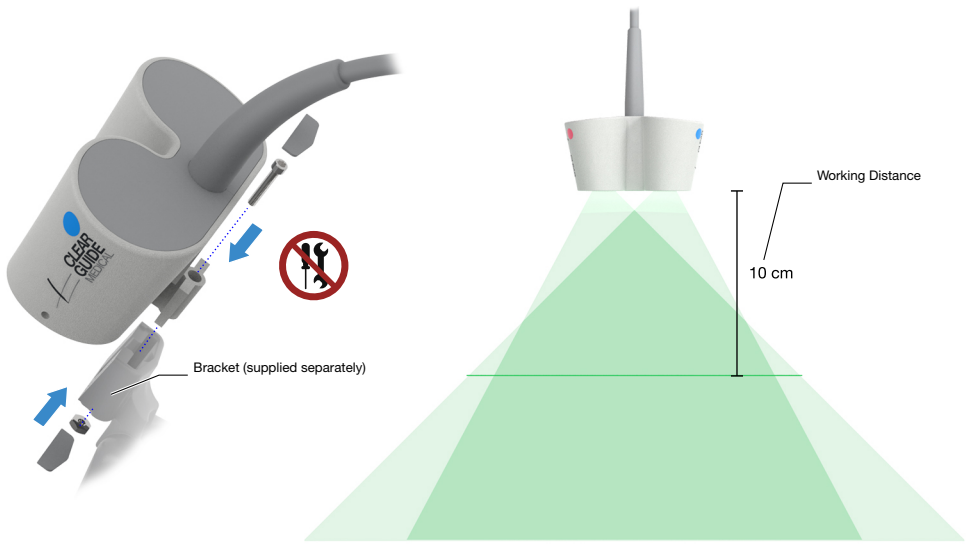


CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

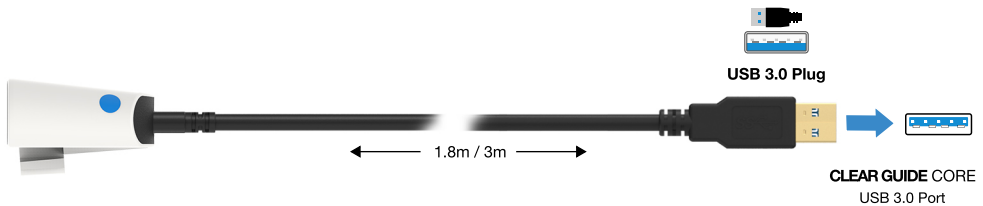
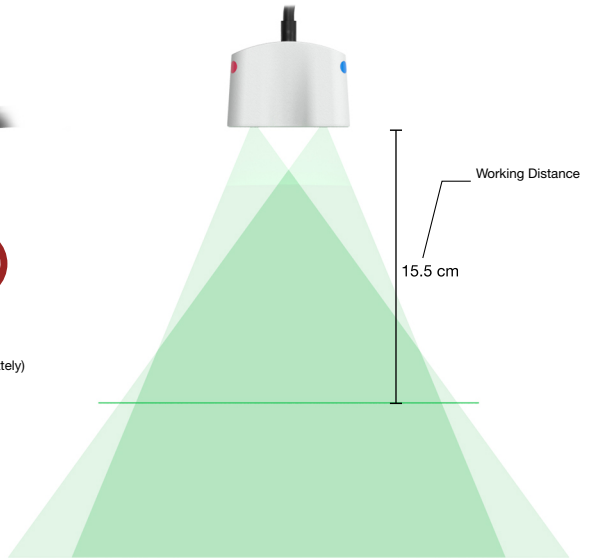
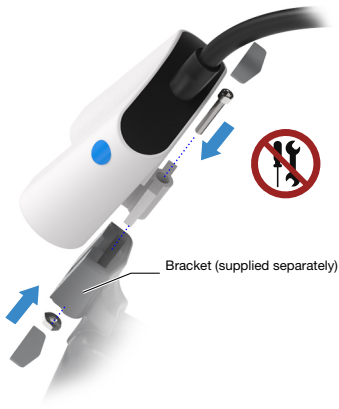


Physical Connectivity

Optical Head CG-OH



Optical Head CG-OH-M



Indications for Use

The device operates as an accessory hardware for compatible image guided systems to collect and transmit stereo videography, odometry and other ambient sensory information. The device holds no operator or patient data. The device may provide safe levels of illumination to the operational field in the visible and/or near infrared spectrum to aid sensor fidelity. The device may be rigidly attached to an existing ultrasound transducer.

