Instruction For Use
C-MAC® video laryngoscope 8401xxx, Electronic Module 8401/8402 X, C-MAC® PM 8401 XD
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</table>
1 General information

1.1 Reading the instructions for use

It is recommended that the suitability of the products for the planned procedure be checked prior to use.

These instructions for use are intended to serve as an aid in the proper handling, cleaning and, if need be, sterilization of the C-MAC® Videolaryngoskop and the monitor 8403 ZX. All of the necessary details and actions are clearly explained. We thus ask that you read these instructions carefully before proceeding to work with the instrument. Keep these instructions available for ready reference.

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

1. Read the instructions for use carefully and follow them completely.
2. Keep the instructions for use clearly visible next to the product.

Note the instructions for use of the C-MAC® monitor (Art. No. 96076008D)!

1.2 Scope

These instructions for use are valid for the following models: C-MAC® video laryngoscope 8401 AX/BX/HX/AXC/BXC/DXC/GXC/KXC/HXP in connection with Electronic Module 8401 X/8402 X and Monitor 8401 ZX/8402 ZX/8403 ZX or C-MAC PM 8401 XD.
2 Intended use

2.1 Intended use
The C-MAC® video laryngoscope 8401 AX/BX/HX/AXC/BXC/DXC/GXC/KXC/HXP is used in conjunction with the Electronic Module 8401 X/8402 X and the monitor 8401 ZX/8402 ZX/8403 ZX or the C-MAC® PM for endotracheal intubation and the inspection of the oropharynx. The Monitor 8403 ZX has separate instructions for use (96076008D).

2.2 Contraindications
No contraindications relating directly to the product are currently known. The use of the C-MAC® video laryngoscope is contraindicated if, in the opinion of a responsible physician, the health of the patient is endangered by its use, for example, due to the patient's general condition, or if laryngoscopy as such is contraindicated.

2.3 Target user populations
The C-MAC® Videolaryngoskop may only be used by persons with an appropriate medical qualification and who are acquainted with the laryngoscopy technique. The information in these instructions for use is intended only to instruct in the correct handling, cleaning and sterilization of the C-MAC® Videolaryngoskop, and is not suitable as an introduction to laryngoscopy technique. The use of the C-MAC® video laryngoscopes must be used in accordance with the airway algorithm in the respective country of application or the official specifications for airway management.

2.4 User qualifications
Only physicians and medical support staff with a relevant specialist qualification and who have received training on the product may use the product. Only persons with appropriate specialist training may provide training. The user profile includes the following features:
- Recognized medical qualification of the user (specialist physician, qualified medical staff)
- Adequate powers of comprehension to rationally assess the current surgical situation
- Adequate language skills in the languages used in the instructions for use
- Be thoroughly trained in the operation and use of the medical device
- Knowledge of the contents of the instructions for use
- No physical impairments that could diminish perception of activation and alarm signals (visual and acoustic)

2.5 Safety precautions when using the C-MAC® video laryngoscope
The C-MAC® video laryngoscope must be used according to the medical rules and procedures recognized for laryngoscopy.

- The C-MAC® video laryngoscope has been successfully tested on helicopters BK 117 B2, EC 135 and EC 145 for electromagnetic compatibility according to DRF EMI Test REPORT (Rev. C).

- The C-MAC® video laryngoscope as well as the C-MAC® Monitor 8402 ZX have been successfully tested on the RTCA/DO-160F (Section 21).

- The C-MAC® video laryngoscope as well as the C-MAC® Monitor 8402 ZX have been successfully subjected to a fall and crash test.
The C-MAC® video laryngoscope as well as the C-MAC® Monitor 8402 ZX have been successfully tested on the MIL-STD-461F, RE102 (Fixed Wing).

The C-MAC® video laryngoscope as well as the C-MAC® Monitor 8402 ZX have been successfully tested by the German Army’s Technical and Airworthiness Centre for Aircraft (Wehrtechnische Dienststelle für Luftfahrzeuge (WTD 61)) on the aircraft types Sea Lynx Mk. 88A and Sea King Mk. 41 for SAR (Search and Rescue) missions.

