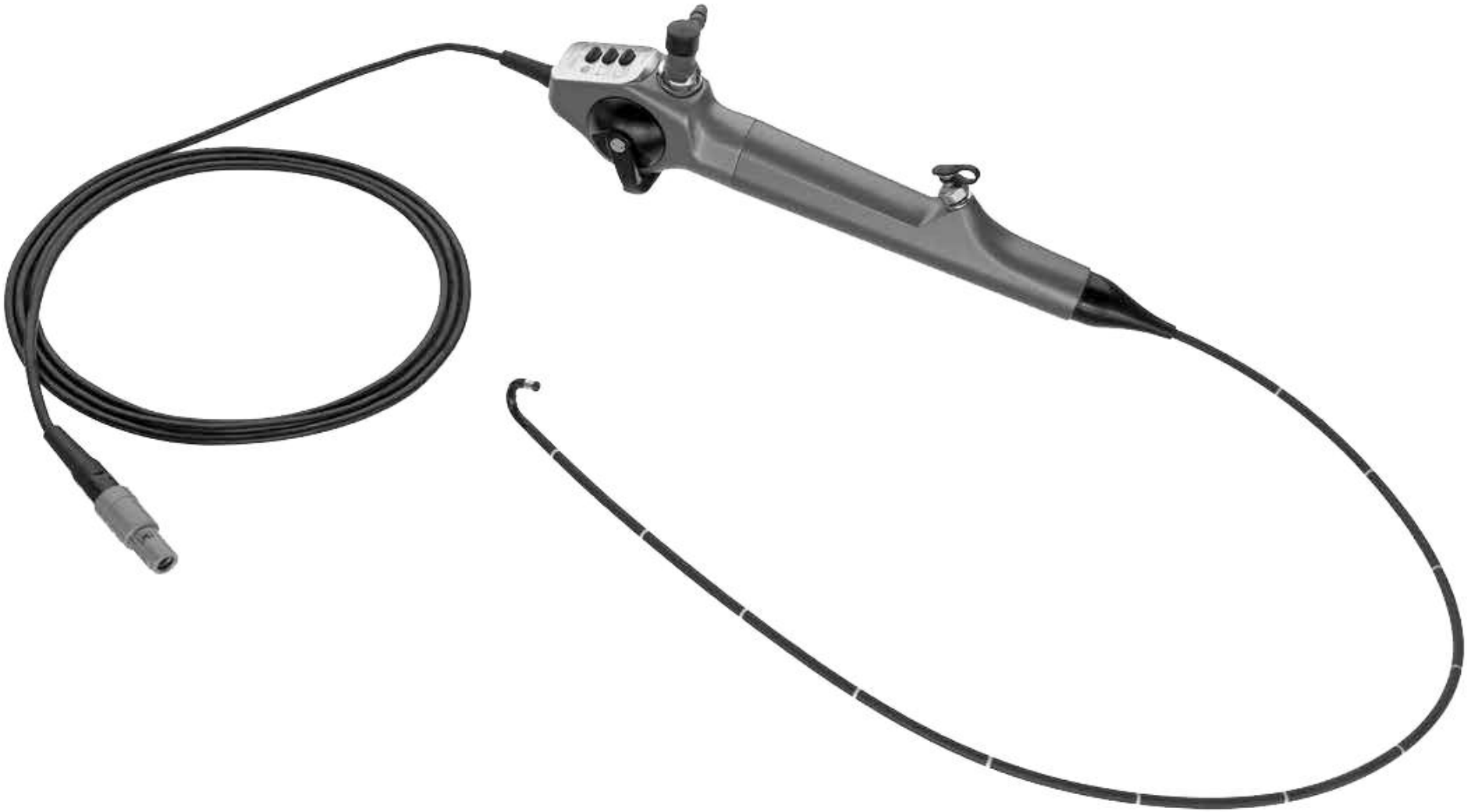
KARL STORZ — ENDOSKOPE

Instruction Manual



KARL STORZ — ENDOSKOPE

Flexible Intubation Video Endoscope 11302 BDX
Monitor 8403 ZX

KARL STORZ — ENDOSKOPE

Important Information for Users of KARL STORZ Instruments

Thank you for your expression of confidence in the KARL STORZ brand name. Like all of our other products, this product is the result of years of experience and great care in manufacture. You and your organization have decided in favor of a modern, high-quality item of equipment from KARL STORZ.

This instruction manual is intended to serve as an aid in the proper handling, cleaning, disinfection and, where required, sterilization of the Flexible Intubation Video Endoscope. All essential details of the equipment and all actions required on your part are clearly presented and explained. We thus ask that you read this manual carefully before proceeding to work with the instrument. Keep this manual available for ready reference.

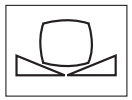
Warning: KARL STORZ instruments are provided non-sterile, and must be cleaned, disinfected and/or sterilized prior to the initial use and before each subsequent use.

KARL STORZ is constantly working on the further development of all products. Please appreciate that changes to the scope of supply in form, equipment and technology are possible for this reason. Therefore, no claims may be deduced from the information, figures and descriptions in this manual.

CAUTION:: Federal (USA) law restricts this device to sale by or on the order of a physician.

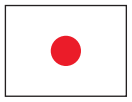
Symbol description

Follow the instruction manual



White balance

Single image capture



Video recording

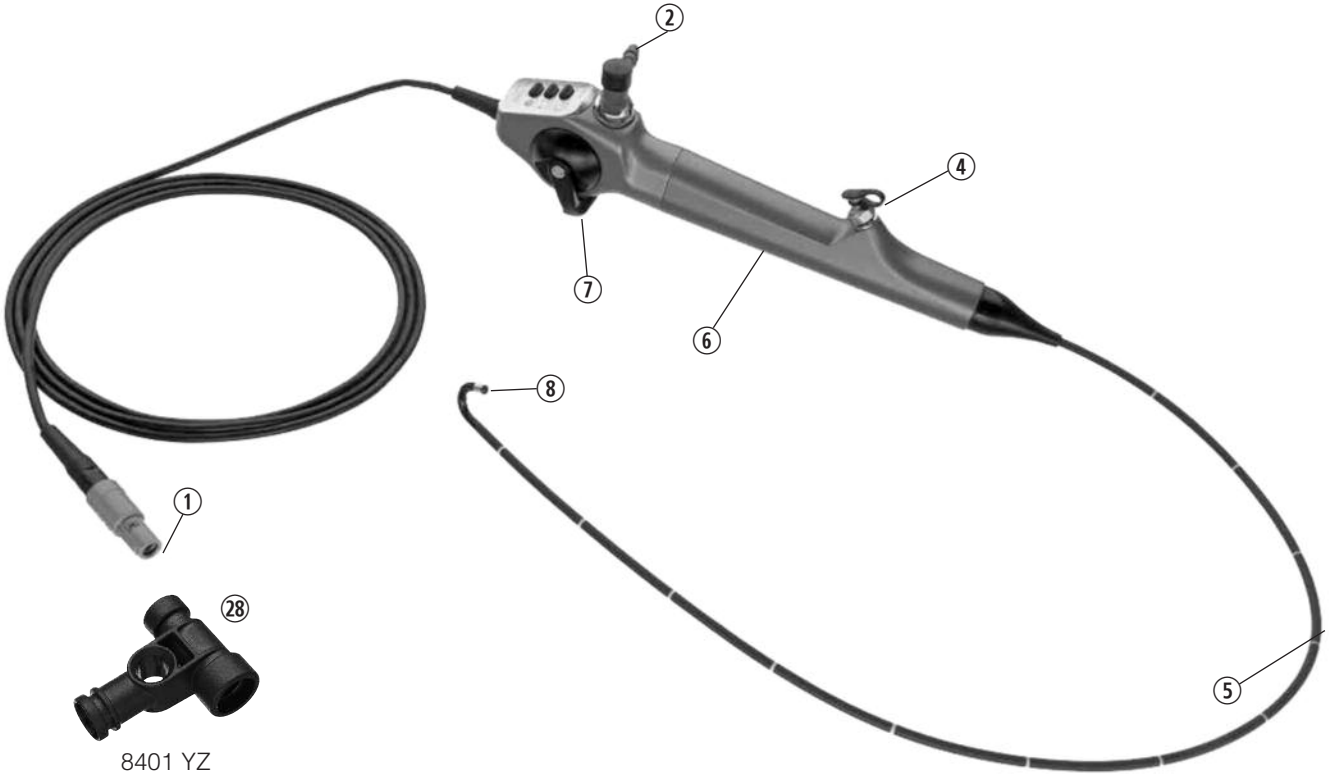
This device has been marked in accordance with the European Directive 2002/96/EC on waste electrical and electronic equipment (WEEE).

