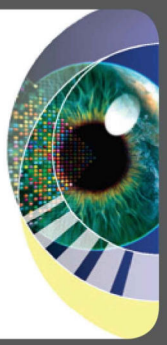
KARL STORZ — ENDOSKOPE

en

Instructions for use
IMAGE1 S 4U Rubina OPAL1 NIR/ICG Camera Head



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1 General information

1.1 Read the instructions for use

If the instructions for use are not followed, patients, users, and third parties may be injured or the product may be damaged.

- ▶ Read the instructions for use carefully and follow all the safety notes and warnings.
- ▶ Read the reprocessing instructions carefully and follow all the safety notes and warnings. The reprocessing instructions can be downloaded from www.karlstorz.com/ifu by entering the item number.
- ▶ Keep the instructions for use and reprocessing instructions in a safe place.

1.2 Read the instructions for use of compatible products

If the instructions for use of compatible products are not followed, patients, users, and third parties may be injured or the product may be damaged.

- ▶ Read the instructions for use of the compatible products carefully and follow all the safety notes and warnings.
- ▶ Read the reprocessing instructions of the compatible products carefully and follow all the safety notes and warnings.

1.3 Scope

This instruction manual is valid for:

Product name	Item number
IMAGE1 S 4U RUBINA, OPAL1 NIR/ICG, Two-Chip 4K UHD Camera Head	TH121

1.4 General signs and symbols

The signs and symbols used in this document have the following meaning:

Practical tip

ⓘ This sign refers to useful and important information.

Actions to be performed

Action to be carried out by several steps:

✓ Prerequisite that must be met before carrying out an action.

1. Step 1
   ⇨ Interim result of an action
2. Step 2

⇨ Result of a completed action

Actions in safety notes or in the case of a single step:

- ▶ Step 1

Lists

1. Numbered list

- Unnumbered list, 1st level
  - Unnumbered list, 2nd level

1.5 Description of warning messages

To prevent any injury to persons or damage to property, the warnings and safety notes in the instructions for use must be observed. The warnings use the following levels of danger:

⚠ WARNING

WARNING

Designates a possible imminent risk. If this is not avoided, it could lead to death or serious injuries.

⚠ CAUTION

CAUTION

Designates a possible imminent risk. If this is not avoided, it could lead to minor injuries.

NOTICE

NOTICE

Designates a possibly harmful situation. If this is not avoided, the products could be damaged.

2 Normal use

2.1 Intended use

The camera head is used together with the camera control unit and is connected to a telescope during endoscopic or microscopic procedures. It can also be used for fluorescence applications.

2.2 Indications

The camera heads and adaptors do not come into direct contact with the patient; instead, they are used in conjunction with the corresponding accessories (camera control unit, endoscopes, light source, and monitor) and the applied parts for the purpose of visualizing and documenting endoscopic and exoscopic procedures. Use is not restricted to certain medical disciplines.

2.3 Contraindications

No contraindications relating directly to the medical device are currently known. Use is contraindicated if, in the opinion of the responsible physician, the device is not compatible with successful completion of the planned procedure due to its technical design.

2.4 Target user populations

The medical device may only be used by doctors and medical assistants with a relevant specialist qualification.

2.5 Patient population

There are no restrictions in terms of patient groups for this product.

3 Safety and warning

⚠ WARNING

Danger due to non-observance of warnings and safety notes

This chapter contains warnings and safety notes structured according to hazards and risks.

- ▶ 1. Carefully read and observe all warnings and safety notes.
- ▶ 2. Follow the instructions.

3.1 Serious incidents

A 'serious incident' includes incidents which, directly or indirectly, had, could have had or could have any of the following consequences:

- – Death of a patient, user, or another person
- – Temporary or permanent serious deterioration in the medical condition of a patient, user, or another person
- – A serious threat to public health

- ▶ The manufacturer and appropriate authority must be notified of all serious incidents.

3.2 Correct handling and product testing

If the product is not handled correctly, patients, users, and third parties may be injured.

- ▶ Only persons with the necessary medical qualification and who are acquainted with the application of the product may work with it.
- ▶ Check that the product is suitable for the procedure prior to use.
- ▶ Check the product for the following properties, for example, before and after every use:
- – Functionality
- – Damage
- – Changes to the surface
- – In the case of several components: completeness and correct assembly

- ▶ Do not continue to use damaged products.
- ▶ Dispose of the product properly.

3.3 Combination with other components

The use of unauthorized devices and components or unauthorized changes to the product can result in injuries.

