

STORZ

KARL STORZ—ENDOSKOPE

en Instructions for use
IMAGE1 S™ H3 Camera Heads



01-2021

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1 General information

1.1 Read the instructions for use

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

1. Read the instructions for use of the product carefully and follow them completely.
2. Keep the instructions for use clearly visible next to the product.
3. Observe the instructions for use of products used in combination.

It is recommended to check the suitability of the products for the planned procedure prior to use.

1.2 Scope

This instruction manual is valid for:

Product	Item no.
IMAGE1 S™ H3-Z	TH100
IMAGE1 S™ H3-ZI	TH101
IMAGE1 S™ H3-P	TH103
IMAGE1 S™ H3-ZA	TH104
IMAGE1 S™ H3-M COVIEW®	TH106

1.3 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 warning messages describe 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.

ATTENTION

ATTENTION

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

2 Normal use

2.1 Intended use

In combination with the corresponding camera control unit, light source, monitor, and telescopes or microscopes, camera heads are used to display the endoscopic or open operating field in diagnostic or surgical procedures.

Camera heads do not have body contact.

2.2 Indications

In combination with appropriate accessories, camera heads can be used to display the endoscopic or open operating field in diagnostic or surgical procedures.

2.3 Contraindications

No contraindications relating directly to the medical device are currently known. The responsible physician must decide whether the anticipated application is admissible based on the general condition of the patient.

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 groups

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

3 Safety

3.1 Serious incidents

According to the Medical Device Regulation (MDR), a “serious incident” includes incidents that directly or indirectly had, could have had, or could have any of the following consequences (MDR, Art. 2, No. 65 [1]):

- 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 Unsterile product

The product is not sterile when delivered. The use of non-sterile products poses a risk of infection for patients, users, and third parties.

- ▶ Reprocess the product in line with the reprocessing instructions before initial use and every subsequent use.

3.3 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.

3.4 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.
- ▶ Set the light source output to a level that is just high enough to ensure optimal illumination of the operating area.
- ▶ Make sure the light output is sufficiently far away from tissue and operating accessories.

3.5 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



TH100 H3-Z

- | | | | |
|---|------------------------|---|---|
| 1 | Instrument coupler | 4 | Scroll down / Activate camera function
User control button: for scrolling
(downwards) through the menu or acti-
vating a camera function |
| 2 | Focus ring/Focus wheel | 5 | Scroll up / Select |
| 3 | Zoom ring | 6 | Call up menu / Select |



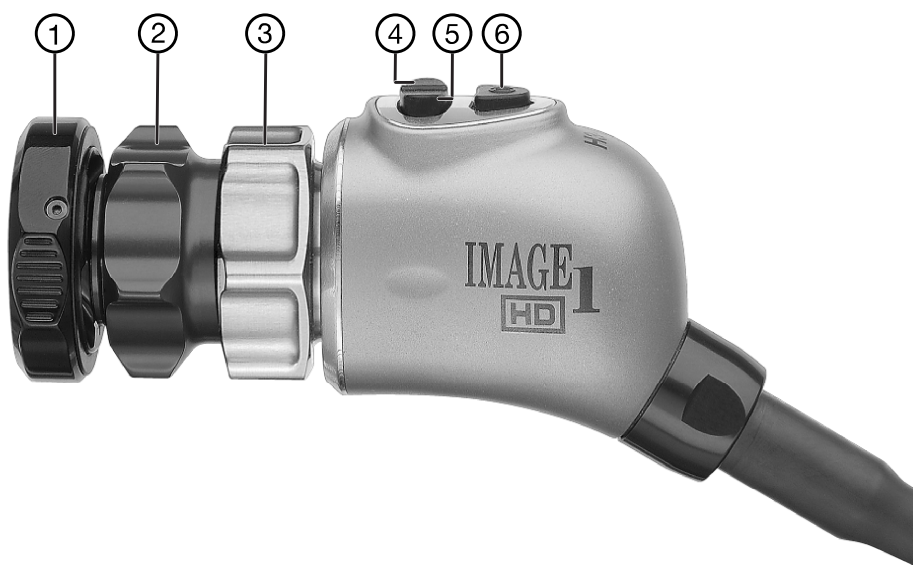
TH101 H3-ZI

- | | | | |
|---|------------------------|---|--|
| 1 | Instrument coupler | 4 | Scroll down / Activate camera function |
| 2 | Focus ring/Focus wheel | 5 | Scroll up / Select |
| 3 | Zoom ring | 6 | Call up menu / Select |