Device type BF

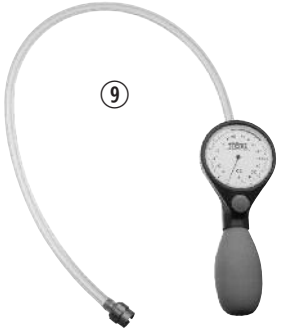
Electronic information product pollution control (China RoHS)

Manufacturer

Illustrated Description

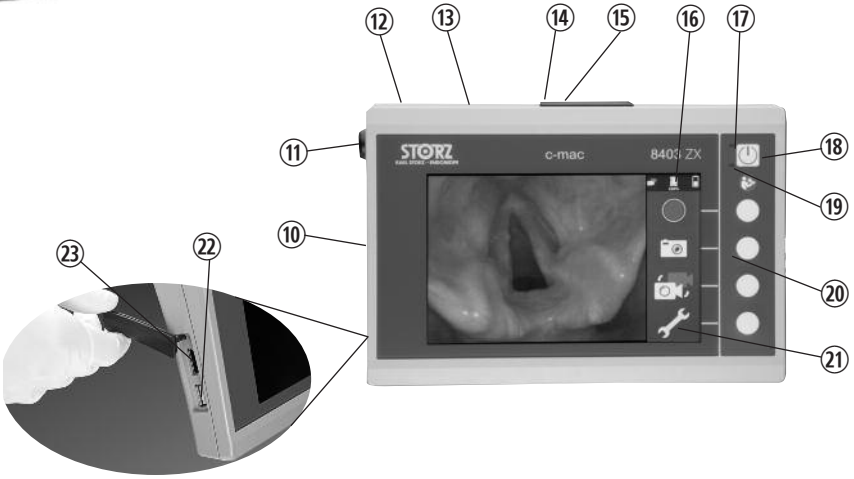


8401 YZ



13242 XL Leakage Tester

Z11457 Pressure Compensation Cap



① Connecting cord and cable connector
② Suction valve 11301 CE1/11301 CD1
③ Connection for Leakage Tester (P/N 13242XL) or pressure compensation cap (vent port)
④ Instrument channel port
⑤ Shaft
⑥ Handle
⑦ Deflection lever
⑧ Distal tip
⑨ Leakage Tester (P/N 13242XL)
⑩ Monitor/CCU
⑪ Connection 2
⑫ Connection 1
⑬ Mains connection
⑭ Reset button
⑮ Holder for SD memory card
⑯ Status bar
⑰ Pilot lamp
⑱ On/Off switch
⑲ Pilot lamp charging (orange)
⑳ Control keys
㉑ Function symbols
㉒ USB port
㉓ HDMI port
㉔ Video recording Start/Stop
㉕ White balance
㉖ Still image recording
㉗ pressure compensation cap Z11457
㉘ Cleaning cap 8401 YZ

KARL STORZ — ENDOSKOPE

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Please read these safety instructions carefully before using the device. Before using the instrument on the patient it is imperative that you be acquainted with how the instrument operates and is controlled.

Indications for Use

The Flexible Intubation Video Endoscope is intended to be used for examination and visualization of a patient's upper airway and for aiding placement of a tracheal tube.

User Qualification

The KARL STORZ Flexible Intubation Video Endoscope may only be used by persons with an appropriate medical qualification and who are acquainted with the laryngoscopic technique. The information given in these instructions only serves to instruct in the correct handling and preparation of the Flexible Intubation Video Endoscope.

It is not intended as an introduction to the technique of laryngoscopy.

Warnings and Cautions

Please read this manual carefully and follow the instructions exactly. The words Warning, Caution, and Note convey special meanings. Wherever they are used in this manual, they should be carefully reviewed to ensure the safe and effective operation of this product. To further emphasize the words Warning, Caution and Note, they are preceded by a pictogram.

Warning: A Warning indicates that the personal safety of the patient or physician may be involved. Disregarding a Warning could result in injury to the patient or physician.

CAUTION: A Caution indicates that particular service procedures or safety precautions must be followed to avoid any damage to the product.

Note: A note indicates special information about operating the product, or clarifies important information. Please read this manual carefully and follow the instructions exactly.

Safety Precautions When Using the Flexible Intubation Video Endoscope

The Flexible Intubation Video Endoscope must be used according to the recognized medical rules and procedures of endoscopy.

Note: The patient leakage current limit of the CF application part may be exceeded when CF application parts (application on heart) are used in combination with other BF application parts.

In this case, the reduction of the patient leakage current should be effected using only CF application parts as far as this is possible.

Warning: Every time the Flexible Intubation Video Endoscope is used, you must first check that it, and any accessories used in combination with it, is in perfect condition. Damaged Flexible Intubation Video Endoscopes or damaged accessories must not be used.

Warning: Combinations of medical devices are only then assured to be safe if they are identified as such in the respective instruction manual or the intended purpose and the interface specifications of the devices used in combination permit this.

Pay careful attention to the instructions and interface specifications of medical products used in combination.

Warning: The Flexible Intubation Video Endoscope is delivered non-sterile and must be cleaned and disinfected/sterilized before initial and subsequent use.

Warning: The pressure compensation cap (P/N Z11457) ㉗ must be removed from the vent port ③ for:

- endoscopic interventions
- immersing in liquid, e.g. disinfectant solution.

Warning: Danger of glare and burns! Never look directly into the light of the Flexible Intubation Video Endoscope. The LED light radiated through the Flexible Intubation Video Endoscope may cause glare or high temperatures at the distal light outlet and therefore lead to burns.

Warning: Danger of explosion if flammable gases are used in the immediate proximity of the Flexible Intubation Video Endoscope. The Flexible Intubation Video Endoscope must not be used in the presence of flammable or combustible media.

