KARL STORZ — ENDOSKOPE

en **Instructions for use**
C-MAC® Video Laryngoscopes Series 8403

04-2021

CE

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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.
- ▶ Keep the instructions for use clearly visible next to the product.

1.2 Read the instructions for use of combinable products

If the instructions for use of combinable 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 combinable products carefully and follow all the safety notes and warnings.

1.3 Scope

These instructions for use are valid for the following products:

Product	Item number
C-MAC® Video Laryngoscope	8403AX
	8403AXC
	8403BX
	8403BXC
	8403HX
	8403DXC
	8403EXC
	8403GXC
	8403KXC
	8403MXC
	8403HXP
	8403NXC
Video connecting cable	8403X

1.4 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.

NOTICE
ATTENTION

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

2 Normal use

2.1 Intended use

Video laryngoscopes (CMOS) are used for visualizing the respiratory tracts and vocal cords during endotracheal intubation and for the inspection and examination of the upper respiratory tract. Video laryngoscopes (CMOS) are designed for transient use in invasive procedures through a body orifice.

C-MAC® Monitor accessories are used for transmitting energy. C-MAC® Monitor accessories are used in conjunction with the C-MAC® System for visualizing the respiratory tracts and vocal cords during endotracheal intubation and for inspecting and examining the upper respiratory tract. C-MAC® Monitor accessories are non-invasive and are designed for transient use in invasive procedures through a body orifice.

2.2 Indications for use

The use of laryngoscopes and video laryngoscopes is indicated if, in the opinion of the responsible physician, inspection of the upper respiratory tract or endotracheal intubation is indicated.

2.3 Contraindications

The use of laryngoscopes and video laryngoscopes is contraindicated if, in the opinion of the responsible physician, use is contraindicated or the patient is not able to undergo surgery or anesthesia due to his or her general condition. Laryngoscopes and video laryngoscopes must not be used for procedures in direct contact with the central nervous system (CNS) and central cardiovascular system.

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 Correct handling

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 points before and after every use:

- Completeness
- Good working order
- Rough surfaces left inadvertently
- Sharp corners
- Burred edges
- Correct assembly of the components
- Functionality

▶ Do not leave broken-off components inside the patient.

▶ Do not overload the product with mechanical stress.

▶ Do not bend bent products back to their original position.

3.3 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.

3.4 Damaged products

Damaged products can result in injury to patients, users, or third parties.

▶ Before each use, check all components of the product for damage.

▶ Do not use damaged products.

3.5 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 (see IEC 60601-1-1 or clause 16 of the 3rd edition of IEC 60601-1).

- Only combine the product with devices and components that are approved for joint use by the manufacturer.
- Comply with national and local regulations.
- Observe the instruction manuals and interface specifications of the devices and components used in combination.
- Only use devices and components that have standardized interfaces and do not breach the intended use of the product.
- Only make changes to the product if these changes are approved by KARL STORZ.

3.6 Electromagnetic interference

Medical electrical products are subject to special precautions regarding electromagnetic compatibility and must be installed and commissioned according to the tables on electromagnetic compatibility. If other products (e.g. for MRT, CT, diathermy, electrocautery, or RFID) emit electromagnetic radiation, the function of the product may be impaired. High-frequency communication equipment can affect electrical medical products and impair their performance.

- Do not use the product in the vicinity of a magnetic resonance tomograph (MRT).
- Do not use the product next to or together with other devices. If such use is required, monitor the product and the other devices, and follow the relevant instructions for use in the event of malfunctions.
- Portable RF communications equipment including peripheral devices (e.g., antenna cables and external antennas) should be used no closer than 30 cm from the product, including cables specified by the manufacturer.
- Observe the information on electromagnetic compatibility; see chapter Electromagnetic compatibility [p. 26].
- In case of uncertainties, seek expert advice from KARL STORZ.
- Before use, a clinical/biomedical engineer or an EMC specialist should carry out an ad-hoc test of the electromagnetic radiation.

The use of accessories and cables other than those specified in the instruction manual may result in increased emissions or decreased immunity of the product. When using other accessories and cables, the operator is responsible for checking compliance with IEC 60601-1-2 for this particular product.

- To prevent increased electromagnetic emissions or reduced electromagnetic immunity of the product, only use accessories, transducers, and cables recommended or supplied by the manufacturer.

3.7 Patient leakage current

Patient leakage currents from products may add up if powered endoscopes and powered endotherapy devices are used simultaneously.

Excessively high leakage current levels may result in the patient becoming injured.

- ▶ Only use products of the same type together; e.g., CF.