2.6 Safety precautions when using the C-MAC® PM

The C-MAC® PM with C-MAC video laryngoscope blade must be used according to the medical rules and procedures recognized for laryngoscopic methods.

The C-MAC® PM has been successfully tested on the RTCA/DO-160F (Section 21).

Note: The C-MAC® PM has been successfully tested on the MIL-STD-461F, RE102 (Fixed Wing).

2.7 Training in the operation and function of the device

Your local representative or responsible KARL STORZ member of staff is available to provide training and information on further training alternatives.

2.8 Target patient populations

<table>
<thead>
<tr>
<th>Gender</th>
<th>No restriction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>No restriction</td>
</tr>
<tr>
<td>Weight</td>
<td>No restriction</td>
</tr>
<tr>
<td>Medical condition</td>
<td>Suitable for the treatment, taking into account the indications and contraindications, according to the opinion of the physician</td>
</tr>
</tbody>
</table>
3 Safety

3.1 Serious incidents
A "serious incident" includes, according to MDD incidents, those which, directly or indirectly, had, could have had or could have any of the following consequences (MDD, 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 should be notified of all serious incidents.

3.2 Description of warnings
To prevent any injury to persons or damage to property, the warning messages and safety instructions in the instructions for use must be observed. The warnings describe the following levels of danger.

**WARNING**

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

**CAUTION**

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

**ATTENTION**

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

3.3 Unsterile instruments
These products are not sterile when delivered. The use of unsterile products poses a risk of infection for patients, users, and third parties.
- Reprocess products before first use.
- Inspect products for visible contamination before use. Do not use contaminated products.

3.4 Correct reprocessing
Incorrectly reprocessed products expose patients, users, and third parties to a risk of infection.
- The instructions for use "Cleaning, Disinfection, Care, and Sterilization of KARL STORZ Instruments" (item no. 96216003) must be downloaded from http://www.karlstorz.com and followed.

3.5 Risks due to damaged parts
- Check the following points before and after every use of the product:
  1. Completeness
  2. Good working order
  3. Correct assembly of the components
4. Functionality

- Inspect products for visible contamination before use. Do not use contaminated products.
- Reprocess the products before use.
- Do not leave missing or broken-off components inside the patient.

3.6 Combination with other devices and accessories

Combinations of medical devices are only assured to be safe if
- they are identified as such in the respective instructions for use or
- the intended use and interface specifications of the devices used in combination permit this.

The use of unauthorized devices and accessories 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 (e.g., IEC 60950 for data processing equipment). 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).

Anybody connecting additional equipment to medical electrical equipment is a system configurator and is therefore responsible for the system’s compliance with the standard requirements for systems. Please note that local laws take priority over the above-mentioned standard requirements. Should you have any queries, please contact your local specialist dealer or the Technical Service (Standard/directive references: IEC 60601-1+A1+A2:1995: 6.8.2.c, 19.2.b, 19.2.c, IEC 60601-1:2005: 7.9.2.5, 8.1, 16.2.d, MDD 93/42/EEC: Annex I clause 13.6.c).

3.7 Damage to the instrument

- The C-MAC® video laryngoscopes may not be cleaned in an ultrasound bath.
- The C-MAC® video laryngoscopes may not be sterilized with steam.

3.8 Damaged products

⚠️ WARNING
Risk of injury from damaged products

Before each use the outer surfaces of the parts of the laryngoscope and all the laryngoscopic accessories which are to be inserted into the patient must be checked in order to ensure that there are no unintentional rough surfaces, sharp corners or projecting parts which could present a hazard to the patient.