Warning: The Flexible Intubation Video Endoscope may only be repaired by personnel authorized by KARL STORZ. Unauthorized repairs may impair functioning and safety, and are therefore strictly forbidden.KARL STORZ gives no warranty for Flexible Intubation Video Endoscopes that are repaired by unauthorized personnel.

Warning: Damage to the Flexible Intubation Video Endoscope and injury to the patient or user resulting from incorrect operation are not covered by the manufacturer's warranty.

Warning: Always unplug the Flexible Intubation Video Endoscope before carrying out any maintenance and cleaning work on it.

Warning: The Flexible Intubation Video Endoscope must not be used during the discharge of a cardiac defibrillator. Remove the Flexible Intubation Video Endoscope from the operation area before discharge takes place.

Warning: When in operation, the integrated LED light source heats up the Flexible Intubation Video Endoscope. Switch off the Intubation Videoscope before putting it down and do not place it in the proximity of the patient.

Warning: Only KARL STORZ devices (monitor 8403 ZX) may be used. Disregarding this warning can endanger the patient and user.

Warning: If the Flexible Intubation Video Endoscope should malfunction during application on a patient, stop the application immediately. Place the distal tip of the Flexible Intubation Video Endoscope in the neutral, nondeflected position and remove the Flexible Intubation Video Endoscope slowly and carefully from the patient.

CAUTION: Only use accessories (wires, etc.) from KARL STORZ. Accessories from other manufacturers may damage the Flexible Intubation Video Endoscope.

CAUTION: Do not steam sterilize (autoclave) the Flexible Intubation Video Endoscopes under any conditions.

CAUTION: The maximum permissible temperature for decontamination and sterilization is 65° C.

CAUTION: The pressure compensation cap (P/N Z11457) ㉗ must be in place on the vent port ③ for:

- gas sterilization
- shipping

CAUTION: The cleaning cap 8401 YZ ㉘ must be in place on the connecting cord and cable connector ① for:

- Immersing in liquid, e.g. disinfectant solution

CAUTION: Do not allow any electrically live components or instruments to come into contact with the Flexible Intubation Video Endoscope.

CAUTION: Do not place the Flexible Intubation Video Endoscope on devices that become very hot. Do not expose it to direct sunlight or excessive heat.

CAUTION: Flexible Intubation Video Endoscopes must never be exposed to X-rays.

CAUTION: Do not hit the distal tip of the Flexible Intubation Video Endoscope against hard objects, and never use a sharp object to remove dirt.

CAUTION: Never lay heavy objects on the Flexible Intubation Video Endoscope.

CAUTION: To avoid damaging the monitor, do not remove the SD card or connecting cord while a video is recording.

CAUTION: To avoid damaging the monitor, always switch it off before replacing the SD card.

Unpacking the Device

Warning: The Flexible Intubation Video Endoscope is delivered non-sterile, so it has to be disinfected/sterilized prior to initial use and before each subsequent reuse.

Check for missing items and evidence of shipping damage.

File any complaints immediately with KARL STORZ or the supplier.

Basic Equipment

The set 11302 BDX comprises:

1	11302 BDX Flexible Intubation Video Endoscope
1	Carrying case 27677 FV
1	Instruction manual Z17844US
1	Leakage Tester 13242XL
1	Pressure compensation cap Z11457
1	Suction valve insert for single use, pack of 20 11301 CE1
1	Adaptor for cleaning the working channel in cleaning machines (black) 11301 CA/1
1	Flat cleaning brush 27652/3
1	Long cleaning brush 11276 CL2/10
1	Short Cleaning Brush
1	Long cleaning brush 110910-50
1	Cleaning cap 8401 YZ
1	Luer plug 29100-BK
1	Adapter for channel cleaning 11301 CD1

Operating Conditions

Flexible Intubation Video Endoscope:

Ambient temperature: 15° C–37° C (59° F–98.6° F)

Humidity: 15%–80%

Monitor 8403 ZX:

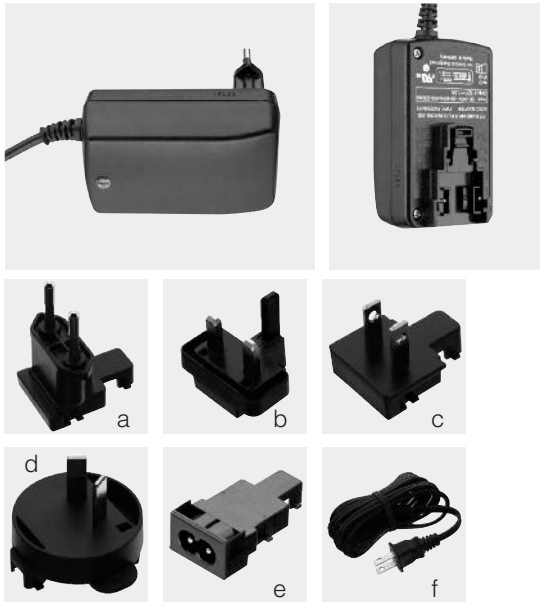
Ambient temperature: 0° C–37° C (32° F–98.6° F)

Humidity: 30%–70% relative humidity

Electromagnetic Compatibility

This device has been tested and is found to comply with the EMC limits of EN/IEC 60601-1-2 CISPR 11 Class B.

External System Components



Charger

Using the medically approved charger (P/N 40150031), the Li-Ion battery of the monitor can be recharged extremely quickly.

Moreover, this charger enables the monitor to be operated with a discharged Li-Ion battery.

The charger has a green LED display which indicates that the output voltage is correct.

Country specific configuration

The charger features interchangeable primary adapters, which allow the system to be adapted to the country-specific power supply outlets.

a Primary adaptor for EUROPE: ET27-30-0004 516

b Primary adaptor for UK: ET27-30-0004 5178

c Primary adaptor for US/Japan: ET27-30-0004 520

d Primary adaptor for Australia: ET27-30-0004 519

e Primary adaptor USA ET27-30-0004369

f Adaptor cable ET27-30-0004 370

1

Press the button on the power supply unit to change the adaptor (figure 1). This releases the adaptor which can then be lifted out.

2

When inserting a new adaptor, this must be placed in the guide (fig. 2) and pushed toward the cable until there is an audible click (fig. 2, see arrow).

Handling

The Flexible Intubation Video Endoscope must be used according to the medical rules and procedures recognized for the laryngoscopic methods.

Note: Damage to the Flexible Intubation Video Endoscope resulting from incorrect operation is not covered by the manufacturer's warranty.

Operating

The following instructions outline the correct operation of the Flexible Intubation Video Endoscope and the corresponding accessories. This is not an introduction to the techniques of laryngoscopy. Instructions on the endoscopic technique can be found in the relevant medical literature.

The Flexible Intubation Video Endoscope is used for endotracheal intubation and inspection of the oropharynx.

Holding Correctly

Grip the handle of the Flexible Intubation Video Endoscope in your left or right hand, as shown in the picture. With this kind of control grip, the Flexible Intubation Video Endoscope can be operated with one hand.

