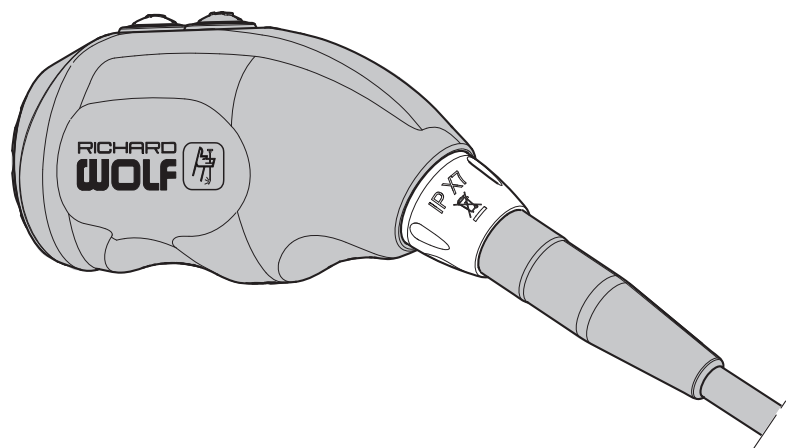


Instructions for use



Logic 4K camera head

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Manufacturer



RICHARD WOLF GmbH
Pforzheimer Straße 32
75438 Knittlingen
GERMANY
Telephone: +49 70 43 35-0
Telefax: +49 70 43 35-4300
www.richard-wolf.com

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1 General notes and instructions for use

Make sure that this product is used only as intended and described in this instruction manual, and by adequately trained and qualified medical personnel. Maintenance and repair must be carried out by authorized experts.

Use the product only in the combinations and with the accessories and spare parts specified in this instruction manual. Other combinations, accessories and wear and tear parts should be used only if these are expressly referred to in the instruction manual. Use other combinations, accessories and wear and tear parts only if they are expressly intended for the planned use and do not impair the performance characteristics or safety requirements. The product must not be altered in any way.

Reprocess the product in accordance with the manual before every use and before return shipment to protect the patient, user and third parties.

This manual is an integral part of the product and must be stored in such a way that it is accessible at any time during its entire life cycle.

Immediately upon receipt, check the product and its accessories for completeness and possible damage. Should the shipment give rise to complaints, please inform the manufacturer or supplier immediately.

Subject to technical changes!

Due to the ongoing development of the products, the descriptions, illustrations and technical data may deviate from the current state.

For further information about our products please contact Richard Wolf GmbH or your representative.

1.1 Safety instructions and levels of danger



⚠ WARNING

This signal word is used to indicate a potentially dangerous situation. Not avoiding this situation can result in death or extremely serious injuries.



⚠ CAUTION

This signal word is used to indicate a potentially dangerous situation. Not avoiding this situation can result in slight injury or damage to the product.

ATTENTION

This signal word without warning symbol is used to indicate a possible danger of material damage.










NOTE

This signal word provides the reader with useful information such as tips for easy operation and cross references.

2 General information

2.1 Symbols

Symbols	Designation
	Follow the instruction manual
	Item number
	Serial number
	Manufacturing date
	Manufacturer
	Discard this product separately. Do not discard together with other waste.
	Identification in conformity with Medical Devices Directive 93/42/EEC, only valid if the product and/or packaging is marked with this identification . Products of category IIa and above, as well as sterile products or products with measuring function of category I, are additionally marked with the code no. of the notified body (0124).

2.2 Intended use

Logic 4K Camera Head 85525942 is used for applications in conjunction with cameras of the Logic HD Camera Controller 552510X series and Logic 4K Camera Controller 5525301 for diagnostic and therapeutic interventions.

This product is exclusively intended for use by specialized medical personnel and may only be used by adequately qualified and trained medical doctors.

2.3 Indications and field of use

This product is used for diagnosis and therapy in conjunction with endoscopic accessories.

On the basis of the patient's general condition, the user in charge must decide whether the planned use is possible or not. For further notes and instructions please refer to the latest medical literature.



CAUTION

The product may fail during therapeutic use.

Therapeutic use may have to be interrupted.

- In case of therapeutic applications a second, equivalent product should be available

2.4 Contraindications and side effects

2.4.1 Contraindications

Contraindications directly related to the product and presently unknown. On the basis of the patient's general condition the doctor in charge must decide whether the planned use is possible or not.

For further notes and instructions please refer to the latest medical literature.

2.4.2 Side effects

No side effects must be expected if the system is used as intended.