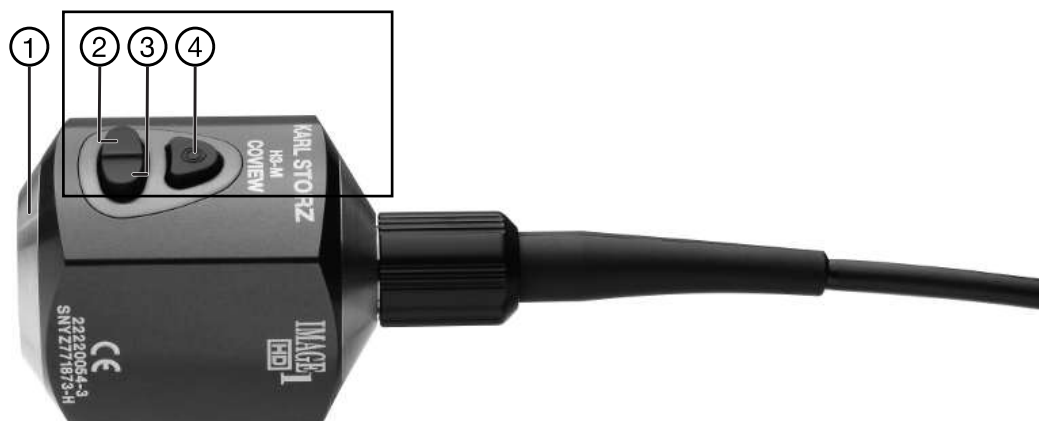
TH103 H3-P

- | | | | |
|---|--|---|-----------------------|
| 1 | Instrument coupler | 4 | Scroll up / Select |
| 2 | Focus ring/Focus wheel | 5 | Call up menu / Select |
| 3 | Scroll down / Activate camera function | | |



TH 104 H3-ZA

- | | | | |
|---|------------------------|---|--|
| 1 | Instrument coupler | 4 | Scroll down / Activate camera function |
| 2 | Focus ring/Focus wheel | 5 | Scroll up / Select |
| 3 | Zoom ring | 6 | Call up menu / Select |



TH106 H3-M COVIEW®

- | | | | |
|---|--|---|-----------------------|
| 1 | C-MOUNT connection | 3 | Scroll up / Select |
| 2 | Scroll down / Activate camera function | 4 | Call up menu / Select |

4.2 Possible combinations

The product can be combined with the following camera control units (CCU):

- IMAGE1 S CONNECT® (TC200)
- IMAGE1 S CONNECT® II (TC201)
- IMAGE1 HD (22 2020 20-1xx)
- IMAGE1 HUB™ HD (22 2010 20-1xx)

The camera control units (CCU) can be connected to the following LINK module:

- IMAGE1 S™ H3-LINK (TC300)

The products TH100, TH101, TH103, and TH104 can be connected to endoscopes or adaptors via the following connection:

- Eyepiece connection

The product TH106 can be connected to endoscopes or adaptors via the following connection:

- C-MOUNT connection

4.3 Technical data

Description	IMAGE1 S™ H3 camera head	Value
Image sensor		3x 1/3" CCD
Image format		16:9
Image refresh rate		50/60 Hz
Applied part type according to IEC 60601-1		CF
Focal length	TH 100 H3-Z	15–31 mm
	TH 101 H3-ZI	15.6 mm
	TH 103 H3-P	15–31 mm