Installing the suction valve (P/N 11301CE1)

Place the suction valve insert onto the valve connection ② and turn it until the lateral projections on the insert are located above the recesses on the connection.

Installing the Tube holder

Push the tube holder onto the Flexible Intubation Video Endoscope starting at the distal end until it clicks into place.

Handling the Shaft

CAUTION: Do not carry the Flexible Intubation Video Endoscope by the shaft. Do not pull, clamp or twist the shaft of the Flexible Intubation Video Endoscope.

The shaft of the Flexible Intubation Video Endoscopes must never be kinked or coiled up too tightly. It is best to store the Flexible Intubation Video Endoscopes in a suspended position by cradling the handle and letting the shaft hang down or to keep it sterilized in a tray specifically designed for sterilizing and storage (39405 AS).

Warning: Do not apply lubricant to the lens, to avoid clouding the image and thus posing a risk to the patient!

Use a suitable water-soluble lubricant (no silicone) for the distal section of the insertion shaft.

Handling the Deflection Mechanism

Note: The neutral position of the distal end is straight.

Warning:: The distal end of the Flexible Intubation Video Endoscope must be in the neutral position when inserted into the patient.

Warning: The deflection lever must never be operated with force or abruptly to avoid perforation and injury to the patient or damaging the device irreparably.

Warning: Before removing the Flexible Intubation Video Endoscope from the patient, the distal tip must be in the neutral position.

Warning: If the distal end can no longer be properly controlled via the deflection lever, or if the deflection mechanism develops any other fault, the Flexible Intubation Video Endoscope must not be used.

Warning: If a functional defect occurs with the Flexible Intubation Video Endoscope during use on the patient, discontinue use immediately. Put the distal end of the Flexible Intubation Video Endoscope into the neutral position and remove slowly and carefully from the patient.

CAUTION: The force required to push/pull the deflection lever increases as the distal end angle of deflection increases.

The distal end is deflected by actuating the deflection lever slowly. The distal end will deflect in accordance with the direction of actuation.

Handling the Working Channel

Do not force cleaning brushes through the instrument channel. This can damage the cladding, especially if the tip of the instrument is angled. Do not insert brushes through the channel when the distal end is in the neutral position.

When connecting and operating light sources and suction/irrigation devices, pay attention to the instruction manuals for the particular devices. The irrigation devices recommended by KARL STORZ are set to a maximum pressure of 54 kPa (400 mmHg/0.54 bar/7.8 psi).

Connection to the Monitor 8403 ZX

The Flexible Intubation Video Endoscope can be used together with the KARL STORZ MONITOR 8403 ZX.

Warning: It must be ensured that the electrically non-insulated parts of the Flexible Intubation Video Endoscope do not come into contact with conductive surfaces, or voltage-carrying elements of other units, at any time.

Insert the connecting cord ① of the Flexible Intubation Video Endoscope into either connection socket ⑪ or ⑫ on the monitor.

The connecting cord ① can be connected or disconnected during operation. Insert the cable from the power supply into the connection socket ⑬ of the monitor and connect the power supply with the mains socket. The power cord can be fixed to the connection using the union nut.

The battery is charged automatically as soon as the monitor is connected to the power supply. This will be indicated by the lighting up of the orange colored LED ⑲.

CAUTION: The Flexible Intubation Video Endoscope can only be connected to the monitor 8403 ZX.

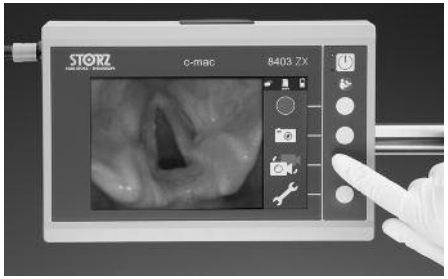
Use of the HDMI Output

The device features a port for an external monitor. An HDMI cable can be used to send the video signal to an external monitor.

CAUTION: The C-MAC® Monitor must be switched off when an external monitor is connected.

Note: The connected monitor must support a resolution of 1024 × 768 or 1280 × 720.

Note: To connect the C-MAC® Monitor to a KARL STORZ monitor, the HDMI-DVI adaptor with article number 20 9190 10 is required.



Functions of the Monitor 8403 ZX

A more detailed description of the functions can be found in the instruction manual for the monitor “C-MAC® Monitor 8403 ZX” (P/N 96076008D).

Focus

The image focus is fixed. Manual adjustment is not necessary.

The system is now ready for use.

Function Buttons of the Flexible Intubation Video Endoscope

The Flexible Intubation Video Endoscope is equipped with 3 keys, which are used to activate the functions displayed as symbols on the Flexible Intubation Video Endoscope.

The following functions are available:

Video recording ㉔: Starts or stops the recording of a video stream on the SD memory card inserted in the receptacle ⑮.

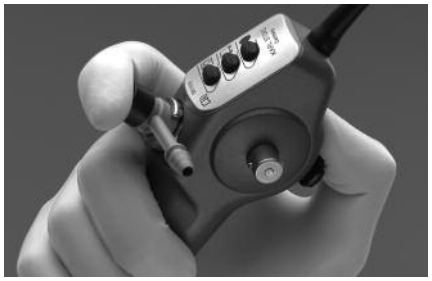
White balance ㉕: Enables the user to carry out a manual white balance. Point the tip of the videoscope at a white surface and press the button for 1 sec.

Single image capture ㉖: Saves the live image on the screen on the SD memory card.

Preparation Prior to Use

Warning: Every time the Flexible Intubation Video Endoscope is used, you must first check that it, and any accessories used in combination with it, are in perfect condition. Damaged Flexible Intubation Video Endoscopes or damaged accessories must not be used.

Inspecting the Suction Function



The suction function can be triggered by pressing the suction valve (P/N 11301CE1) ② (when the suction pump is connected and switched on).

Note: The opening of the working channel should be sealed (P/N. 29100-BK) to ensure that no secondary air is sucked in.

Inspecting the Insufflation

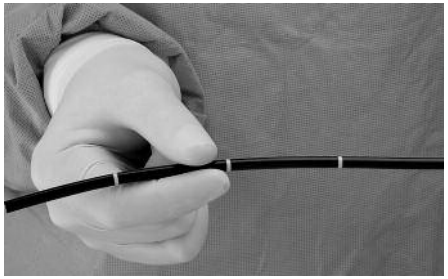
Connect the O_2 tube up to the instrument channel:

- using the barbed tube (P/N 600007) on the instrument channel or,
- if you are using the three-way double stopcock adaptor with LUER lock (P/N. 6927691), connect the tube to the tube holder on the angled part of the adaptor.

CAUTION: The instruction manuals of the supply units used must be observed.

Switch the corresponding supply units on.

Inspecting the Surfaces



Warning: The surface of the flexible sheath must be inspected visually and by carefully feeling it, to detect any cracks, cuts, dents, foreign bodies, or other forms of damage.

CAUTION: Do not squeeze the distal tip of the Flexible Intubation Video Endoscope too tightly.

Every time the Flexible Intubation Video Endoscope is used, you must first check that its surface, and above all the surface of the shaft and distal tip, is in perfect condition and that there are no sharp edges. Intubation videoscopes with sharp edges must not be used.

Inspect the connecting cord and connector for damage (such as breaks, cracks, twisted or squashed sections or loose connections).