2.5 Combinations

The Logic 4K camera head must only be used following the instructions in manual GA-A282 for the ENDOCAM Logic HD Camera Controller 552510X series and ENDOCAM Logic 4K Camera Controller 5525301.

- As of camera controller software **V2.0.0** the Logic 4K camera head is also compatible with the ENDOCAM Logic HD Camera Controller 552510X series, however with reduced resolution.
- The Logic 4K camera head is **not** compatible with ENDOCAM Logic HD lite Camera Controller 5525201.



⚠ CAUTION

Do not combine products incorrectly!

Wrong product combinations may can injure the patient, user or others, and damage the product.

- Different products should only be used in combination if their intended uses and relevant technical data (working length, diameter, etc.) are the same.
- Follow the instruction manuals of the products used in combination with this product.

3 Illustration

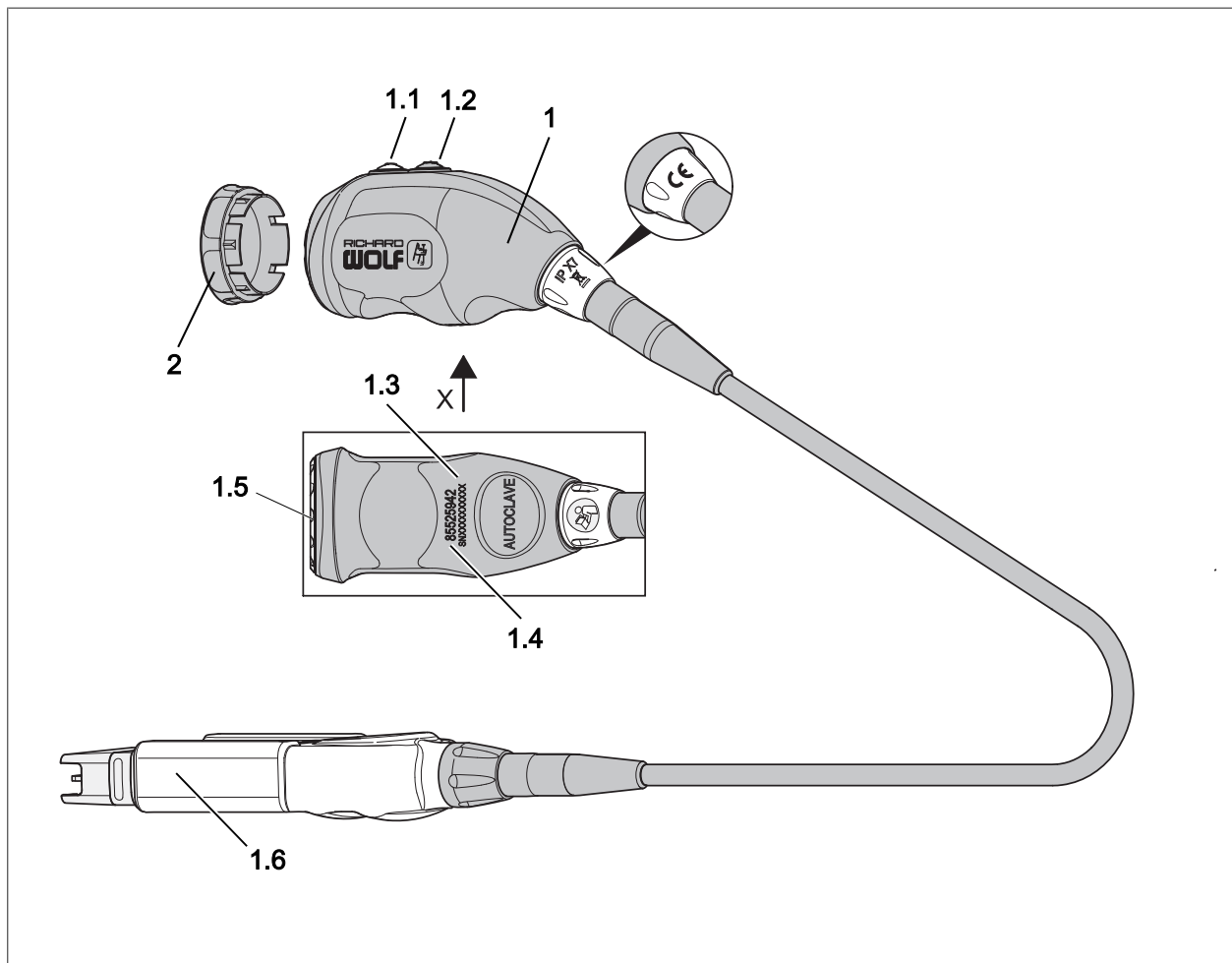


Fig. 1

1	Camera head	1.4	Product no.
1.1	Head button 1 (light color) for remote control (for button assignment see GA-A282)	1.5	C-mount thread for objective lens
1.2	Head button 2 (dark color) for remote control (for button assignment see GA-A282)	1.6	Camera plug
1.3	Serial no.	2	Protection cap

4 Preparation



⚠ WARNING

The applied part is not protected against explosions.