3.9 Allergic reactions

C-MAC® laryngoscope blades contain a nickel compound and may cause nickel allergy in predisposed individuals.
4 Product description

4.1 Product overview
**Product description**

* Models 8401 AXC/BXC/DXC/GXC/KXC/HXP without guidance for suction catheter

** 8401 AX/BX/HX with guidance for suction catheter

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Laryngoscope blade with holder for electronic module</td>
</tr>
<tr>
<td>2</td>
<td>Electronic module</td>
</tr>
<tr>
<td>3</td>
<td>Connecting cable for video monitor</td>
</tr>
<tr>
<td>4</td>
<td>Function key for video recording</td>
</tr>
<tr>
<td>5</td>
<td>Function key for single image capture</td>
</tr>
<tr>
<td>6</td>
<td>Video connection socket on laryngoscope blade</td>
</tr>
<tr>
<td>7</td>
<td>LED illumination</td>
</tr>
<tr>
<td>8</td>
<td>Image sensor</td>
</tr>
<tr>
<td>9</td>
<td>Connection for electronic module</td>
</tr>
<tr>
<td>10</td>
<td>C-MAC®Pocket Monitor</td>
</tr>
<tr>
<td>11</td>
<td>TFT monitor</td>
</tr>
<tr>
<td>12</td>
<td>Battery status display</td>
</tr>
</tbody>
</table>
4.2 Packaging symbols

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>📚</td>
<td>Consult the instructions for use</td>
</tr>
<tr>
<td>☀</td>
<td>Keep away from sunlight</td>
</tr>
<tr>
<td>🌧️</td>
<td>Keep dry</td>
</tr>
<tr>
<td>🌡️</td>
<td>Temperature limit</td>
</tr>
<tr>
<td>🗝️</td>
<td>In accordance with US federal law (21 CFR 801.109), this product may only be sold to or on prescription from a licensed physician.</td>
</tr>
<tr>
<td>⏰ %</td>
<td>Humidity limitation</td>
</tr>
</tbody>
</table>

4.3 Symbols on the product

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>⚖️</td>
<td>Follow the instructions for use</td>
</tr>
<tr>
<td>♂</td>
<td>Type BF device</td>
</tr>
<tr>
<td>🏷️</td>
<td>Serial number</td>
</tr>
</tbody>
</table>

4.4 Charging Unit for C-MAC® PM

⚠️ WARNING
Danger of electric shock

Do not touch the patient and the charger plug at the same time. For this reason, the battery should be recharged outside the patient environment.

ℹ️ Use only the charging station Art. No. 8401 XDL for recharging. The procedure is described in the instructions for use of the charging station (Art. No. 96076005D)

ℹ️ After only 1 hour, approx. 80% of the charging process is complete. It takes around 3 hours to charge the battery fully.

1. Insert the C-MAC® PM into the charging compartment.
   ➤ The charge status display (14) of the C-MAC® PM lights up orange.

2. When the status display lights up green, remove the C-MAC® PM from the charging compartment.
3. Test for proper operation.
5 Installation and commissioning

5.1 Visual and functional test

Visual inspection

The medical device must be inspected for completeness, damage and integrity before and after every use. Tools such as a magnifying glass may be necessary to carry out the inspections.

Missing components, surface changes or other damage to the medical device limit its life span and may mean that the device can no longer be used for its intended purpose.

Check the instrument for:

- Mechanical damage and changes, for example, sharp edges, burred edges, rough surfaces, protruding and bent parts (example: Fig. 1)

- Signs of rust or corrosion
- Damage to the coating
- Complete and intact seals (that are not cracked, porous or swollen) and joints
- Complete, intact and securely positioned telescope and lens systems, e.g. with a magnifying glass (example: Fig. 2). In the example below (Fig. 3), the covering glass and the lens are missing.
Installation and commissioning

3

- Residues and/or moisture present at the interfaces
- All components present and correctly positioned
- Mobility of all mobile components, if necessary once the components have been assembled in the case of instruments that can be dismantled

Test for proper operation
Check the instrument for the following characteristics:
- Fully functional function keys
- Securely positioned connecting cable
- Functional image transmission
- Sufficient image quality
- Light transmission

5.2 Initial operation

WARNING

Optical radiation
The optical radiation of the instrument can injure the eyes of patients, users, and third parties.
- Never look into the light output of a connected light transmission or endoscope.
- Wear suitable protective equipment.

WARNING

Increased temperatures
The high-intensity light emitted by the laryngoscope can result in increased temperatures at the light outlet of the LED.