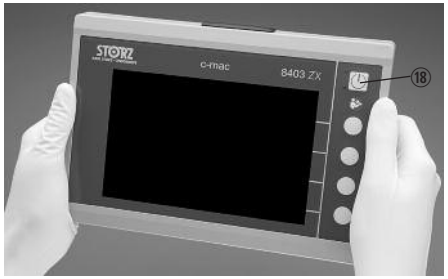
Checking the Deflection

Warning: Actuate the deflection lever gently and carefully as far as the limit stop. The deflection lever must never be operated with force or abruptly, to avoid injuring the patient or damaging the device! Move the deflection lever smoothly and slowly!

Warning: Before use, always check that the deflection lever and the distal tip connected to it function correctly. Defective Flexible Intubation Video Endoscopes must not be used.

The distal end will deflect in accordance with the direction of actuation (forward or backward).

Switching the Flexible Intubation Video Endoscope On/Off



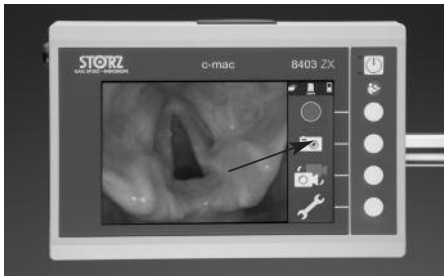
Switching on/off: The Flexible Intubation Video Endoscope with the integrated LED light source is switched on by pressing the power button ⑱ on the monitor. Pressing the key a second time switches the unit off.

Warning: Danger of glare: Do not look directly into the light beam emitted from distal tip of the Flexible Intubation Video Endoscope.

Warning: When in operation, the integrated LED light source heats up the Flexible Intubation Video Endoscope. Switch off the Flexible Intubation Video Endoscope before putting it down and do not place it in the proximity of the patient.

Note: The function keys on the monitor are used for switching the unit on/off. The Flexible Intubation Video Endoscope itself does not have an on/off button.

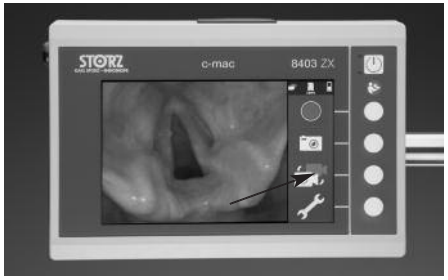
Video Recording



When the control key ‘Video recording”on the monitor or the Intubation Videoscope is pressed, the Flexible Intubation Video Endoscope records a video stream on the SD memory card. Pressing the key a second time stops the recording.

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

Single Image Capture



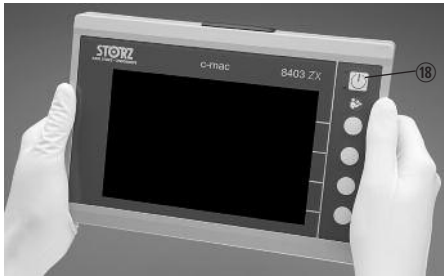
When the control key “Single image capture” on the monitor or the Intubation Videoscope is pressed, the current image on the monitor is saved on the SD memory card.

Inspecting the Image Quality

Check the image quality before using the Flexible Intubation Video Endoscope. Do not use the scope if the image is missing, or unclear/blurry.

Warning: If the image fails or there is interference during use in the patient, put the distal tip into the neutral position and remove the Flexible Intubation Video Endoscope from the patient's body gently and carefully. If the Flexible Intubation Video Endoscope is used in the patient after the image has failed or when there is interference, this may result in serious injury to the patient.

Switching Off the Monitor



Standby: Briefly pressing the power button ⑱ will set the monitor to standby operation mode. In the case of brief interruptions, this enables the monitor to be ready for operation again quickly. The standby mode is indicated by a flashing green pilot lamp ⑰ above the power button.

After 5 minutes, the system switches itself from standby mode to the off mode.

Power off: Pressing the power button ⑱ for more than approximately 3 seconds will switch off the monitor. The green pilot lamp ⑰ will go out.

Note: When the monitor is switched off, the integrated light source in the Flexible Intubation Video Endoscope also switches off.

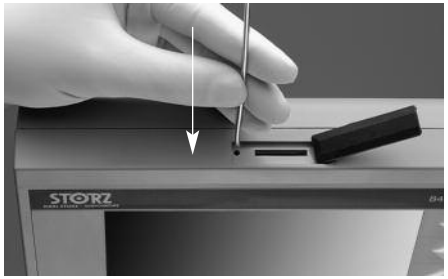
Note: A more detailed description of the functions can be found in the instruction manual for the monitor "C-MAC® Monitor 8403 ZX" (P/N 96076008D).

Attaching the Monitor to a Holder

Press the holder together to allow the stand bar to be pushed through the openings.

Release the holder in the desired position. The selected position is fixed by the holder's basic tension.

The optionally available clamp 8401 YB (see accessories) can similarly be secured to the VESA 75 holder and is used to attach the electronic module to rods with a diameter of less than 25 mm and/or to rails with a cross section of less than 25 mm.



System Reset

If a system error occurs (unit no longer reacts, although connections and power supply are in order), a system reset has to be implemented. This is the equivalent of rebooting a computer. For this, a thin screwdriver or similar is inserted into the round opening next to the SD card holder ⑮ and carefully pushed downward in order to activate the reset button ⑭.

The system will now be rebooted.

Monitor Bag 8403 YD

The optionally available protective bag 8403 YD facilitates the mobile use of the monitor.

General Information

Warning: The flexible endoscope is delivered non-sterile and must be thoroughly cleaned and high- level disinfected (as a minimum) or sterilized before initial and subsequent uses. The FDA recommends sterilization over high-level disinfection, if available.

Warning: Occupational safety guidelines must be observed and applied when cleaning contaminated flexible endoscopes and instruments. Ensure appropriate Personal Protective Equipment (PPE) is used by all staff during reprocessing.

Warning: Ensure adequate ventilation is used for manual High-Level Disinfection (HLD) as per the HLD manufacturer's instructions.

Warning:: Sterilization/high-level disinfection can only be performed successfully if:

- The instruments are freed of organic materials and residues of pharmaceutical products and cleaning products (i.e. thoroughly cleaned).
- The recommended sterilization and high-level disinfection parameters are maintained.
- Sterilization equipment is properly maintained and calibrated.

CAUTION: High-level disinfection is the minimum requirement for "semi-critical" devices that only come in contact with intact mucous membranes or non-intact skin.

CAUTION: The maximum permitted temperature is 65° C (149° F) for decontamination and sterilization.

CAUTION: Personal Protective Equipment (PPE) is required to ensure safety of the operator when cleaning any contaminated medical device. Follow occupational safety guidelines and your institution's policies for PPE requirements.

CAUTION: The flexible endoscope must be protected from objects that could cause damage to the device such as wire bristle brushes, sharp objects etc. Soft, lint-free cloths and/or sponges along with ONLY the correct KARL STORZ cleaning brush(es) should be used to clean the flexible endoscope.

CAUTION: To prevent biofilm formation it is critical that flexible endoscopes be thoroughly dried prior to storage. Biofilm formation will interfere with sterilization and high level disinfection of the flexible endoscope and could lead to infection transmission.