Description	IMAGE1 S™ H3 camera head	Value
	TH 104 H3-ZA	15–32 mm
	TH 106 H3-M COVIEW®	Depending on the TV adaptor used
Dimensions (L x H x W)	TH 100 H3-Z	100 x 48 x 38 mm
	TH 101 H3-ZI	
	TH 103 H3-P	88 x 47 x 38 mm
	TH 104 H3-ZA	100 x 49 x 39 mm
	TH 106 H3-M COVIEW®	45 x 50 x 60 mm
Weight (without cable)	TH 100 H3-Z	270 g
	TH 101 H3-ZI	270 g
	TH 103 H3-P	227 g
	TH 104 H3-ZA	299 g
	TH 106 H3-M COVIEW®	240 g

4.4 Symbols employed

4.4.1 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 instructions for use

Symbol	Meaning
	Note for the user to consult the instructions for use for important cautionary information such as warnings and precautions.
	Unsterile
	Keep dry
	Fragile, handle with care
	Federal (USA) law restricts this device to sale by or on the order of a physician.
	CE conformity mark With this mark, the manufacturer declares the compliance of the products with the applicable regulation (EU) 2017/745. A code number after the CE mark indicates the responsible notified body.

4.4.2 Symbols on the product

Symbol	Meaning
	Applied part type CF defibrillation protection. When used in conjunction with a KARL STORZ camera control unit with a CF-defib symbol on the connection port.
	CE conformity mark With this mark, the manufacturer declares the compliance of the products with the applicable regulation (EU) 2017/745. A code number after the CE mark indicates the responsible notified body.
	Zoom in
	Zoom out

4.5 Ambient conditions

Storage/transport conditions	
Temperature	-10 °C ... 60 °C
Relative humidity	20–95%
Operating conditions	
Temperature	5 °C ... 35 °C
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 evidence of shipping 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 Testing the product

1. Inspect the product for visible contamination. Do not use if contaminated.
2. Inspect the product for the following characteristics:
 - Good working order
 - Functionality
 - Correct assembly of the components
 - Completeness

5.3 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. If the endoscope is connected to a pendulum camera head, make sure that the pendulum lock is engaged.
3. Tighten the outer ring on the grasping mechanism.
4. Rotate the outer ring of the instrument coupler counterclockwise to tighten it.

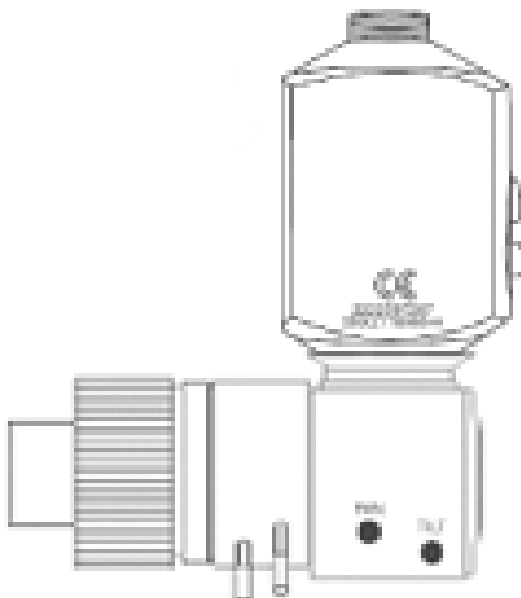
5.4 Connecting the light cable

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



5.5 Connecting the TH106 microscope camera head

A TV adaptor (e.g., KARL STORZ QUINTUS® TV adaptor) is used to connect the IMAGE1 S™ H3-M COVIEW® microscope camera head to a suitable interface on the surgical microscope. Suitable interfaces are optical beam splitters and co-observer connectors. These options are available for all surgical microscopes.