5.2.1 Operating the C-MAC® PM
Push the C-MAC® PM (12) into the receptacle of the C-MAC® video laryngoscope (1) (Fig. A)

Switching on the Open-to-Intubate (OTI) display
1. Fold the OTI display (13) upwards (Fig. A, B).
2. Flip the OTI display to the left (Fig. C).
3. Adjust the OTI display so that the image is optimally visible (Fig. D).
   The image focus is adjusted automatically. Manual adjustment is not necessary.
Depending on the composition of the image, there may be slight image deterioration in the first 5-8 seconds.

The C-MAC® video laryngoscope with C-MAC® PM is ready for operation.

**WARNING**

Switching off the display

After 10 minutes, the display of the C-MAC® PM turns off automatically and must be turned back on again by closing it and reopening it.

Switching off the Open to intubate (OTI) display

1. Put the OTI display (13) into the horizontal position (Fig. C).
2. Flip the OTI display to the right (Fig. B).
3. Fold the OTI display downwards (Fig. A).
   
   ⇒ The C-MAC® PM is switched off.

   The C-MAC® PM can be removed from the C-MAC® video laryngoscope during operation and inserted into another C-MAC® video laryngoscope.

   It is not necessary to perform a white balance.
5.2.2 Energy management

ℹ️ The battery charge status is shown on the display for the first 10 seconds of operation.
The lithium ion battery can be used for approx. 1 hour when fully charged.

**WARNING**

**Low battery**

If the charge status symbol flashes red, the charge of the C-MAC® PM is too low. In this state, it will only function for another 10 minutes.

- Connect the C-MAC® PM to the corresponding charge station (8401 XDL) when the charge status symbol flashes red at the latest.
- For the C-MAC® PM there is a specially designed bag 8402 YE available, which can be ordered as an option (see chapter 15.1, Accessories [34]). The C-MAC® PM is also included in a set which includes several different C-MAC® video laryngoscopes. The article number is 8400 B "Intubation Set -C22-, Model ULM".

### 5.2.3 Putting the electronic module into service

- Push the electronic module (2) into the receptacle of the video laryngoscope.
- The electronic module can be removed from the laryngoscope and inserted into another laryngoscope during operation.

### 5.2.4 Focus

When using C-MAC® video laryngoscope blades, the image is focused automatically. Manual focusing is not possible/necessary.
6 Application

6.1 Function keys for the video laryngoscope

*Video recording:* When the function key "Video recording" (4) is pressed, the C-MAC® video laryngoscope saves a video stream on the SD memory card incorporated in the connected Monitor 8403 ZX. Pressing the key a second time stops the recording.

The video stream can only be viewed on a PC if an MPEG 4-codec is installed on the PC.

*Single image capture:* When the function key "Single image capture" (5) is pressed, the current image on the monitor is saved on the SD memory card incorporated in the connected Monitor 8403 ZX.

6.2 Monitor function keys

The monitor is equipped with 4 softkeys that can be used to activate several other functions. A more detailed description of the functions can be found in the instructions for use for the monitor "C-MAC® Monitor 8403 ZX" (Art. No. 96076008D).

6.3 Insertion of an oxygen or suction catheter (only with 8401 AX/BX/HX)

If a blade with oxygen or suction catheter guide is used, the probe/catheter is advanced over the guide until visibility in the image is guaranteed.

When using the blade 8401 AX, the catheters 14 Fr. and 16 Fr. can be used. When using the blades 8401 HX and 8401 BX, catheters 16 Fr. and 18 Fr. can be used.
6.4 Disassembly

1. Unplug the connecting cable from the C-MAC® monitor connection.
2. Push the connecting cable or the C-MAC® electronic module (2) (Fig. A) from the video laryngoscope or the C-MAC® PM (12) (Fig. B) out of the video laryngoscope.

6.5 C-MAC® bag 8403 YD

The optionally available protective bag 8403 YD facilitates the mobile use of the C-MAC® system.
7 Reprocessing

7.1 Cleaning and disinfection

⚠️ CAUTION
Damage to the product!

- Only perform reprocessing using chemicals approved by KARL STORZ. A list of approved chemicals can be requested from hygiene@karlstorz.com.