Note: The soft, lint-free cloths should be disposed of after a single use (i.e. use separate cloths for the detergent cleaning, water rinsing and drying phases).

Note: When preparing cleaning and disinfecting solutions, follow the manufacturer's instructions for proper exposure time, dilution and temperatures.

Water Quality Requirements

CAUTION: Flexible endoscopes **must never be immersed in normal saline solution,** as even brief contact can result in pitting and corrosion.

Definitions:

Utility Water: Water as it comes from the tap that meets the specifications as defined per the table below. This water is mainly used for flushing, washing, and rinsing.

Critical Water: Water that is extensively treated (usually by a multistep treatment process that could include a carbon bed, softening, DI and RO, or distillation) to ensure that the microorganisms and the inorganic and organic material are removed from the water; a final submicron filtration could also be part of the treatment process. This water is mainly used for the final rinse.

Type of Water		**Utility Water**		**Critical Water**
Water Use Specifications	**Units**	**Flushing/Washing/Rinsing**		**Final Rinse**
Hardness	mg/L	< 150*		< 1
Conductivity (mg/L = ppm)	µS/cm	< 500		< 10
pH		6 – 9		5 – 7
Chlorides	mg/L	< 250		< 1
Bacteria	cfu/mL	n/a	< 10**	< 10
Endotoxin	EU/mL	n/a	< 20**	< 10

* If hardness is greater than 150 mg/L, a water softener is recommended unless used for washing and the cleaning chemistry is capable of handling higher levels of hardness.

** After high-level disinfection.

Source: AAMI TIR 34:2014 Water for the Reprocessing of Medical Devices

Cleaning Equipment and Accessories

Mild/neutral pH enzymatic cleaning solution (e.g. Enzol)

Cleaning basin or sink

Flat Cleaning brush (P/N 27652/3)

Short Cleaning brush (P/N 9990/50)

Long cleaning brush (P/N 110910-50)

Long Cleaning brush (P/N 11276 CL2/10)

60 cc Syringe

Soft, lint-free cloth

Lens cleaner or cotton tip applicator

70% Isopropyl alcohol

Luer plug (P/N 29100-BK)

Cleaning adaptor (P/N 11301 CD1)

Sterile suction valve (P/N 11301 CE1)

Rinse tube assembly (P/N 11301 CDT)

Cleaning cap (P/N 8401 YZ)

Pressure compensation cap (P/N Z11457)

Leakage Tester (P/N 13242XL)

Bedside Pre-cleaning (at point of use)

Water Quality Recommendation: Utility water

1. Wipe the entire exterior of the flexible endoscope with a soft, lint-free, cloth, moistened with water, or a diluted mild/neutral pH enzymatic cleaning solution (e.g. Enzol). This step is to remove gross debris from the exterior of the flexible endoscope.

2. Ensure the instrument port is plugged during this process (e.g. use the Luer plug (P/N 29100-BK) or a gloved finger to cover the port). Immerse the distal tip of the flexible endoscope in a basin of water. Depress the suction valve (P/N 11301CE1) and suction (using a syringe or suction pump attached to the suction outlet) the channel with a minimum of 100 mL (3.4 oz.) of water, or a diluted mild/neutral pH enzymatic cleaning solution (e.g. Enzol).

3. Disconnect the flexible endoscope from the monitor.

4. Inspect the vent port and the video pin connector area removing any visible debris on the external surface with a 70% isopropyl alcohol wipe.

5. Carefully place the flexible endoscope into a covered tray or container and transport the scope to the decontamination area. Ensure the flexible endoscope is kept protected during transport.

6. Dispose of all valves and plugs.

Note: Complete cleaning of the patient-used flexible endoscope should be started **within two hours** of the bedside pre-cleaning. If transit time is greater than **2 hours**, ensure that additional manual cleaning (see Manual Cleaning Section) is performed if visible residual debris is still present.

Leakage Test

Water Quality Recommendation: Utility water

CAUTION: Before proceeding to manual cleaning, always perform a leak test on the flexible endoscope. Leaking flexible endoscopes must not be used in medical procedures as they pose a patient safety risk. If a flexible endoscope is leaking, it should be sent to KARL STORZ for repair or replacement (see Endoscope Return Instructions). The use of unauthorized repair facilities voids the product warranty and recommended reprocessing methods from KARL STORZ.

CAUTION: KARL STORZ requires the use of the KARL STORZ Leakage Tester (P/N 13242XL) to prevent possible damage to the flexible endoscope.

CAUTION: Check the KARL STORZ Leakage Tester (P/N 13242XL) for any damage prior to use. Damaged KARL STORZ Leakage Testers (P/N 13242XL) should not be used and should be returned to KARL STORZ for repair or replacement.

CAUTION: The cleaning cap (P/N 8401 YZ) MUST be in place on the video pin connector before immersing in liquids.

CAUTION: The KARL STORZ Leakage Tester (P/N 13242XL) should be disinfected prior to use by wiping it down with a 70% isopropyl alcohol wipe.

CAUTION: The pressure compensation cap (P/N Z11457) must be removed from the vent port (if present) before immersion in any liquids.

Note: In lieu of the KARL STORZ Leakage Tester (P/N 13242XL), an automated air pump, Zutron Medical Automated Leak Tester (P/N ZUTR30005) may be used to pressurize the flexible endoscope during the wet leak test. Refer to the pump manufacturer's instructions for operating procedures.

Note: Disinfect the sink or basin to be used for leak testing using a healthcare approved surface disinfectant. After disinfecting, be sure to thoroughly rinse the sink or basin with water to remove all of the disinfectant chemicals.

1. If present, remove the pressure compensation cap (P/N Z11457) from the flexible endoscope.
2. Inspect the video pin connector and vent port. Confirm that the area is clean. If debris is present carefully remove the debris with a 70% isopropyl alcohol wipe.
3. Put on the cleaning cap (P/N 8401 YZ) for the video pin connector and ensure that it is securely in place. Fluid entering this area can cause damage to the flexible endoscope.
4. Ensure that both the flexible endoscope vent port and KARL STORZ Leakage Tester (P/N 13242XL) are completely dry before conducting the leak test.

5. Attach the KARL STORZ Leakage Tester (P/N 13242XL) or automated leak tester using the adaptor at the end of the tubing to the flexible endoscope's vent port using a clockwise push and turn motion until it stops.

6. Pump up the KARL STORZ Leakage Tester (P/N 13242XL) until a pressure of 200 mmHg is reached. Fully articulate the distal tip 5 times in each direction using the control lever, then reduce the pressure by pressing the pressure release button until the pressure reaches 160 mmHg.

Note: If using an automated leak tester, set the leak tester pressure to 160 mmHg and turn it on.

Warning: If 160 mmHg pressure decreases on the KARL STORZ Leakage Tester (P/N 13242XL), do not continue with reprocessing. Refer to Endoscope Return Instructions for return instructions.

Warning: Do not perform a wet leak test in water containing detergent as bubble observation is difficult to perform with detergent present.