The device is indicated for any interventional or diagnostic procedure where image guidance is needed. The device is intended for use by, or under the direction of a qualified physician in a clinical setting as part of a compatible medical device.

Installation



NOTICE The installation of **CLEAR GUIDE** Optical Head is performed by a trained professional on a qualified Optical Head bracket.



Pre-Use Instructions

1. Inspect all **CLEAR GUIDE** Optical Head before use.

CAUTION If the device appears damaged, **do not** proceed with using the **CLEAR GUIDE** Optical Head. Contact **CLEAR GUIDE** MEDICAL customer support.

2. Prior to each use, ensure that the **Optical Head** is clean – free of debris, ultrasound gel, prep, or unusual odors.

WARNING Failure to follow cleaning and disinfecting instructions could lead to contamination hazards.

FOR SAFETY If sterility is desired, use the **CLEAR GUIDE** SteriMASK drape. For correct sterile sleeve placement, refer to the **CLEAR GUIDE** SteriMASK instructions for use (IFU).



WARNING Do not obstruct the Optical Head window with the sterile sleeve.

Cleaning and Disinfection

i **FOR SAFETY** Always use protective gloves when cleaning and disinfecting equipment.

1. Disconnect the **CLEAR GUIDE** Optical Head from the system.

⚠ **CAUTION** Do not attempt to remove the installed Optical Head from its bracket. Removing the Optical Head attachment will break the system.



⚠ **WARNING** To avoid electrical shock, disconnect **CLEAR GUIDE** Optical Head from the **CLEAR GUIDE** CORE prior to any cleaning or disinfection.

2. Wipe any fluids from the Optical Head with a damp cloth moistened with a mild soap or cleaning solution. Apply the solution to the cloth instead of applying it directly to the Optical Head surface.

⚠ **CAUTION** Do not use abrasive cleaners, cloths, or other materials or tools that may scratch the front window of the Optical Head. This may affect tracking quality negatively.

⚠ **CAUTION** Do not use isopropyl alcohol directly on the serial number labeling as repeated applications may deteriorate labeling quality over time.

3. If necessary, wipe Optical Head with a water-dampened cloth to remove any lingering soap residue.

⚠ **WARNING** Never submerge or rinse the **CLEAR GUIDE** Optical Head. This could damage the equipment.

4. Ensure that the Optical Head is dry before storing by wiping with a dry cloth or air drying.

⚠ **WARNING** Do not disinfect and sterilize **CLEAR GUIDE** Optical Head with techniques including steam autoclave, irradiation, or gas. High temperatures, ionizing radiation, and corrosive gas exposure may degrade optical and electronic components resulting in severe equipment damage.

Operating Environmental Conditions



Recommended continuous operation is below **100 Gauss**. Exceeding **300 Gauss** will impact equipment operation.



WARNING Do not operate **CLEAR GUIDE** Optical Head in the presence of flammable anesthetics.



WARNING Improper handling of the **CLEAR GUIDE** Optical Head –e.g. dropping or striking against a hard surface– could result in possible loss of calibration and in damaged equipment, including housing and other electrical safety features.



Startup Instructions

1. The **CLEAR GUIDE** Optical Head is powered upon connection to the **CLEAR GUIDE** CORE through the USB port.
2. Follow the system messages and prompts for any further action. In case of a connection problem, reconnect the **CLEAR GUIDE** Optical Head.



WARNING Do not pull the cable. Applying excessive force may cause equipment damage.



Usage

1. Point the cameras of the **CLEAR GUIDE** Optical Head towards the intervention area of interest.

CAUTION Do not point the **CLEAR GUIDE** Optical Head (CG-OH) towards eyes. It emits invisible **infrared light**, which may cause complications when applied continuously directly to the eye from very short distances.



CAUTION Do not point **CLEAR GUIDE** Optical Head (CG-OH-M) directly towards eyes when the bright LED lights are on.