- The instructions for use "Cleaning, Disinfection, Care, and Sterilization of KARL STORZ Instruments" (item no. 96216003) must be downloaded from http://www.karlstorz.com and followed.

ℹ️ NOTE: The connector and the corresponding sockets in the laryngoscope and in the electronic module are absolutely water-tight in all eventualities. All three connections are also resistant to the process chemicals used in the validated reprocessing methods employed. You may leave the connections unprotected during the validated reprocessing procedures. In particular when the tray holder 39501 LC2 is used in a reprocessing machine, no further accessories are needed.

⚠️ CAUTION
Damage to the product

To prevent possible damage, these connections may only be fitted together when dry. If reprocessing is carried out which does not provide for drying or where compressed air drying cannot be carried out, the reprocessing cap 8401 YZ must therefore be used.

The C-MAC® laryngoscope as well as the Electronic Modules 8401 X/8402 X are suitable and validated for the following low-temperature reprocessing methods up to max. 65 °C: manual/machine cleaning and disinfection, sterilization with Steris® AMSCO V-PRO 1, Sterrad® (100/NX) and EtO gas.

The monitor 8402 ZX/8403 ZX can be wipe-down disinfected.

The C-MAC® PM 8401 XD is suitable and validated for the following low-temperature reprocessing methods up to max. 65 °C: manual/machine cleaning and disinfection.

ℹ️ Reprocessing using STERRAD® can cause cosmetic changes to the surface of the blade, although these have no effect on its function.
Damage due to corrosion

The laryngoscope and electronic module are equipped with gold contacts that prevent corrosion. However, particularly in the case of manual reprocessing, the contacts must be thoroughly rinsed using microbiologically pure/sterile water when rinsed for the last time. Afterwards, the contacts and the instrument must be carefully dried, preferably with sterile compressed air.

7.2 Manual cleaning and disinfection

Start reprocessing the used instrument as soon as possible, since encrusted debris can cause irreparable damage. Remove major debris using an active cleaner, e.g. tenside-based, and a disinfected sponge or soft, disinfected brush.

Place in a disinfection solution; avoid air bubbles and ensure complete wetting. Follow the chemical manufacturer's instructions on concentration and exposure time.

Rinse thoroughly with microbiologically pure/sterile water, then dry.

Electrical contacts must be dried very carefully.

7.3 Machine cleaning and disinfection

The choice of cleaning programs must be agreed with the washing machine manufacturer.

Damage to the product

Clean and chemically disinfect the C-MAC® video laryngoscope in the washer-disinfector at a maximum temperature of 65 °C. The temperature of the drying program must not exceed 65 °C.
Clean the optical surfaces of the image chip (8) and LED illuminator (7) on the C-MAC® video laryngoscope with a cotton tip applicator soaked in 70% isopropyl alcohol. i Electrical contacts must be dried very carefully.

### 7.4 Overview table

<table>
<thead>
<tr>
<th>Cleaning, disinfection and sterilization</th>
<th>Ultrasound</th>
<th>Manual cleaning and disinfection</th>
<th>Machine cleaning (65°C)</th>
<th>Machine cleaning (83°C)</th>
<th>Steam sterilization</th>
<th>Gas sterilization</th>
<th>Hydrogen peroxide sterilization</th>
<th>Steris System 1®</th>
</tr>
</thead>
<tbody>
<tr>
<td>C-MAC® video laryngoscopes</td>
<td>X</td>
<td>•</td>
<td>•*</td>
<td>X</td>
<td>X</td>
<td>•</td>
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</tr>
<tr>
<td>C-MAC® PM 8401 XD</td>
<td>X</td>
<td>•</td>
<td>•*</td>
<td>X</td>
<td>X</td>
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<td>X</td>
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<tr>
<td>Electronic Module 8401 X/8402 X</td>
<td>X</td>
<td>•</td>
<td>•*</td>
<td>X</td>
<td>X</td>
<td>•</td>
<td>•</td>
<td>X</td>
</tr>
</tbody>
</table>

• Suitable methods
X Unsuitable procedures
* Device-specific

### 7.5 Sterilization

**CAUTION**

**Danger due to steam sterilization**

Do not steam sterilize the C-MAC® video laryngoscope, the Electronic Module 8401 X/8402 X and the C-MAC® PM 8401 XD.