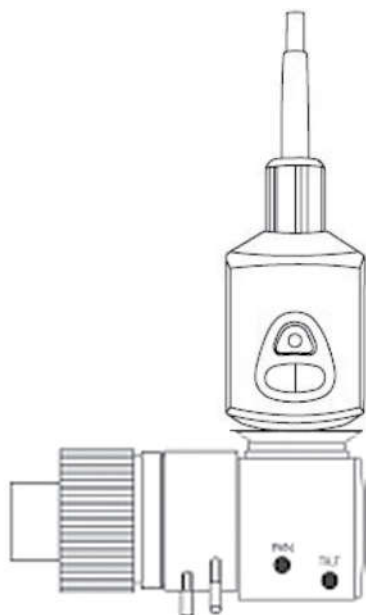


Some surgical microscopes are equipped with a C-MOUNT connection to which the IMAGE1 S™ H3-M COVIEW® camera head can be directly connected.

The IMAGE1 S™ H3-M COVIEW® camera head is delivered with a 9 m cable as standard.

KARL STORZ recommends detaching the camera head cable from the camera head in order to make installation easier.

1. To detach the camera cable, unscrew the cable connector from the camera head by turning in the counterclockwise direction and carefully pull out the cable.
2. Screw the camera head onto the C-MOUNT connection.
3. Secure the camera head and TV adaptor to the co-observer interface of the surgical microscope.



4. Align the tip of the cable plug with the recess provided and press the cable onto the camera head.
5. Tighten the cable connection by turning clockwise.

6 Application

6.1 Using the product

i 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/focus wheel to adjust the image sharpness on the camera lens.



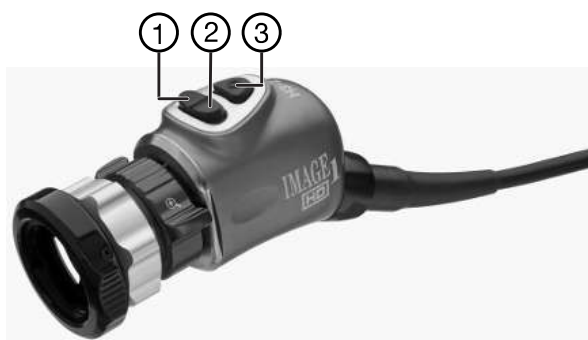
3. Turn the zoom ring to adjust the image size.



6.2 Camera head buttons

All camera heads feature three buttons for retrieving programmed functions and for menu control:

- Scroll down: Scrolls down the menus or options.
- Scroll up: Scrolls up the menus or options.
- Menu/selection: Display of live menu. Activation of highlighted option.



- 1 Scroll down
- 2 Scroll up

- 3 Menu/selection

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
Sterile covers for KARL STORZ cameras	040113-01, 040114-01, 040115-01, 040112-01
Extension cable, 5.2 m	22220072
Plastic container for sterilization and storage of IMAGE1 S™ H3-Z (TH100), IMAGE1 S™ H3-ZA (TH104), and IMAGE1 S™ H3-Z FI (TH102) camera heads, autoclavable	39301Z3TS
H3-M COVIEW® camera head cable, 9 m	22220071
Plastic container for sterilization and storage of IMAGE1 S™ H3-ZI (TH101) and IMAGE1 S™ H3-P (TH103) camera heads	39301PHTS

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).

- i** 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.

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	<u>Voltage dip:</u> Dip to 0% for 1 cycle at 0° phase angle Dip to 70% for 25/30 cycles at 0° phase angle Dropout to 0% for 0.5 cycles @ 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° phase angles	<u>Voltage dip:</u> Dip to 0% for 1 cycle at 0° phase angle Dip to 70% for 25/30 cycles at 0° phase angle Dropout to 0% for 0.5 cycles @ 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° phase angles	The power supply quality should be that of a typical commercial or hospital environment. If the user of the product requires continued operation in the event of interruptions to the power supply network, it is recommended that the product be oper-

Interference immunity tests	EN/IEC 60601 test level	Compliance level	Electromagnetic environment – guidelines
	<u>Voltage interruption:</u> 100% for 250/300 cycles	<u>Voltage interruption:</u> 100% for 250/300 cycles	ated 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 & 17	Pulse modulation 217 Hz	9	9
745					
780					
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE band 5	Pulse modulation 18 Hz	28	28
870					
930					