7. While pressurized, submerge the entire flexible endoscope into a basin or sink containing a minimum of 10 L (2.6 gallons) of room temperature water (no detergent). The leak tester should be outside the basin or sink and should not be immersed. Ensure the flexible endoscope is COMPLETELY submerged. If surface bubbles are visible on the flexible endoscope after submerging, use a syringe filled with water to remove them.

8. While submerged, attach the rinse tube assembly (P/N 11301CDT) to the cleaning adaptor (P/N 11301CD1) and attach the cleaning adaptor (P/N 11301CD1) to the suction port. Draw at least 10 mL of water using a syringe. Attach the filled syringe to the rinse tube assembly (P/N 11301CDT) and flush the water.

9. Keep the flexible endoscope submerged for 1 minute, while fully deflecting the distal tip as follows:
   - Place the distal tip in the neutral (straight) position and hold for 15 seconds.
   - Articulate the distal tip to the full up position and hold for 15 seconds.
   - Articulate the distal tip to the full down position and hold for 15 seconds.
   - Place the distal tip in the neutral (straight) position again and hold for 15 seconds.

10. Observe for a formation of bubbles on the exterior of the flexible endoscope or a stream of air bubbles.

11. If the flexible endoscope has a leak as determined by a fall in pressure as seen on the KARL STORZ Leakage Tester (P/N 13242XL) or if bubbles are discovered per the steps above, immediately remove the flexible endoscope from the water. Press the pressure release button on the KARL STORZ Leakage Tester (P/N 13242XL) or turn off the automated leak tester to reduce the pressure to 0. Detach the Leakage Tester (P/N 13242XL) from the flexible endoscope and refer to the "Endoscope Return Instructions" for further instructions.

12. If the flexible endoscope does not leak, remove it from the water bath and press the pressure release button on the KARL STORZ Leakage Tester (P/N 13242XL) to release pressure to "0" or follow the air pump's manufacturer instructions for releasing pressure from the flexible endoscope.

13. After the pressure drops to "0", detach the KARL STORZ Leakage Tester (P/N 13242XL) or automated leak tester from the flexible endoscope and proceed to manual cleaning.

Manual Cleaning

CAUTION: When preparing and using the cleaning solutions, follow the manufacturer's instructions for proper solution concentration and temperature.

CAUTION: Flexible endoscope must not be cleaned in an ultrasonic bath.

CAUTION: The pressure compensation cap (P/N Z11457) must be removed from the vent port (if present) before immersion in any liquids.

CAUTION: All brushing/flushing should be done with the endoscope fully immersed under water to avoid formation of aerosols. Aerosols of material from a patient-used endoscope pose an infection risk to reprocessing personnel and may lead to contamination of the environmental surfaces. Immersion during cleaning reduces these risks.

CAUTION: Never use a needle or other sharp objects for removing dirt particles from the device, as this may cause damage.

CAUTION: The flexible endoscope must be in the neutral (distal end straight) position whenever a cleaning brush is inserted into the working channel to prevent possible damage to the instrument channel from occurring.

CAUTION: Inserting a brush of incorrect size or forceful insertion can damage the flexible endoscope / instrument channel.

CAUTION: Only use cleaning accessories from or approved by KARL STORZ.

Note: Complete cleaning of the patient-used endoscope should be **started within two hours** of the bedside pre-cleaning. If transit time post patient procedure is greater than **2 hours**, ensure that additional cleaning is performed if visible residual debris is present.

Detergent Cleaning

Water Quality Recommendation: Utility or critical water

1. Disinfect the sink or basin to be used for cleaning following the healthcare facility recommended methods. After disinfecting, thoroughly rinse the sink or basin with water to remove all of the disinfectant chemicals.

2. Prepare the diluted mild/neutral pH enzymatic cleaning solution in the sink or basin.

3. Ensure the video cable is wiped with a cleaning solution soaked soft, lint free cloth and the cleaning cap (P/N 8401 YZ) is securely in place.

4. Attach rinse tube assembly (P/N 11301CDT) to the cleaning adaptor (P/N 11301CD1) and attach the cleaning adaptor (P/N 11301CD1) to the suction port. Attach a 60 cc syringe to the rinse tube assembly (P/N 11301CDT).

5. Plug the instrument port with the Luer plug (P/N 29100-BK).

6. Completely immerse the scope in the enzymatic cleaning solution.

7. While immersed, suction a minimum of 100 mL of cleaning solution through the channel using the 60 cc syringe attached to the rinse tube assembly (P/N 11301CDT).

8. Discard the solution drawn through the channel in a separate container.

CAUTION:: DO NOT discard in the basin the Flexible Videoscope is being cleaned in.

9. Remove the rinse tube assembly (P/N 11301CDT) and cleaning adaptor (P/N 11301CD1) from the suction port and the Luer plug from the instrument port.

10. While immersed, use a soft, lint-free cloth to clean the exterior of the entire Flexible Videoscope. A minimum of one complete wipe of the entire exterior of the Flexible Videoscope should be performed. If visible debris remains, continue wiping until no debris is visible.

11. Use the soft, flat cleaning brush (P/N 27652/3) to brush the exterior surfaces of the scope handle, including the areas between the deflection lever and handle, and suction and instrument port. Brush the entire handle surface a minimum of 3 times. If visible debris remains, continue wiping until no debris is visible.

12. Clean the suction outlet and the instrument port with the short cleaning brush (P/N 9990/50). Insert the brush and rotate 360° three times.

13. Insert the long cleaning brush (P/N 110910-50) into the suction port and slowly push the brush into the channel until resistance is felt. Pull the brush back out of the channel. Rub the bristles to remove any debris and repeat two more times (for a minimum of 3 brushes). If visible debris remains, repeat until no visible debris is observed on the brush bristles.

CAUTION: Do not force the long cleaning brush (P/N 110910-50) through the entire channel. The long cleaning brush (P/N 110910-50) is intended to clean the channel between the suction port and the instrument port. When brushing, remove the brush from the suction port once resistance is felt in the channel and repeat the brushing process as described in Step 13.

14. Insert the long cleaning brush (P/N 11276CL2) into the suction port and push through the channel until the brush exits the distal end. Rub the bristles to remove any debris and pull the brush back through the channel. Rub the bristles to remove any debris and repeat two more times (for a minimum of 3 brush passes). If visible debris remains, repeat until no visible debris is observed on the brush bristles.

15. Insert the same long cleaning brush (P/N 11276CL2) into the instrument port and repeat a minimum of 3 brush passes through the channel. If visible debris remains, repeat until no visible debris is observed on the brush bristles.

16. Attach rinse tube assembly (P/N 11301CDT) to the cleaning adaptor (P/N 11301CD1) and attach the cleaning adaptor (P/N 11301CD1) to the suction port. Then, attach a 60 cc syringe to the rinse tube assembly (P/N 11301CDT).

17. Plug the instrument port with the Luer plug (P/N 29100-BK).

18. Draw a minimum of 50 mL of cleaning solution into the syringe and then flush back through the channel.

19. Remove the Luer plug (P/N 29100-BK) and attach a 60 cc syringe to the instrument port.

20. Draw a minimum of 50 mL of cleaning solution into the syringe and flush back through the channel.

21. Keep the Flexible Videoscope immersed for the manufacturer's recommended contact time (e.g. Enzol immersion for a minimum of 1 minute).