Danger of explosion.

- Do not operate the applied part in flammable atmosphere.

ATTENTION

Do not direct the camera head at the sun or at bright light sources in the vicinity. The high energy radiation in the visible and ultraviolet wavelength range may cause damage to the image sensor surface. This may result in color distortion and image noise.

When the camera head is not in use, always install the protection cap.

ATTENTION

The camera cable has only limited strength.

Excessive force and high mechanical loads can cause damage to the camera cable or to the wiring, which in turn can cause image interference or image blackout.

- Do not squash or pinch or overbend the camera cable. Do not pull on the camera cable.

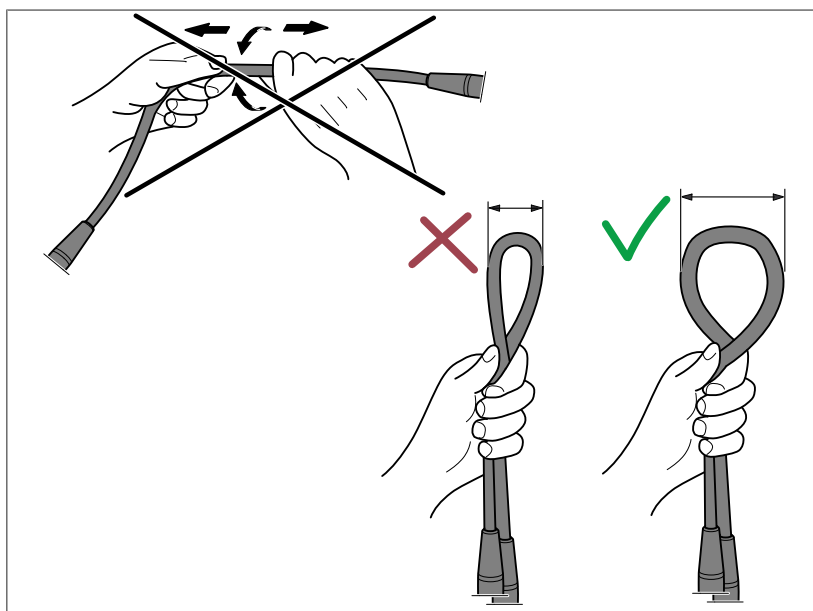


Fig. 2

4.1 Connecting the objective lenses and endoscopes to the camera head

ATTENTION

- Before assembling the endoscope and objective lens, check that the glass surfaces of the endoscope, objective lens and camera head are dry and dust-free.
- Any soiling can be removed with a cotton swab soaked with alcohol (wooden or plastic swab carrier, not metal).

- ◇ Clean the glass surfaces on the objective lens with a cotton swab soaked with alcohol (Isopropanol 70%) of until no residues are visible on the glass surface.

Specification of the cotton swab:

- Solvent resistant.
- Head made of 100% pure cotton.
- Wooden or plastic swab carrier, no metal swab carrier.
- Head diameter 35 mm.



NOTE

For a detailed description and overview of the objective lenses, see instruction manual GA-S 022.

Connecting a C-mount objective lens

1. Remove the caps from the camera head and objective lens.
⇒ Slide the snap-on locking mechanism in direction of arrow. Snap-on mechanism locks in the open position.
2. Screw the C-mount objective lens onto the camera head by turning clockwise.

Connecting the endoscope

1. Place the endoscope onto the objective lens.
⇒ The snap-on locking mechanism is in open and pre-tensioned state - insert the endoscope - the snap-on locking mechanism locks automatically, locking the endoscope in place.
2. Check that the components are securely connected.

Removing the endoscope:

- ◇ To remove the endoscope, pull the snap-on locking mechanism backwards to its unlocking position and remove the endoscope.