Additional devices connected to electrical medical equipment must comply with the relevant IEC or ISO standards. Furthermore, all configurations must comply with the requirements for medical electrical systems.

- ▶ Only combine the product with devices and components that are approved for combined use by the manufacturer.
- ▶ Only use devices and components that have standardized interfaces and do not breach the normal use of the product.
- ▶ Do not modify this equipment without authorization of the manufacturer.

3.4 Dangers from electrical current

An improper power supply may cause an electric shock and injure patients, users, or third parties.

- ▶ Make sure that the plug is completely clean and dry.
- ▶ Never allow HF devices to come into contact with the product or system.

3.5 Hot components

The high level of light intensity produced by the light source may cause the distal end, the light connections, and adjacent components to heat up. This can cause burns to patients, users, and third parties.

- ▶ Set the output of the adjustable light sources to a level that is just high enough to ensure optimal illumination of the operating area.
- ▶ Prevent the distal end, light connections, and adjacent components from coming into contact with tissue and operating room accessories.

3.6 High light intensity

The high level of light intensity produced by the light source may lead to permanent eye damage or blindness, and may cause tissue and items facing the light output to heat up.

- ▶ Do not look into the light output.

3.7 Risk of injury due to HF instruments

The product offers no insulation against high-frequency voltages. Using HF instruments may injure the user or patient and damage the product.

- ▶ Never allow HF devices to come into contact with the product or system.

3.8 Failure of devices

The product may fail during use.

- ▶ Have a replacement product ready for each application or plan for an alternative surgical technique.

4 Product description

4.1 Product overview

1 Instrument coupler

2 Focus ring

3 Scroll down
Activate camera function

4 Scroll up
Select

5 Call up menu
Select

4.2 Possible combinations

It is recommended that the suitability of the products for the intended procedure be checked prior to use. Please note that the products listed here may not yet be available in all countries due to differences in approval requirements.

Combination with camera control unit (CCU)

Camera head	CCU	LINK module
TH121	IMAGE1 S CONNECT II (TC201)	IMAGE1 S 4U-LINK (TC304)

Combination with endoscopes or adaptors

The product can be connected to endoscopes or adaptors via the eyepiece connection.

4.3 Technical data

Description	Value
Image sensor	2x 1/2.5" CMOS
Image format	16:9
Image refresh rate	50/60 Hz
Focal length	19 mm

Description	Value
Dimensions (L x H x W)	150 x 55 x 41 mm
Weight (without cable)	260 g
Applied part type according to IEC 60601-1	CF

4.4 Symbols on the packaging

Symbol	Meaning
	Manufacturer
	Date of manufacture
	Medical device
	Article no.
	Serial number
	Number of products in the product packaging
	Unique Device Identifier
	Consult the printed or electronic instructions for use
	Note for the user to consult the instructions for use for important cautionary information such as warnings and precautions.
	Unsterile

Symbol	Meaning
	Fragile, handle with care
	Federal (USA) law restricts this device to sale by or on the order of a physician.
	CE marking With this marking, the manufacturer declares the conformity of the product with the applicable EU directives. A code number after the CE mark indicates the responsible notified body. The EU directives relevant to the product can be found in the EU Declaration of Conformity, which can be requested from KARL STORZ.

4.5 Ambient conditions

Storage and transport conditions	
Temperature	-10°C ... 60°C (14°F ... 140°F)
Relative humidity	20–95%

Operating conditions	
Temperature	5°C ... 35°C (41°F ... 95°F)
Relative humidity (non-condensing)	20–95%

5 Preparation

5.1 Unpacking the product

1. Carefully remove the product and accessories from the packaging.
2. Check the delivery for missing items and any possible damage.
3. In the case of damage, hidden defects, and short deliveries, document their nature and extent and contact the manufacturer or supplier immediately.

5.2 Assembling the product

The product has an integrated instrument coupler and an integrated telescope.

1. Rotate the outer ring of the coupler clockwise and insert the endoscope eyepiece.
2. Rotate the outer ring of the instrument coupler counterclockwise to tighten it.

5.3 Connecting the light cable

1. Tighten the knurled screw on the light cable by a quarter turn to connect the light cable.

6 Application

6.1 Adjusting the focus

ⓘ The image display can be impaired by intense laser light.

1. Ensure that the correct video image is displayed on the monitor before starting the procedure.
2. Turn the focus ring to adjust the image sharpness on the camera lens.