Test frequency MHz	Frequency band MHz	Radio service	Modulation	Immunity test level V/m	Compliance level V/m
1,720	1,700 – 1,990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE band 1, 3, 4, 25, UMTS	Pulse modulation 217 Hz	28	28
1,845					
1,970					
2,450	2,400 – 2,570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE band 7	Pulse modulation 217 Hz	28	28
5,240	5,100 – 5,800	WLAN 802.11 a/n	Pulse modulation 217 Hz	9	9
5,500					
5,785					

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 transmitter manufacturer and d is the recommended separation distance in meters [m].
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
			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 device is intended for use in such an environment as specified below. The customer or user of the device 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
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	public 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.

- ① The product was tested for compatibility with HF surgical devices in accordance with IEC 60601-2-2 Appendix BB.

10 Subsidiaries

KARL STORZ SE & Co. KG
Dr.-Karl-Storz-Straße 34, 78532 Tuttlingen/Germany
Postfach 230, 78503 Tuttlingen/Germany
Phone: +49 7461 708-0, Fax: +49 7461 708-105
Email: info@karlstorz.com

KARL STORZ Endoskope Berlin GmbH
Scharnhorststr. 3, 10115 Berlin/Germany
Phone: +49 30 3069090, Fax: +49 30 30 19452

KARL STORZ Endoscopy Canada Ltd.
7171 Millcreek Drive, Mississauga, Ontario L5N 3R3 Canada
Phone: +1 905 816-4500, Fax: +1 905 816-4599
Toll free (Canada only) Phone: 1-800-268-4880, Fax: 1-800-482-4198 (Canada only)
Email: info-canada@karlstorz.com

KARL STORZ Endoscopy-America, Inc.
2151 East Grand Avenue, El Segundo, CA 90245-5017, USA
Phone: +1 424 218-8100, Fax: +1 424 218-8525
Toll free (USA only) Phone: 800 421-0837, Fax: 800 321-1304 (USA only)
Email: communications@ksea.com

KARL STORZ Veterinary Endoscopy-America, Inc.
1 South Los Carneros Road, Goleta, CA 93117, USA
Phone: +1 805 968-7776, Fax: +1 805 685-2588
Email: info@karlstorzvet.com

KARL STORZ Endoscopia Latino-America, Inc.
815 N. W. 57th Avenue, Suite 480, Miami, FL 33126-2042, USA
Phone: +1 305 262-8980, Fax: +1 305 262-8986
Email: info@ksela.com

KARL STORZ Endoscopia México S.A. de C.V.
Edificio Atlantic, Oficina 3G, Calle D e/ 1ra y 3ra, 10400 Vedado, Havana, Cuba
Phone: +537 836 95 06, Fax: +537 836 97 76
Email: kstorzcuba@gmail.com

KARL STORZ Endoscopia México S.A. de C.V.
Av. Ejercito Nacional No. 453 Piso 2, Colonia Granada, Alcaldia Miguel Hidalgo, C.P. 11520 Ciudad de México
Phone: +52 (55) 1101 1520
Email: mx-info@karlstorz.com

KARL STORZ Marketing América Do Sul Ltda.
Rua Joaquim Floriano, nº. 413, 20º andar – Itaim Bibi, CEP-04534-011 São Paulo, Brasil
Phone: +55 11 3526-4600, Fax: +55 11 3526-4680
Email: br-info@karlstorz.com

KARL STORZ Endoscopia Argentina S.A.
Zufriategui 627 6° Piso, B1638 CAA - Vicente Lopez, Provincia de Buenos Aires, Argentina
Phone: +54 11 4718 0919, Fax: +54 11 4718 2773
Email: info@karlstorz.com.ar

KARL STORZ Endoskopi Norge AS
Stamveien1, 1483 Hagan, Norway
Phone: +47 6380 5600, Fax: +47 6380 5601
Email: post@karlstorz.no