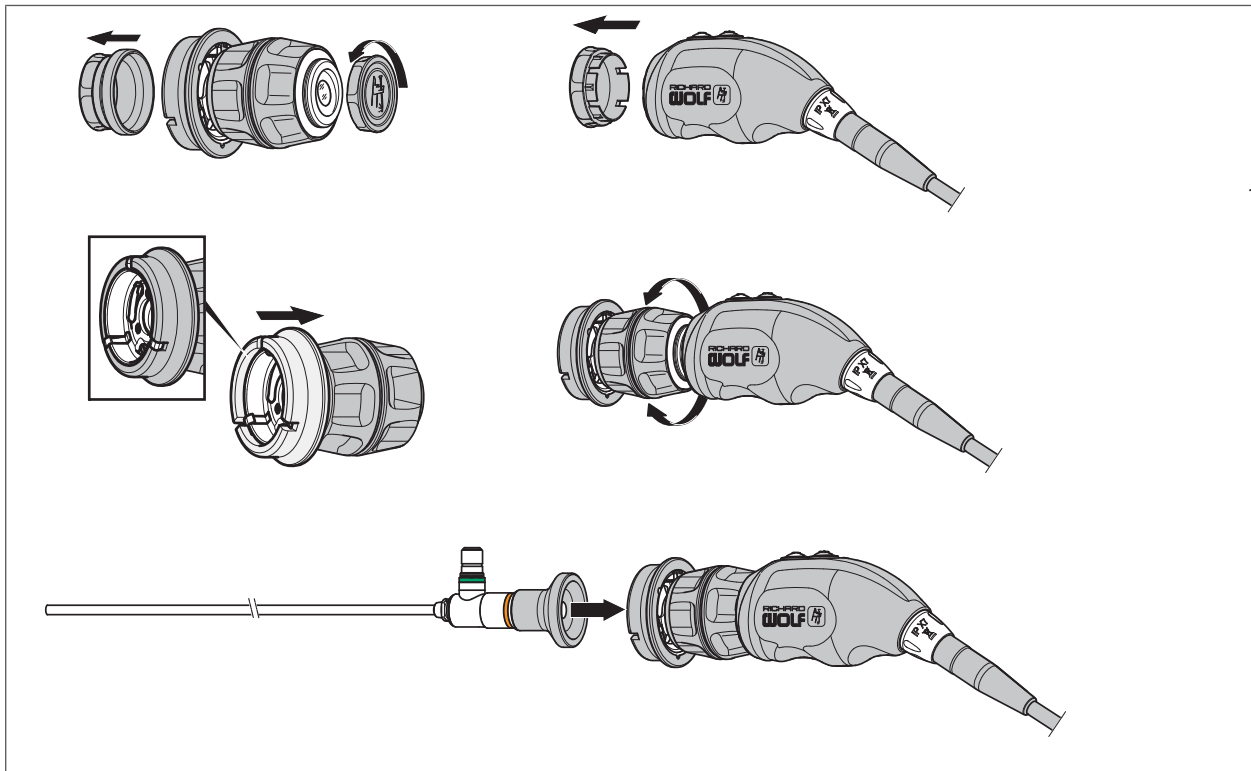


Fig. 3

5 Checks



⚠ CAUTION

Danger of injury due to damaged or incomplete products!

Injuries of the patient, user and others are possible.

- Carry out checks before and after each use.
- Do not use the products if they are damaged, incomplete or have loose parts.
- Return damaged products together with any loose parts for repair.
- Do not attempt to do any repairs yourself.

5.1 Visual check

1. Before and after each use, check the camera head and the accessories for damage, sharp edges, loose or missing parts and rough surfaces.
2. Check the connection cables and adapters for damage.
3. Any inscription, lettering or labeling necessary for the safe intended use must be legible.
 - ⇒ Missing or illegible inscriptions, lettering or labeling leading to wrong handling or reprocessing must be reinstated.
4. Fogging or functional impairment may indicate the ingress of liquid.

5.2 Function check

1. Carry out a function check of the camera together with the cameras of the ENDOCAM Logic HD camera controller 552510X or ENDOCAM Logic 4K camera controller 5525301 model series in accordance with instruction manual **GA-A282**.
2. After connecting the camera head, an interference-free live image must appear on the monitor.
 - ⇒ If the live image is poor (black, interference or color bars), disconnect the camera head and reconnect after 3 seconds.
3. Restart the camera controller if there is no interference-free live image.

6 Use

ATTENTION

The camera heads **cannot** be used for fluorescence diagnostics.