3.8 National guidelines on airway management

Failure to observe the national guidelines on airway management may put the patient at risk.

- ▶ National guidelines on airway management must be observed in addition to the documentation accompanying the product.

3.9 Hot components

The high level of light intensity may cause the distal end, the light connections for the endoscope and fiber optic light cable, and adjacent components to heat up. This can cause burns to patients, users, or third parties.

The high level of light intensity may cause the distal end of the endoscope to heat up. This can cause burns to patients, users, or third parties.

- ▶ Set the light source output to a level that is just high enough to ensure optimal illumination of the operating area.
- ▶ Avoid contact with the distal end and light connections of the endoscope and fiber optic light cable.
- ▶ Avoid contact with the distal end of the endoscope.

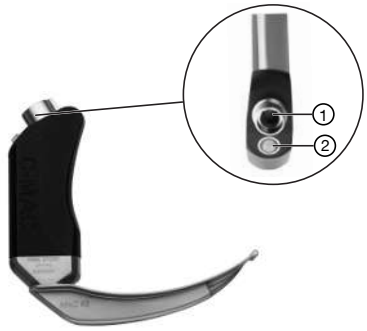
3.10 High light intensity

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.

4 Product description

4.1 Product overview



Video laryngoscope (8403AXC/BXC/DXC/GXC/KXC/MXC/HXP) without guidance for suction catheter

1 Socket for video connecting cable 2 Multifunction button

Video laryngoscope (8403EXC) without guidance for suction catheter

Video laryngoscope (8403AX/BX/HX) with guidance for suction catheter

Video connecting cable (8403X)

1 Laryngoscope connection socket 2 Monitor connection socket

4.2 Possible combinations

The C-MAC® Video Laryngoscopes from series 8403 can be operated with the following monitors:

- C-MAC® Monitor 8403ZX (software version: 704v300 or higher)
- C-MAC® Monitor 8404ZX
- C-MAC® Pocket Monitor 8403XD
- With other monitors via the camera control unit C-HUB® II (20290320) (software version: 721v105 or higher)

The C-MAC® Video Laryngoscopes from series 8403 can be combined with the following catheters:

- Blade 8403AX with 14 Fr. and 16 Fr. catheters
- Blade 8403HX and 8403BX with 16 Fr. and 18 Fr. catheters

4.3 Technical specifications

Video laryngoscope 8403AX/BX/HX/AXC/BXC/KXC/HXP

Designation	Value
Immersion protection	IPX8
Camera technology	CMOS
Resolution	640 x 480
Illumination:	LED, white, 1 W

Video laryngoscope 8403AX/BX/HX/AXC/BXC/KXC/HXP serial number 80.000 and higher

Designation	Value
Immersion protection	IPX8
Camera technology	CMOS
Resolution	300 x 400
Illumination	LED, white, 1 W

Video laryngoscope 8403DXC/EXC/GXC/MXC/NXC

Designation	Value
Immersion protection	IPX8
Camera technology	CMOS
Resolution	300 x 400
Illumination	LED, white, 1 W

4.4 Symbols employed

4.4.1 Symbols on the packaging

Symbol	Meaning
	Number of products in the product packaging
	Article no.
	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.
	Consult instructions for use
	Manufacturer
	Serial number
	Keep dry
	Keep away from sunlight
	Temperature limit
	Date of manufacture
	In accordance with US federal law (21 CFR 801.109), this product may only be sold to or on prescription from a licensed physician.
	Not MR safe

4.4.2 Symbols on the product

Symbol	Meaning
	Follow instructions for use
	Type BF device
	Serial number
	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.

4.5 Ambient conditions

Storage/transport conditions	
Temperature	-20°C ...+50°C
Relative humidity (non-condensing)	5–95%

Operating conditions	
Temperature	0°C ...40°C
Relative humidity (non-condensing)	30–70%
Air pressure	700–1,080 hPa

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

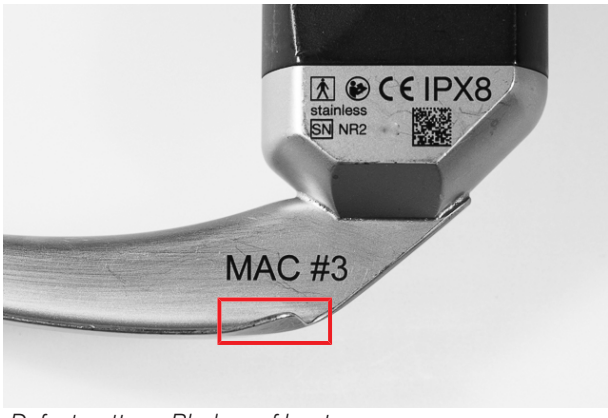
5.2.1 Visual inspection

Missing components, surface changes, or other damage limit the life span of the product and may mean that the product can no longer be used for its intended use.