KARL STORZ Endoskop Sverige AB
Storsätragränd 14, 127 39 Skärholmen, Sweden
Phone: +46 8 505 648 00
Email: kundservice@karlstorz.se

KARL STORZ Endoscopy Suomi OY
Taivaltie 5, 01610 Vantaa, Finland
Phone: +358 (0)96824774, Fax: +358 (0)968247755
Email: asiakaspalvelu@karlstorz.fi

KARL STORZ SE & Co. KG
Representation Office
Kęstućio st. 59 / Lenktoji st. 27, 08124 Vilnius, Lithuania
Phone: +370 5 272 0448, Mobile: +370 685 67 000
Email: info-lt-lv@karlstorz.com

KARL STORZ Endoskopi Danmark A/S
Skovlytoften 33, 2840 Holte, Denmark
Phone: +45 45162600, Fax: +45 45162609
Email: marketing@karlstorz.dk

KARL STORZ Endoscopy (UK) Ltd.
415 Perth Avenue, Slough, Berkshire, SL1 4TQ, United Kingdom
Phone: +44 1753 503500, Fax: +44 1753 578124
Email: info-uk@karlstorz.com

KARL STORZ Endoscopie Nederland B. V.
Displayweg 2, 3821 BT Amersfoort, Netherlands
Phone: +31 (0)33 4545890
Email: info-nl@karlstorz.com

KARL STORZ Endoscopy Belgium N. V.
Phone: +31 (0)33 4545890
Email: info-be@karlstorz.com

KARL STORZ Endoscopie France S. A. S.
12, rue Georges Guynemer, Quartier de l'Europe, 78280 Guyancourt, France
Phone: +33 1 30484200, Fax: +33 1 30484201
Email: marketing-fr@karlstorz.com

KARL STORZ Endoskop Austria GmbH
Landstraßer Hauptstr. 148/1/G1, 1030 Wien, Austria
Phone: +43 1 71 56 0470, Fax: +43 1 71 56 0479
Email: storz-austria@karlstorz.com

KARL STORZ Endoscopia Ibérica S. A.
Parque Empresarial San Fernando, Edificio Munich – Planta Baja, 28830 Madrid, Spain
Phone: +34 91 6771051, Fax: +34 91 6772981
Email: info-es@karlstorz.com

KARL STORZ Endoscopia Italia S. r. l.
Via dell'Artigianato, 3, 37135 Verona, Italy
Phone: +39 045 8222000, Fax: +39 045 8222001
Email: info-ita@karlstorz.com

KARL STORZ Croatia d.o.o.
Capraška 6, 10000 Zagreb, Croatia
Phone: +385 1 6406 070, Fax: +385 1 6406 077
Email: info@karlstorz.hr

KARL STORZ Endoskopija d.o.o.
Cesta v Gorice 34b, 1000 Ljubljana, Slovenia
Phone: +386 1 620 5880, Fax: +386 1 620 5882
Email: pisarna@karlstorz.si

KARL STORZ Polska Sp. z o.o.
ul. Bojkowska 47, 44-100 Gliwice, Poland
Phone: +48 32 706 13 00, Fax: +48 32 706 13 07
Email: info-pl@karlstorz.com

KARL STORZ Endoszkóp Magyarország Kft.
Toberek utca 2. fsz. 17/b, HU-1112 Budapest, Hungary
Phone: +36 195 096 31, Fax: +36 195 096 31
Email: info-hu@karlstorz.com

KARL STORZ Endoscopia Romania srl
Str. Prof. Dr. Anton Colorian, nr. 74, Sector 4, 041393 Bukarest, Romania
Phone: +40 (0)31 4250800, Fax: +40 (0)31 4250801
Email: info-ro@karlstorz.com

KARL STORZ Endoskope Greece M.E.P.E.*
Patriarhou Grigoriou E' 34, 54248 Thessaloniki, Greece
Phone: +30 2310 304868, Fax: +30 2310 304862
Email: info-gr@karlstorz.com
*Repair & Service Subsidiary