7 Maintenance, servicing, repairs, and disposal

7.1 Repairs to the product

Repair work may only be performed by KARL STORZ or by a company authorized by KARL STORZ.

- ▶ Please contact your local KARL STORZ subsidiary or authorized dealer (see the list of subsidiaries).

Contaminated devices may not be shipped. To prevent contact infections and airborne infections, products must first be decontaminated. KARL STORZ reserves the right to send back contaminated products.

7.2 Disposing of the product

The product meets the requirements of the Directive on Waste Electrical and Electronic Equipment (WEEE).

Within the scope of application of this directive, KARL STORZ SE & Co. KG is responsible for the proper disposal of this product.

1. The product must be disposed of in accordance with the applicable national laws and regulations at a suitable collection point for the reprocessing of electrical and electronic equipment.
2. Contact KARL STORZ SE & Co. KG, a KARL STORZ branch or an authorized dealer to find out the address of the collection point in your area.

8 Accessories and spare parts

8.1 Accessories

ⓘ Not all articles are available in all regions.

Article	Order no.
Adaptor, autoclavable	533TVA
Dust cap for camera heads	6349190
Camera Cover, sterile, for single use, pack of 40	040112-40
Camera Cover, sterile, for single use, pack of 50	040113-50
Camera Cover, sterile, for single use, pack of 15	040114-15
Camera Cover, sterile, for single use, pack of 40	040115-40
Camera Cover, sterile, for single use, pack of 40	040169-40
Camera Cover, sterile, for single use, pack of 25	040170-25

9 Electromagnetic compatibility

9.1 General notes on the operating environment

The product is suitable for use in professional healthcare settings. Professional healthcare facilities include physician offices, dental offices, limited care facilities, freestanding surgical centers, freestanding birth centers, multiple treatment facilities, hospitals (emergency rooms, patient rooms, intensive care, surgical rooms, outside the HF-shielded room of an ME system for MRT).

ⓘ The emission characteristics of this product make it suitable for use in industrial areas as well as in hospitals (CISPR 11 Class A) and other professional healthcare environments. If it is used in a residential environment (for which CISPR 11 Class B is normally required), the product may not offer sufficient protection for radio transmission operation. The user might need to take mitigation measures, such as relocating or re-orienting the product.

⚠ WARNING

Degradation of performance! Malfunction!

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) could result in degradation of the performance of the product.

- ▶ Do not use portable communications equipment closer than 30 cm (12 inches) to any part of the product, including cables.

9.2 Table 1 – Compliance level for immunity tests

Guidelines and manufacturer's declaration – electromagnetic immunity

The product is intended for use in the electromagnetic environment specified below. The user of the product should make sure that it is used in such an environment.

Interference immunity tests	EN/IEC 60601 test level	Compliance level	Electromagnetic environment – guidelines
Electrostatic discharge (ESD) acc. to IEC 61000-4-2	± 8 kV contact discharge ± 15 kV air discharge	± 8 kV contact discharge ± 15 kV air discharge	Floors should be made of wood, concrete, or covered with ceramic tiles. If floors are covered with synthetic material, the relative humidity must be at least 30%.
Electrical fast transients/bursts acc. to IEC 61000-4-4	± 2 kV for power lines ± 1 kV for input and output lines 100 kHz repetition	± 2 kV for power lines ± 1 kV for input and output lines 100 kHz repetition	The power supply quality should be that of a typical commercial or hospital environment.
Surges acc. to IEC 61000-4-5	± 1 kV voltage outer conductor – outer conductor ± 2 kV voltage outer conductor – ground	± 1 kV voltage outer conductor – outer conductor ± 2 kV voltage outer conductor – ground	The power supply quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations acc. to IEC 61000-4-11	Voltage dip: Dip to 0% for 1 cycle at 0° phase angle Dip to 70% for 25/30 cycles at 0° phase angle	Voltage dip: Dip to 0% for 1 cycle at 0° phase angle Dip to 70% for 25/30 cycles at 0° phase angle	The power supply quality should be that of a typical commercial or hospital environment. If the user of the product requires continued operation in