2. Ensure that the tracked instrument (e.g., needle) and/or fiducial markers are visible within the stereo camera field of view as specified in your system user manual.

WARNING Do not grab or touch the **CLEAR GUIDE** Optical Head during operation.



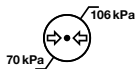
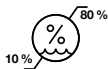
Shutdown Instructions

Turn off the connected host computer per the system instructions, or disconnect the USB cable from **CLEAR GUIDE CORE** to immediately shutdown the **CLEAR GUIDE** Optical Head.

Post-Use Instructions

1. After procedure, clean **CLEAR GUIDE** Optical Head in accordance with its instructions.
2. Follow system instructions for disinfecting the **CLEAR GUIDE** Optical Head. Failure to follow proper disinfecting instructions could lead to contamination hazards.

Storage Conditions



NOTICE **CLEAR GUIDE** Optical Head should be appropriately stored to avoid mechanical shocks and other stresses (e.g., vibrations, drops, temperature, or humidity extremes), and away from dust or water.



NOTICE Do not store **CLEAR GUIDE** Optical Head under direct sunlight.



Maintenance

Contact **CLEAR GUIDE** MEDICAL Customer Support for any maintenance questions.



WARNING Do not disassemble or open the **CLEAR GUIDE** Optical Head for troubleshooting. Servicing may only be performed by qualified personnel authorized by **CLEAR GUIDE** MEDICAL.



Power Ratings

Unit CG-OH	CLEAR GUIDE Optical Head DC Input: 5V = 500mA (USB 2)	
Unit CG-OH-M	CLEAR GUIDE Optical Head DC Input: 5V = 900mA (USB 3)	

Electromagnetic Compatibility

The **CLEAR GUIDE** Optical Head may encounter or cause electromagnetic phenomena. Users of the device should understand that portable and mobile RF Communications Equipment can affect Medical Electrical Equipment.

i NOTICE

CLEAR GUIDE Optical Head device has been evaluated according to IEC 60601-1, Clause 17, as well as the collateral standard IEC 60601-1-2. It has been found to comply with these electromagnetic compatibility limits for medical devices, which are designed to protect against harmful interference.

CLEAR GUIDE Optical Head needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided herein (Accompanying Documents).

WARNING Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the **CLEAR GUIDE** Optical Head, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.



WARNING A risk of increased emissions or decreased immunity may result if any additional cables are attached.



WARNING Use of this equipment adjacent to or stacked with other equipment **should be avoided** because it could result in improper operation. If such use is necessary, this equipment and the other equipment **should be observed** to verify that they are operating normally.



WARNING Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.



CAUTION The **emissions** characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.




The **CLEAR GUIDE Optical Head** is intended for use in the electromagnetic environment specified below. The customer or user of the device should ensure that it is used in such an environment.

Emissions Test	Compliance	Guidance on Electromagnetic (EM) Environment
RF Emissions CISPR 11	Group 1	CLEAR GUIDE Optical Head uses RF energy only for its internal function. Therefore, its RF emissions are very low and are no likely to cause any interference in near by electronic equipment.
RF Emissions CISPR 11	Class A	<p>CLEAR GUIDE Optical Head is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded:</p> <p>WARNING: This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the device or shielding the location.</p>

Electromagnetic Emissions

Immunity Test	IEC 60601 Test Level	Compliance Level	Guidance on EM Environment
Electrostatic discharge (ESD) IEC 61000-4-2	±8kV Contact ±15kV Air	±8kV Contact ±15kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Power Frequency (50/60Hz) Magnetic Field IEC 61000-4-8	30 A/m	30A/m	Power frequency magnetic fields should be a levels characteristic of a typical location in a typical commercial or hospital environment.

continued...