For sterilization with gas or with Steris System 1®, country-specific laws and regulations must be observed.

**CAUTION**

**Damage to the product**

For sterilization in the Steris System 1® and Steris System 1E, the reprocessing cap 8401 YZ must be put on first.
Chemically sterilize the C-MAC® video laryngoscope in dismantled condition.
8 Service and repair

8.1 Servicing and repair program

Defective instruments must be serviced and repaired exclusively by persons authorized by us; all repair work must employ original parts.

To bridge the repair period, you will generally receive a device on loan, which must then be returned to KARL STORZ as soon as you receive the repaired device. In Germany you can refer repairs directly to:

KARL STORZ SE & Co. KG
Abt. ReparaturService
Take-off Gewerbepark 83
78579 Neuhausen, Germany
Service hotline: +49 7461/708 980
E-mail: technicalsupport@karlstorz.com

In other countries, please contact your local KARL STORZ subsidiary or authorized dealer.

8.2 Complaint shipments

In the interests of our employees' health, only sterilized or disinfected products are accepted as return shipments. These should be marked as such; otherwise no further processing may be performed.
9 Limitation of Liability

As a supplier of this instrument, we consider ourselves responsible for the safety, reliability and performance of the instrument only if: Assembly, extension, new adjustments, changes or repairs are carried out by persons authorized by KARL STORZ and the instrument is used in accordance with the instructions for use.
10 Guarantee

For information concerning the guarantees provided, please see the Standard Conditions of Business of KARL STORZ. The medical device must always be sent to your local subsidiary (see the section 'Subsidiaries'), even during the warranty period. Opening of the equipment or performance of any repairs or modifications to the equipment by unauthorized persons shall relieve us of any liability for its performance. Any such opening, repair, or modification performed during the warranty period shall void all warranty.
11 Standards, directives and regulations

11.1 Standards, directives and regulations

According to Medical Device Directive (MDD):
Class I medical devices. These medical devices bear the CE mark in accordance with the Medical Device Directive (MDD) 93/42/EEC.

11.2 Standard compliance

(for 8401 AX, BX, HX, AXC, BXC, DXC, GXC, KXC, HXP, X, XD, ZX, for 8402 X/ZX, 8403 ZX)
Complies with EN 60601-1, EN 60601-2-18, UL 2601, CSA 601.1:
- Provides Type BF protection when used in conjunction with a KARL STORZ camera control unit with a BF symbol on the connection port.
- Type of protection against electric shocks: Protection Class II (does not apply to 8401 XD)

According to IEC 60601-1-2:
Please read the electromagnetic compatibility information in chapter 16 [35].

Additional standards:
(for 8401 AX, BX, HX, AXC, BXC, DXC, GXC, KXC, HXP, X, ZX, for 8402 X/ZX)
DO-160F, EMI Test Report (DRF Luftrettung)
(for 8401 AX, BX, HX, AXC, BXC, DXC, GXC, KXC, HXP, X, XD, ZX for 8402 X/ZX)
for 8402 X/ZX)
MIL-STD-461F (Fixed Wing)
(for 8401 XD)
DO-160F
12 Disposal

This device has been marked in accordance with the European Directive on waste electrical and electronic equipment (WEEE). At the end of its useful operating life, dispose of the unit as electronic scrap. Please ask KARL STORZ SE & Co. KG, a KARL STORZ subsidiary or your authorized dealer about the collection point in your area. Within the scope of application of this directive, KARL STORZ SE & Co. KG is responsible for the proper disposal of this device. National regulations/laws must be observed.
## 13 Technical data

### Electronic module 8401 X/8402 X

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Classification</td>
<td>IEC Class II</td>
</tr>
<tr>
<td>Line frequency</td>
<td>DC</td>
</tr>
<tr>
<td>Voltage</td>
<td>5 V</td>
</tr>
<tr>
<td>Power consumption</td>
<td>2 VA</td>
</tr>
<tr>
<td>Immersion protection</td>
<td>IPX8</td>
</tr>
</tbody>
</table>