6.1 Function assignment of the camera head buttons



NOTE

For the function assignment of the camera head buttons, see instruction manual **GA-A282** for the ENDOCAM Logic HD camera controller 552510X and ENDOCAM Logic 4K camera controller 5525301 camera model series.

7 Reprocessing

ATTENTION

Damaged products due to wrong reprocessing!

- Reprocess the products in accordance with the instruction manual before each use and before returning them for repair, in order to protect the patient, user and others.
- Do **not** use disinfectants containing peracetic acid without corrosion protection, phenols or chlorine components the reprocessing of Richard Wolf products.
- For the maximum immersion time of the disinfectants used adhere to the manufacturer's specifications.



NOTE

Follow the latest notes and instructions in manual GA-J 020, "Reprocessing of RICHARD WOLF Heat-stable Instruments".

7.1 Reprocessing of heat-resistant camera heads

7.1.1 Checks

- ◇ Check all parts for possible damage and replace if necessary.

7.1.2 Contaminated camera plug

- Carry out the following cleaning, disinfection and rinsing steps if the camera plug is visibly contaminated:
 1. Rinse the camera plug under tap water until all surfaces look clean.
 - ⇒ Carefully dry with compressed air, e.g. using a cleaning gun, until any visible moisture has been removed (maximum pressure 2.5 bar).
 2. Immerse the camera plug in a enzymatic or neutral disinfection solution and observe the recommended immersion time.
 3. Rinse the camera plug with sterile water thoroughly.
 4. Carefully dry with compressed air, e.g. using a cleaning gun, until any visible moisture has been removed (maximum pressure 2.5 bar).
 - ⇒ Residual moisture in the contacts can impair signal transmission (e.g. interruptions, poor contacts).



NOTE

For immersion time and concentration follow the chemical manufacturer instructions.

7.2 Reprocessing procedure

ATTENTION

As a result of the product design and the materials used, it is not possible to determine a defined limit of possible reprocessing cycles. The service life of medical products is determined by their function and gentle handling.

Before returning defective products for repair, they must have gone through the entire reprocessing cycle.

The user must make sure that the reprocessing process including the resources, materials and personnel is suitable for yielding the required results.

The state of the art and national laws require that validated processes be followed.



NOTE

Preparation of the cleaning and disinfectant solution in accordance with the chemical manufacturer's instructions / manual.



NOTE

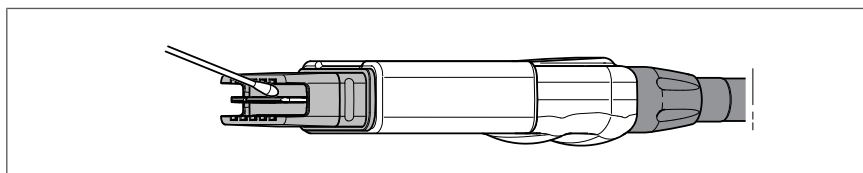
Use enzymatic or neutral cleaning solution.

7.2.1 Heat-resistant camera heads

Preparation at the point of use ◇ **Directly** after use, remove any coarse soiling from the camera head.
⇒ Do not use fixing agents or excessively hot water (max. 40 °C) as this may bake residues to the surfaces and may jeopardize the cleaning success.

Transportation To avoid damage and contamination, safely store the camera heads in a reprocessing basket (model 38047111) and transport them to the reprocessing location.

Pre-cleaning ◇ Clean the contact surfaces of the PCB on the camera plug with a cotton swab soaked with alcohol (70% isopropanol).



Ultrasonic cleaning Ultrasonic cleaning is **not** permissible, as this may damage the camera head.

Manual cleaning

1. Immerse in a disinfection bath (e.g. model 509.81) filled with cleaning solution at ambient temperature for 6 minutes.
2. Clean the buttons and the camera head with a brush with soft bristles (e.g. model 86.90) for 40 seconds. Make sure that the buttons and the area around the buttons is really clean.

3. Immerse the camera head with camera cable in a disinfection bath (e.g. model 509.81) filled with demineralized water at ambient temperature for 5 minutes.
4. Remove the camera head with camera cable from the bath and dry carefully with a lint-free cloth.

- Manual disinfection**
1. Immerse the camera head in a disinfectant solution and follow the manufacturer's specifications for the exposure time.
 2. Immerse the camera head with camera cable in a container (e.g. model 509.81) filled with sterile water. Disinfect the container before use.

- Manual drying** ◇ Dry the camera heads with a sterile lint-free disposable cloth or swab.