Interference immunity tests	EN/IEC 60601 test level	Compliance level	Electromagnetic environment – guidelines
	Dropout to 0% for 0.5 cycles @ 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° phase angles Voltage interruption: 100% for 250/300 cycles	Dropout to 0% for 0.5 cycles @ 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° phase angles Voltage interruption: 100% for 250/300 cycles	the event of interruptions to the power supply network, it is recommended that the product be operated with an uninterruptible power supply or a battery.
Magnetic field at the power frequency (50/60 Hz) acc. to IEC 61000-4-8	30 A/m at 50 Hz / 60 Hz	30 A/m at 50 Hz / 60 Hz	If image distortion occurs, it may be necessary to install the product further from sources of electromagnetic fields or to install magnetic shielding. Before the product is installed, the electromagnetic field should be measured to ensure that it is sufficiently low.
Immunity test acc. to IEC 61000-4–3 for radiated, radio-frequency electromagnetic fields	3 V/m 80 MHz to 2.7 GHz * Refer to Table 2 for wireless proximity RF field test levels	3 V/m 80 MHz to 2.7 GHz	
Immunity to conducted disturbances, induced by radio-frequency fields acc. to IEC 61000-4-6	3 V_{rms} on 150 kHz to 80 MHz 1 kHz 80% AM modulation 6 V_{rms} in ISM band	3 V_{rms} on 150 kHz to 80 MHz 1 kHz 80% AM modulation 6 V_{rms} in ISM band	

9.3 Table 2 – Test levels for proximity fields from HF wireless communications equipment

Test frequency MHz	Frequency band MHz	Radio service	Modulation	Immunity test level V/m	Compliance level V/m
385	380 – 390	TETRA 400	Pulse modulation 18 Hz	27	27
450	430 – 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine wave	28	28
710	704 – 787	LTE band 13 and 17	Pulse modulation 217 Hz	9	9
745					
780					

Test frequency MHz	Frequency band MHz	Radio service	Modulation	Immunity test level V/m	Compliance level V/m
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE band 5	Pulse modulation 18 Hz	28	28
870					
930					
1720	1700 – 1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE band 1, 3, 4, 25, UMTS	Pulse modulation 217 Hz	28	28
1845					
1970					
2450	2400 – 2570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	28	28
5240	5100 – 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	9	9
5500					
5785					

9.4 Table 3 – Test levels for radiated and conducted immunity tests

Guidelines and manufacturer's declaration – electromagnetic immunity

The product is intended for use in the electromagnetic environment specified below. The user of the product should make sure that it is used in such an environment.

Interference immunity tests	EN/IEC 60601 test level	Compliance level	Electromagnetic environment – guidelines
Conducted HF disturbances acc. to IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	3 V_{rms}	Portable and mobile HF communications equipment should be used no closer to any part of the product, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distances: $d = 1.2\sqrt{P}$ Where P is the rated power of the transmitter in watts [W] according to the information provided by the
Radiated HF disturbances acc. to IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

Interference immunity tests	EN/IEC 60601 test level	Compliance level	Electromagnetic environment – guidelines
			transmitter manufacturer and d is the recommended separation distance in meters [m]. Field strengths from fixed HF transmitters as determined by an electromagnetic site survey [a] should be less than the compliance level in each frequency range [b]. $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz Interferences 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. The propagation of electromagnetic waves is affected by absorptions and reflections of buildings, objects, and people.			
[a] Field strengths from fixed transmitters, e.g., 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 transmitters, an electromagnetic site survey should be considered. If the measured field strength at the location where the device is used exceeds the above compliance levels, the device should be monitored to ensure proper function. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the product. [b] Over the frequency range from 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

9.5 Table 4 – Emission class and group

Guidelines and manufacturer's declaration – Electromagnetic emissions

The product is intended for use in such an environment as specified below. The customer or user of the product should ensure that it is used in such an environment.

Interference emission measurements	Compliance	Electromagnetic environment – guidelines
RF emissions acc. to CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions acc. to CISPR 11	Class A	The device is suitable for use in all establishments other than domestic and those directly connected to the public
Emission of harmonic oscillations acc. to IEC 61000-3-2	Class A	

Interference emission measurements	Compliance	Electromagnetic environment – guidelines
Voltage fluctuations/flicker emissions acc. to IEC 61000-3-3	Complies	low voltage power supply network that supplies buildings used for domestic purposes.

9.6 Table 5 – Recommended separation distances between portable and mobile HF communications devices and the product

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

Rated power of the transmitter [W]	Separation distance d [m] according to frequency of transmitter		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2 \sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters whose maximum rated power is not listed in the table above, the recommended separation distance d in meters (m) can be estimated using the equation from the respective column, whereby P is the maximum rated power 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. The propagation of electromagnetic waves is affected by absorptions and reflections of buildings, objects, and people.			

ⓘ The product was tested for compatibility with HF surgical devices in accordance with IEC 60601-2-2 Appendix BB.

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