### Blade 8401 AX/BX/HX/AXC/BXC/DXC/GXC/KXC/HXP

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immersion protection</td>
<td>IPX8</td>
</tr>
<tr>
<td>Camera technology</td>
<td>CMOS</td>
</tr>
<tr>
<td>Resolution</td>
<td>320 x 240</td>
</tr>
<tr>
<td>Illumination</td>
<td>LED, white, 1 W</td>
</tr>
</tbody>
</table>

### Average life cycle

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reprocessing cycles</td>
<td>200*</td>
</tr>
</tbody>
</table>

* Value indicates the number of tested cycles. The device’s life span may be compromised if the recommended number of cycles is exceeded.

Inspect the device for damage before and after every use (see the chapter “Symbols and danger notes” and the chapter “Visual and functional test”).

### Color settings

#### Back Page Settings

<table>
<thead>
<tr>
<th>Blade</th>
<th>Brightness</th>
<th>Contrast</th>
<th>Saturation</th>
<th>Hue</th>
</tr>
</thead>
<tbody>
<tr>
<td>8403 ZX</td>
<td>40%</td>
<td>35%</td>
<td>40%</td>
<td>50%</td>
</tr>
<tr>
<td>8402 ZX</td>
<td>30%</td>
<td>25%</td>
<td>40%</td>
<td>100%</td>
</tr>
<tr>
<td>8401 ZX</td>
<td>56%</td>
<td>50%</td>
<td>20%</td>
<td>0%</td>
</tr>
</tbody>
</table>
### Charging station 8401 XDL

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Classification</td>
<td>IEC Class II</td>
</tr>
<tr>
<td>Line frequency</td>
<td>DC</td>
</tr>
<tr>
<td>Voltage</td>
<td>5 V</td>
</tr>
<tr>
<td>Power consumption</td>
<td>2 VA</td>
</tr>
<tr>
<td>Weight</td>
<td>Approx. 230 g</td>
</tr>
</tbody>
</table>

### C-MAC® PM 8401 XD

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Line frequency</td>
<td>DC</td>
</tr>
<tr>
<td>Voltage</td>
<td>3.7 V</td>
</tr>
<tr>
<td>Power consumption</td>
<td>1.5 W</td>
</tr>
<tr>
<td>Immersion protection</td>
<td>IPX8</td>
</tr>
</tbody>
</table>
## 14 Fault correction

### 14.1 Troubleshooting

Always unplug the device before doing any cleaning and maintenance work on the device.