KARL STORZ Industrial**

Gedik Is Merkezi B Blok, Kat 5, D 38-39, Bagdat Cad. No: 162, Maltepe
Istanbul, Turkey

Phone: +90 216 442 9500, Fax: +90 216 442 9030

**Sales for Industrial Endoscopy

000 KARL STORZ Endoscopy – WOSTOK

Derbenyevskaya nab. 7, building 4, 115114 Moscow, Russia

Phone: +7 495 983 02 40, Fax: +7 495 983 02 41

Email: info-ru@karlstorz.com

TOV LLC KARL STORZ Ukraine

Avenue Geroyiv Stalingrada Str. 2D, office 717 Kyiv, 04210/Ukraine

Phone: +38 095 000-895-0, +38-097-000-895-0, +38 073 000-895-0

Email: marketing@karlstorz.com.ua

KARL STORZ SE & Co. KG Representation Office

Sabit Orudschow 1184, apt. 23, 1025 Baku, Azerbaijan

Phone: +99 450 613 30 60

Email: info-az@karlstorz.com

KARL STORZ ENDOSKOPE – East Mediterranean and Gulf (Offshore) S.A.L.

Spark Tower 1st floor Charles Helou St., Horch Tabet – Sin El Fil, Beirut,
Lebanon

Phone: +961 1 501105, Fax: +961 1 501950

Email: info@karlstorz-emg.com

KARL STORZ Endoscopy (South Africa) (Pty) Ltd.

P.O. 6061, Roggebaai, 8012 Cape Town, South Africa

Phone: +27 21 417 2600, Fax: +27 21 421 5103

Email: info@karlstorz.co.za

T00 KARL STORZ Endoscopy Kasachstan

Saryarka, 6, BC "Arman", off. 910, 010000 Astana, Republic of Kazakhstan

Phone: +7 7172 552-549, 552-788, Fax: -444

Email: info@karlstorz.kz

KARL STORZ ENDOSKOPE East Mediterranean & Gulf (branch)

Building West Side 7A – Unit 7WA – 3008, Dubai Airport Free Zone, P.O. Box

54983, Dubai - United Arab Emirates

Phone: +971 (0)4 2958887, Fax: +971 (0)4 3205282

Service Hotline: +971 (0)4 3415882

Email: info-gne@karlstorz-emg.com

KARL STORZ Endoscopy India Private Limited

11th Floor, Dr. Gopal Das Bhawan, 28, Barakhamba Road, New Delhi

110001, India

Phone: +91 11 4374 3000, Fax: +91 11 4374 3010

Email: corporate@karlstorz.in

KARL STORZ SE & CO. KG

Interchange 21 Tower, Level 33, 399 Sukhumvit Road, North Klongtoey,

Wattana, 10110 Bangkok, Thailand

Phone: +84 28 3823 8000 Fax: +84 28 3823 8039

Email: infovietnam@karlstorz.com

KARL STORZ SE & Co. KG

Resident Representative Office

14th Floor, MPlaza Saigon, 39 Le Duan, District 1, Ho Chi Minh City, Vietnam

Phone: +84 28 3823 8000, Fax: +84 28 3823 8039

Email: infovietnam@karlstorz.com

KARL STORZ Endoscopy China Ltd.