Immunity Test	IEC 60601 Test Level	Compliance Level	Guidance on EM Environment
Radiated RF IMMUNITY to proximity fields from RF wireless communications equipment IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz MHz - Modulation - Field Strength: 385 - 18 Hz - 27 V/m 450 - 18 Hz - 28 V/m 710 - 217 Hz - 9 V/m 745 - 217 Hz - 9 V/m 780 - 217 Hz - 9 V/m 810 - 18 Hz - 28 V/m 870 - 18 Hz - 28 V/m 930 - 18 Hz - 28 V/m 1720 - 217 Hz - 28 V/m 1845 - 217 Hz - 28 V/m 1970 - 217 Hz - 28 V/m 2450 - 217 Hz - 28 V/m 5240 - 217 Hz - 9 V/m 5500 - 217 Hz - 9 V/m 5785 - 217 Hz - 9 V/m	(E1)=3 V/m 80 MHz to 2.7 GHz MHz - Modulation - Field Strength: 385 - 18 Hz - 27 V/m 450 - 18 Hz - 28 V/m 710 - 217 Hz - 9 V/m 745 - 217 Hz - 9 V/m 780 - 217 Hz - 9 V/m 810 - 18 Hz - 28 V/m 870 - 18 Hz - 28 V/m 930 - 18 Hz - 28 V/m 1720 - 217 Hz - 28 V/m 1845 - 217 Hz - 28 V/m 1970 - 217 Hz - 28 V/m 2450 - 217 Hz - 28 V/m 5240 - 217 Hz - 9 V/m 5500 - 217 Hz - 9 V/m 5785 - 217 Hz - 9 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the CLEAR GUIDE Optical Head, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d=(3.5/E1)(\sqrt{P})$ 80 to 800 MHz $d=(7/E1)(\sqrt{P})$ 800 MHz to 2.7 GHz $E=(6/d)(\sqrt{P})$ $d=(6/E)(\sqrt{P})$ Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, d is the recommended separation distance in meters (m), and E is the field strength in V/m. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:  NOTE: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Electromagnetic Immunity

i FOR SAFETY

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the **CLEAR GUIDE** Optical Head is used exceeds the applicable RF compliance level above, the **CLEAR GUIDE** Optical Head should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the **CLEAR GUIDE** Optical Head.

The **CLEAR GUIDE** Optical Head is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **CLEAR GUIDE** Optical Head can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **CLEAR GUIDE** Optical Head as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	0.01 W	0.1 W	1 W	10 W	100 W
Separation (m) 80 MHz to 800 MHz $d=(3.5/E1)(\sqrt{P})$	0.117	0.369	1.167	3.689	11.667
Separation (m) 800 MHz to 2.7 GHz $d=(7/E1)(\sqrt{P})$	0.233	0.738	2.333	7.379	23.333
Separation (m) 710 MHz, 745 MHz, 780 MHz, 5240 MHz, 5500 MHz, and 5785 MHz $d=(6/9)(\sqrt{P})$	0.067	0.211	0.667	2.108	6.667
Separation (m) 385 MHz, 450 MHz, 810 MHz, 870 MHz, 930 MHz, 1720 MHz, 1845 MHz, 1970 MHz, and 2450 MHz $d=(6/28)(\sqrt{P})$	0.021	0.068	0.214	0.678	2.143

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Separation distance according to frequency of transmitter (m)

Disposal Information



NOTICE Do not dispose of the **CLEAR GUIDE** Optical Head with household waste. When disposing of electrical products — either at the user's request or at the end of the product's life — refer to local regulations and the requirements of European Commission Directive 93/86/EEC and the "Waste Electrical and Electronic Equipment" Directive (WEEE) 2012/19/EU for guidance.



Symbols

	Read usage instructions		MR Conditional		SGS Q certification. Conforms to ANSI/AAMI ES 60601-1 and CAN/CSA C22.2 No. 60601-1.		General warning sign
	Manufacturer & Manufacturing date						Do not hold or grab Optical Head
	Authorised Representative		Fragile, handle with care		Direct current (DC)		
	European Conformity Mark		Keep away from sunlight		USB (Universal Serial Bus), Port/Plug		Do not pull the Optical Head cable
	Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.		Keep dry		Non-ionizing electromagnetic radiation		Caution, infrared radiation
	Catalogue number		Carrying out servicing by users is prohibited		Electrical equipment is not suitable for a residential area.		Caution, visible radiation. Do not stare into beam
	Part Number		Weight		Ingress Protection (IP) Rating: IP53		
					Humidity Limitation (non-condensing)		
	Serial number		Enclosure Material		Atmospheric pressure limitation		
	Relevant information for use of the product is available in electronic form.		Camera		Color Camera		Infrared lamp
	Follow instructions for use		Do not dispose with household waste!		Lamp; lighting; illumination		

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