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Possible causes</th>
<th>Remedy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete failure of the device. Possible lighting up of status display.</td>
<td>- No power from the power line.</td>
<td>- Check the power supply.</td>
</tr>
<tr>
<td></td>
<td>- Power cord connector is not properly connected to device socket.</td>
<td>- Push the power supply plug firmly into the socket on the device.</td>
</tr>
<tr>
<td></td>
<td>- System error</td>
<td>- Reset.</td>
</tr>
<tr>
<td>No picture, TFT screen dark.</td>
<td>- Electronic module/C-MAC® PM not fully inserted.</td>
<td>- Slide electronic module/C-MAC® PM in as far as it will go.</td>
</tr>
<tr>
<td></td>
<td>- Defective camera electronics.</td>
<td>- Send electronic module/C-MAC® PM or supply unit to KARL STORZ for repair.</td>
</tr>
<tr>
<td></td>
<td>- TFT screen defective.</td>
<td></td>
</tr>
<tr>
<td>Cloudy picture, stripes, streaks, or similar.</td>
<td>- Telescope of the laryngoscope is soiled.</td>
<td>- Clean with cotton swab and alcohol solution or special cleaning paste.</td>
</tr>
<tr>
<td></td>
<td>- Contacts of the electronic module/C-MAC® PM are soiled.</td>
<td>- Clean the contacts of the electronic module/C-MAC® PM.</td>
</tr>
<tr>
<td>Color distortions.</td>
<td>- White balance not carried out correctly.</td>
<td>- Carry out new white balance.</td>
</tr>
<tr>
<td></td>
<td>- Electronic module defect.</td>
<td>- Send the supply unit for repairs to KARL STORZ.</td>
</tr>
<tr>
<td>Color rendering alternates.</td>
<td>- Camera connecting cable is defect.</td>
<td>- Have a new camera connecting cable fitted.</td>
</tr>
<tr>
<td>Image cannot be saved.</td>
<td>- No memory card inserted.</td>
<td>- Insert memory card.</td>
</tr>
<tr>
<td></td>
<td>- Memory card full.</td>
<td>- Change memory card.</td>
</tr>
<tr>
<td></td>
<td>- Memory card is not recognized.</td>
<td>- Insert the memory card while the C-MAC® Monitor is switched off and then turn the monitor on again.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Perform a reset.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Format the memory card on the PC with FAT (standard).</td>
</tr>
<tr>
<td>Fault correction</td>
<td>Reason</td>
<td>Solution</td>
</tr>
<tr>
<td>--------------------------</td>
<td>------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Video stream cannot be</td>
<td>- No MPEG-4 Codec installed.</td>
<td>- Install an MPEG-4 Codec on the PC.</td>
</tr>
<tr>
<td>played back on the PC</td>
<td></td>
<td></td>
</tr>
<tr>
<td>monitor.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SD memory card cannot</td>
<td>- SD memory card is formatted incorrectly.</td>
<td>- Format the SD memory card on the PC with FAT (standard).</td>
</tr>
<tr>
<td>be written on.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
15 Accessories and spare parts

### 15.1 Accessories

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>809125</td>
<td>MAGILL forceps, modified by BOEDEKER, length 25 cm, suitable for the endoscopic removal of foreign bodies, for use with video laryngoscopes of sizes 2 – 4</td>
</tr>
<tr>
<td>809120</td>
<td>MAGILL forceps, for children, modified by BOEDEKER, length 20 cm, suitable for the endoscopic removal of foreign bodies, for use with video laryngoscopes of sizes 1 – 2</td>
</tr>
<tr>
<td>8402YE</td>
<td>Bag for intubation set -C22-, model ULM, made of water-repellent and hard-wearing surface material, washable, the bag contains two compartments with several holding possibilities for C-MAC® video laryngoscopes with C-MAC® Pocket Monitor and for conventional laryngoscopes, for use with C-MAC® Pocket Monitor 8401 XDX, C-MAC® video laryngoscopes and conventional laryngoscopes</td>
</tr>
<tr>
<td>8401 YZ</td>
<td>multifunctional cap for use in the Steris System1® to protect the contacts during reprocessing. Suitable for the C-MAC® video laryngoscope, the C-MAC® electronic module and the C-MAC® PM. The cap is reusable.</td>
</tr>
<tr>
<td>39501 LC2</td>
<td>wire tray for cleaning, sterilization and storage for two C-MAC® video laryngoscope blades incl. an electronic module, with holder for fixing and sealing the electronic connections. External dimensions (W x D x H): 260 x 120 x 170 mm</td>
</tr>
</tbody>
</table>
16 Electromagnetic compatibility

The applied part described in these instructions for use has been tested as a system with the following basic devices. For relevant electromagnetic compatibility (EMC) information, refer to 'Electromagnetic Compatibility (EMC) information' in the instructions for use for these basic devices:

<table>
<thead>
<tr>
<th>Basic device</th>
<th>Instructions for use</th>
</tr>
</thead>
<tbody>
<tr>
<td>C-MAC® Monitor 8403 ZX</td>
<td>96076008 D</td>
</tr>
<tr>
<td>C-MAC® Pocket Monitor 8403 XD</td>
<td>96076020 D</td>
</tr>
<tr>
<td>C-HUB® II 20 2903 20</td>
<td>96206529 D</td>
</tr>
</tbody>
</table>

The EMC warning statements, precautions, notes and Emission/Immunity limits specified in the instructions for use for the basic devices also apply to the applied part described in these instructions for use.