1. The product must be inspected for completeness, damage, and integrity before and after every use. Inspection tools such as magnifying glasses should be used as necessary.
2. Check for the following types of mechanical damage and changes:

– Sharp corners
– Burred edges
– Rough surfaces
– Protruding or bent parts

Defect pattern: Blade tip bent



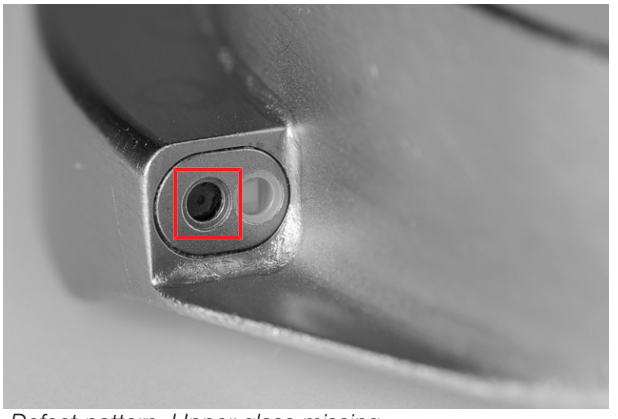
Defect pattern: Blade roof bent

3. Check the product for rust and corrosion.

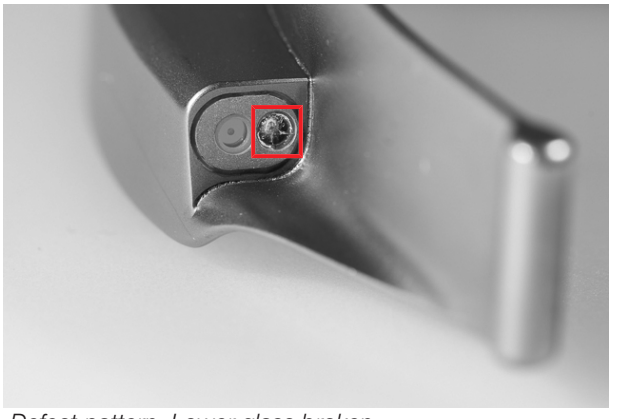
4. Check whether the coating is damaged.

Defect pattern: Poor general condition

5. Ensure that the components and connections are complete, intact, and positioned correctly.
6. Check whether there are residues and/or moisture at the interfaces.
7. Check the mobility of the components. Instruments that can be dismantled should be assembled for this purpose.
8. Use a magnifying glass to check that the telescope is complete, intact, and securely positioned.



Defect pattern: Upper glass missing



Defect pattern: Lower glass broken

5.2.2 Functional test

- ▶ Inspect the product for the following characteristics:
  - – Fully functional control keys
  - – Securely positioned connecting cable
  - – Functional image transmission
  - – Sufficient image quality
  - – Light transmission

5.3 Connecting the C-MAC® Monitor

1. Insert the video connecting cable into the socket of the video laryngoscope. Pay attention to the orientation pin on the plug and socket.

2. Make sure that the cable is fully inserted.

3. Connect the other end of the video connecting cable to the socket on the C-MAC® Monitor.

4. Alternatively, connect the other end of the video connecting cable to the socket on the rear side.

Another laryngoscope can be connected during use.

5.4 Connecting the C-MAC® Pocket Monitor

The Pocket Monitor can be connected to the product while folded up or down.

1. Connect the C-MAC® Pocket Monitor to the socket of the video laryngoscope. Pay attention to the orientation pin on the plug and socket.

2. Make sure that the lugs of the plug connection are opposite each other and the plug is fully inserted.
   ⇨ As soon as the photo/video recording function is ready, the multifunction button lights up blue.

⇨ The video laryngoscope is ready for operation.

ⓘ The monitor can be removed and connected to another laryngoscope during use.

5.5 Connecting C-Hub® II

1. Connect the video connecting cable to the socket on the product. Pay attention to the orientation pin on the plug and socket.

2. Make sure that the cable is fully inserted.

3. Connect the power supply unit to the C-HUB® II.
4. Connect the video connecting cable to the video input on the front of the C-HUB® II.
5. Connect the monitor to the S-Video output or HDMI output on the rear of the C-HUB® II.

6 Application

6.1 Using the product

⚠ WARNING

Wrong viewing mode! Risk of injury!

If the viewing mode settings are changed, this can alter the image display and image position.