Room 2503-05, 25F AXA Tower, Landmark East, No. 100 How Ming Street,

Kwun Tong, Kowloon, Hong Kong, People's Republic of China

Phone: +852 28 65 2411, Fax: +852 28 65 4114

Email: inquiry@karlstorz.com.hk

KARL STORZ Endoscopy (Shanghai) Ltd., Beijing Branch

Room 1805-1807, Building B, 18F Beijing IFC, No. 8, Jianguomenwai Street,

Chaoyang District, 100022, Beijing, People's Republic of China

Phone: +86 10 5638188, Fax: +86 10 5638199

Email: info@karlstorz.com.cn

KARL STORZ Endoscopy (Shanghai) Ltd., Shanghai Branch

Room 701A Building 5 & Room 501 Building 7, No. 3000 Longdong Avenue,

Pilot Free Trade Zone, 201203, Shanghai, People's Republic of China

Phone: +86 21 60339888, Fax: +86 21 60339808

Email: info@karlstorz.com.cn

KARL STORZ Endoscopy (Shanghai) Ltd., Chengdu Branch

Room 803-805, 8F Jin Jiang International Building, No. 1 West Linjiang

Road, Wuhou District, 6100414, Chengdu, People's Republic of China

Phone: +86 28 86587977, Fax: +86 28 86587975

Email: info@karlstorz.com.cn

KARL STORZ Endoscopy (Shanghai) Ltd., Shenyang Branch

Room 2001-2005, 20F N-MEDIA International Center, No. 167 Youth Avenue,

Shenhe District, 110014, Shenyang, People's Republic of China

Phone: +86 24 23181118, Fax: +86 24 23181119

Email: info@karlstorz.com.cn

KARL STORZ Endoscopy (Shanghai) Ltd., Guangzhou Branch

Room 02B & 03 & 04A, 35F Teem Tower, No. 208 Tianhe Road, Tianhe

District, 510620, Guangzhou, People's Republic of China

Phone: +86 20 87321281, Fax: +86 20 87321286

Email: info@karlstorz.com.cn

KARL STORZ Endoscopy Asia Marketing Pte Ltd.

No. 8 Commonwealth Lane #03-02, Singapore 149555, Singapore

Phone: +65 69229150, Fax: +65 69229155

Email: infoasia@karlstorz.com

KARL STORZ Endoscopy Singapore Sales Pte Ltd

No. 8 Commonwealth Lane #03-02, Singapore 149555, Singapore

Phone: +65 69229150, Fax: +65 69229155

Email: infoasia@karlstorz.com

KARL STORZ SE & Co. KG Representative Office Indonesia

Sinarmas MSG Tower Level 37, Jl. Jend. Surdirman No. Kav. 21, Jakarta

Selatan

DKI Jakarta 12920

Email: infoindonesia@karlstorz.com

KARL STORZ Endoscopy Korea Co. Ltd.

9F Hyowon-Building, 97, Jungdae-ro, Songpa-gu, 05719 Seoul, Korea

Phone: +82-70-4350-7474, Fax: +82-70-8277-3299

Email: infokorea@karlstorz.com

KARL STORZ Endoscopy Taiwan Ltd.

12F, No. 192, Sec. 2, Chung Hsin Rd., Sindian District, New Taipei City,

Taiwan

Phone: +886 933 014 160, Fax: +886 2 8672 6399

Email: info-tw@karlstorz.com

KARL STORZ SE & Co. KG Representative Office Philippines

1901 Picadilly Star Bldg., 4th Avenue, BGC, Taguig City 1636, Philippines

Phone: +63 2 317 45 00, Fax: +63 2 317 45 11

Email: philippines@karlstorz.com

KARL STORZ Endoscopy Japan K. K.

Stage Bldg. 8F, 2-7-2 Fujimi, Chiyoda-ku, Tokyo 102-0071, Japan

Phone: +81 3 6380-8622, Fax: +81 3 6380-8633

Email: info@karlstorz.co.jp

KARL STORZ Endoscopy Australia Pty. Ltd .

68 Waterloo Road, Macquarie Park NSW 2113, P O Box 50 Lane Cove NSW

1595, Australia

Phone: +61 (0)2 9490 6700, Fax: +61 (0)2 9420 0695

Toll free: 1800 996 562 (Australia only)

Email: info@karlstorz.au

www.karlstorz.com



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KARL STORZ SE & Co. KG

Dr.-Karl-Storz-Straße 34
78532 Tuttlingen

Postfach 230
78503 Tuttlingen
Germany

Phone: +49 7461 708-0
Fax: +49 7461 708-105
E-mail: info@karlstorz.com
www.karlstorz.com