Machine cleaning Manual precleaning process:

- ◇ In the case of visible soiling, brush the buttons and the camera head for 30 seconds under running water.

Machine cleaning:

1. Place the camera head in the reprocessing basket (model 38047111).
⇒ The camera plug must be stored in upright position resting on its side.
2. Program:
 - 2 min of precleaning with cold water
 - Empty
 - 6 min of cleaning with a neutral enzymatic cleaner at a temperature of at least 45 °C
 - Empty
 - 3 min of intermediate rinsing using warm deionized water (max. 45 °C)
 - Empty

- Machine disinfection in W/D** ◇ Thermal machine disinfection (max. 93 °C) taking into account the national requirements.

- Machine drying in W/D**
1. Dry the camera heads using the drying cycle of the washer-disinfector.
 2. If necessary, dry the camera heads additionally using a lint-free disposable cloth or swab.

- Care** After manual / machine disinfection, **no** additional care is required.

- Function test, maintenance** ◇ Check all surfaces for cleanliness.
⇒ If necessary repeat the reprocessing process until the camera head is visually clean.

- Packaging** Wrap the camera head for sterilization in accordance with the procedure specified in the validation (e.g. single packaging).

Sterilization Steam sterilization:

- Sterilization of products using the fractional pre-vacuum method (ISO13060/ ISO17665) taking into account the corresponding national requirements.
- Temperature exposure time: 4 min at 134 °C ^{+4 °C} (273 °F ^{+7 °F}), 4 min at 132 °C ^{+4 °C} (270 °F ^{+7 °F})
- Drying time: 10 - 20 min
- Maximum sterilization temperature: 138 °C

Low temperature procedure

Hydrogen peroxide plasma:

- STERRAD® 100S: Short Cycle
- STERRAD® NX: Standard cycle
- STERRAD® 100 NX: Standard cycle

Hydrogen peroxide:

- Hydrogen peroxide (VPRO™ 1, VPRO max™)
- VPRO max™: Non-lumen cycle
- VPRO™ 1 Plus: Non-lumen cycle

Storage Store the sterilized products in a dry, clean and dust-free environment at temperatures between 5 °C and 40 °C

7.3 Low-temperature sterilization

ATTENTION

Product damage due to interactions!

The low temperature procedure with hydrogen peroxide and peracetic acid have been approved for endoscopes and endoscopic accessories with regard to their material compatibility.

By no means must these low temperature procedures be used alternately.

Possible interactions between these sterilization procedures can damage the products.

7.4 Maintenance intervals

ATTENTION

To avoid any incidents or damage caused by aging and wear it is necessary to service the product and the accessories at adequate intervals. Depending on the frequency of use, but at least once a year, have an expert check the functional and operational safety of the equipment.

8 Technical Data

Camera head	Length of camera cable	Combinable camera controllers	Type
85525942	3.0 m	ENDOCAM Logic HD camera controller model series	552510X
		ENDOCAM Logic 4K camera controller model series	5525301

Degree of protection against the ingress of liquids	IPX7 (protected against the effects of permanent submersion)
Image capture	3 chip technology
Weight with camera cable and camera plug	Cable length 3.0 m: 0.540 kg (1.19 lbs)
Dimensions of camera head	Diameter, width approx. 40 mm Diameter, height approx. 48 mm Length approx. 102 mm
Cable outlet	30°
Thread for objective lens	C-mount

8.1 Operating, storage, transport and shipping conditions

Operating conditions	+10°C to +30°C, 20% to 75% rel. humidity, atmospheric pressure 700 hPa to 1060 hPa
Storage, transport and shipping conditions	- 20°C to +60°C, 10% to 90% rel. humidity, atmospheric pressure 700 hPa to 1060 hPa

ATTENTION

To prevent damage during transport or shipment of products, we recommend using the original packaging material.

8.2 Spare parts and accessories

Product no.	Designation
15135463	Protection cap for camera head
85261144	Objektive lens, f = 14 mm, C-mount, RIWO
85261244	Objektive lens, f = 24 mm, C-mount, RIWO
85261504	Zoom lens, f = 13 to 29 mm, C-mount, RIWO
38047111	Reprocessing basket for camera heads
Further accessories on request.	



NOTE

The camera cable with camera plug is a wearing part and is therefore excluded from warranty.

8.3 Disposal of product, packaging material and accessories



NOTE

For the disposal comply with the country-specific laws and regulations.

- For further information please contact the manufacturer.
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