- ▶ Before each use, check whether a live image or a saved image is being displayed and whether a correct image position has been selected.

Documentation can be carried out on the C-MAC® Monitor (8403ZX, 8404ZX) and C-MAC® Pocket Monitor (8403XD) using the multifunction button on the video laryngoscope.

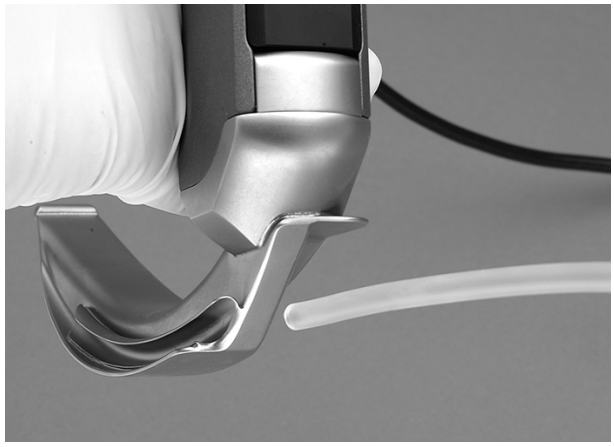
1. Switch on the product in good time so that the optical system can warm up.
2. Switch on the monitor.
   ⇨ As soon as the photo/video recording function is ready, the blue multifunction button lights up.

3. Press the multifunction button briefly to save images individually.

   ⇨ The multifunction button lights up green during the saving process.
4. Press the multifunction button for around 2 seconds to start video recording.
   ⇨ During the video recording, the multifunction button lights up in pulsating green.
5. Press the multifunction button briefly to stop video recording.

6.2 Inserting an oxygen or suction catheter

- ▶ Insert the catheter or the probe into the guide.



7 Disassembly

7.1 Disassembling the product

- Disconnect the C-MAC® Pocket Monitor or the connecting cable from the video laryngoscope.

8 Maintenance, servicing, repairs, and disposal

8.1 Repairs to the product

Repair work may only be performed by KARL STORZ or by a company authorized by KARL STORZ. The interventions described in this instruction manual are exempt from this rule.

- ▶ 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.

8.2 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.

9 Accessories and spare parts

9.1 Accessories

Item	Order no.
Forceps acc. to MAGILL, modified acc. to BOEDEKER, 25 cm	809125
Forceps acc. to MAGILL, for children, modified acc. to BOEDEKER, 20 cm	809120
Bag for intubation set C22, ULM model	8403YE
Protection cap for C-MAC® System Interface	8403YZ
C-MAC® Pocket Monitor connecting cable	8403XDP
C-MAC® Connecting Cable	8403X

10 Electromagnetic compatibility

10.1 Electromagnetic compatibility

The described product has been tested as a system with the following devices. Relevant electromagnetic compatibility (EMC) information can be found in the "Electromagnetic compatibility (EMC)" section of the instructions for use for the devices.

Device	Item number
C-MAC® Monitor	8403ZX
C-MAC® Monitor	8404ZX
C-MAC® Pocket Monitor	8403XD
C-HUB® II	20290320

The EMC warning statements, precautions, notes, and emission/immunity limits specified in the instructions for use for the devices also apply to the product described in these instructions for use.

11 Fault correction

11.1 Product malfunctions

Error description	Possible causes	Actions
Product failed	Power supply failure	▶ Check power supply
	Power plug and socket improperly connected	▶ Push the power plug firmly into the socket on the product
	System error	▶ Perform reset
No picture, TFT screen dark	Connecting cable not connected correctly	▶ Push the cable firmly into the socket on the product
	Defective camera electronics	▶ Send product to KARL STORZ for repair
	TFT screen defective	
Blurry picture, striping, streaking	Telescope is dirty	▶ Clean with cotton swab and alcohol solution or special cleaning paste
	Connecting cable contacts are dirty	▶ Clean the cable contacts
Color distortion	White balance not carried out correctly	▶ Repeat white balance adjustment
Color rendering alternates	Connecting cable broken	▶ Replace connecting cable
Image cannot be stored	No memory card inserted	▶ Insert memory card
	Memory card full	▶ Clean camera plug contacts
	Memory card is not recognized	▶ Insert the memory card while the monitor is switched off and then turn the monitor on again ▶ Perform reset ▶ Format the memory card on the PC with FAT
Video stream cannot be played back	No MPEG-4 Codec installed	▶ Install an MPEG-4 Codec
SD memory card cannot be written on	SD memory card is formatted incorrectly	▶ Format the SD memory card on the PC with FAT

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