22. Remove the 60 cc syringe from the port and re-plug the port with the Luer plug (P/N 29100-BK).

23. Draw air into the 60 cc syringe and attach it to the rinse tube assembly (P/N 11301CDT). Holding the distal end of the Flexible Videoscope out of the cleaning solution, flush the 60 cc of air to expel all the cleaning solution from the channel.

24. Remove the Flexible Videoscope from the cleaning solution.

25. Discard all disposable cleaning accessories and use new accessories for water rinsing.

Water Rinsing

Water Quality Recommendation: Utility or critical water

1. Disinfect a new sink or basin to be used for rinsing following your healthcare facility's recommended method. After disinfecting, be sure to thoroughly rinse the sink or basin with water to remove all of the disinfectant chemicals.

2. Fill the sink with a minimum of 10 L (2.6 gallons) of room temperature water. Ensure there is sufficient volume of rinse water to COMPLETELY immerse the Flexible Videoscope.

3. Completely immerse the Flexible Videoscope in the water.

4. Thoroughly wipe the exterior of the entire Flexible Videoscope with a fresh, soft, lint-free cloth. A minimum of one complete wipe should be done.

5. Attach the rinse tube assembly (P/N 11301CDT) to the cleaning adaptor (P/N 11301CD1) and attach the cleaning adaptor (P/N 11301CD1) to the suction port. Then attach a 60 cc syringe to the rinse tube assembly (P/N 11301CDT).

6. Plug the instrument port with the Luer plug (P/N 29100-BK).
7. Draw a minimum of 50 mL of water into the syringe and flush back through the channel.
8. Remove the Luer plug (P/N 29100-BK) and attach a 60 cc syringe to the instrument port.
9. Draw a minimum of 50 mL of water into the syringe and flush back through the channel.
10. Remove the syringe from the instrument port and re-plug the port with the Luer plug (P/N 29100-BK).
11. Draw air into the 60 cc syringe and attach to rinse tube assembly (P/N 11301CDT). Holding the distal end of the Flexible Videoscope out of the water, flush the 60 cc of air to expel all the water from the channel.
12. Discard the water and repeat with fresh water for a total of two (2) immersion/flush/rinses and air flushes.

Drying

1. Remove the Flexible Videoscope from the water.
2. Remove the cleaning adaptor (P/N 11301CD1) and cleaning cap (P/N 8401 YZ).
3. Discard all disposable cleaning accessories.
4. Dry the exterior with a fresh soft, lint-free cloth.

Inspection

1. Visually inspect the Flexible Videoscope for cleanliness. Do not proceed with sterilization or high-level disinfection if residual soil is visible. Repeat all steps of the manual cleaning if residual soil is observed.
2. Prior to sterilization/high-level disinfection, inspect the Flexible Videoscope for signs of damage (cuts, dents, or scratches) that may trap residual debris. If damage is found, the Flexible Videoscope should be immediately tagged and labeled as damaged to prevent any further patient use. Refer to the “Endoscope Return Instructions” for further instructions.
3. If no damage is found on visual inspection, clean the distal lens using a 70% isopropyl alcohol wipe. Wipe in a circular movement.
4. Proceed to sterilization or high-level disinfection.

Sterilization

Warning:: Before sterilization, the Flexible Intubation Video Endoscope must be thoroughly cleaned and all visible organic material, blood, and cleaning solution be completely removed.

CAUTION: Flexible Intubation Video Endoscopes must not be steam sterilized (autoclaved) under any circumstances.

Warning: The pressure compensation cap (P/N Z11457) must be in place on the vent port for gas sterilization)

Sterilization Methods

Ethylene Oxide (EtO) Sterilization

1. Remove the cleaning cap 8401 YZ on the video connecting cord before sterilization.

2. Place the red pressure compensation cap (P/N Z11457) on the vent port before EtO gas sterilization.

3. Place the flexible endoscope in an FDA-cleared EtO gas sterilization tray.

4. Wrap the sterilization tray with two single layers of FDA-cleared polypropylene EtO gas-compatible sterilization wrap, using a sequential double wrapping technique.

5. Process in 100% Ethylene Oxide Sterilizer under the following parameters:

CONDITIONING PARAMETERS	
Temperature:	55° C (131° F)
Humidity:	70% RH
Conditioning Dwell Time:	30 minutes
STERILIZATION PARAMETERS	
Temperature:	55° C (131° F)
Humidity:	70% RH
Humidity Dwell Time:	30–45 minutes
EtO Gas Concentration:	725 ± 30 mg/L
EtO Gas Exposure Time:	60 minutes
AERATION PARAMETERS	
Time:	12 hours
Temperature:	51–59° C (120°–130° F)

STERRAD Systems Sterilization

CAUTION: STERRAD Sterilization may cause cosmetic changes to the Flexible Intubation Video Endoscope that do not necessarily impact the functionality of the device.

CAUTION: Place the pressure compensation cap (P/N Z11457) on the vent port before STERRAD sterilization.

CAUTION: The Flexible Intubation Video Endoscope must be fully DRIED before loading into the STERRAD sterilizer. Loads containing moisture may cause a cycle cancellation.

CAUTION: Only use FDA-cleared polypropylene sterilization wraps. Do not use paper pouches or sterilization wraps containing wood pulp or cotton.

1. Place the Flexible Intubation Video Endoscope in a STERRAD compatible instrument tray.
2. Place a STERRAD indicator strip in the tray.
3. Double wrap the sterilization tray with two single layers of FDA-cleared polypropylene wrap, using a sequential double wrapping technique.
4. Load the STERRAD sterilizer, arranging the tray such that the vapor hydrogen peroxide can surround it. Do not allow the tray to touch the wall of the sterilizer.
5. Start the STERRAD sterilizer using the 'FLEX' cycle for the 100NX system or the “Advanced” cycle for the NX system.
6. For outside U.S. only: Use the "Long" cycle with the appropriate STERRAD Boosters for the 100S System. Place adaptor 11301CD1 onto the flexible videoscope suction port to attach the STERRAD Booster Adaptor.

Note: Please consult the STERRAD Sterilization System User Guide for detailed instructions for use of the STERRAD Sterilizer, or contact Advanced Sterilization Products (ASP) customer service at (888) 783-7723.

Amsco V-PRO maX Sterilization

CAUTION:: Place the pressure compensation cap (P/N Z11457) on the vent port before Amsco V-PRO maX sterilization.

CAUTION: The Flexible Intubation Video Endoscope must be fully DRIED before loading into the V-PRO sterilizer.

CAUTION: Only use FDA-cleared polypropylene sterilization wraps. Do not use paper pouches or sterilization wraps containing wood pulp or cotton.

1. Place the Flexible Intubation Video Endoscope in a V-PRO compatible tray.
2. Double wrap the sterilization tray with two single layers of FDA-cleared polypropylene wrap, using a sequential double wrapping technique.
3. Load the tray into the V-PRO sterilizer.
4. Start the sterilizer using the “Flexible” Cycle.

STERIS System 1E/1 (SS1E/SS1) Liquid Chemical Sterilant Processing System

Note: The STERIS System 1 is not a legally marketed device in the United States. It may only be used outside of the U.S.

CAUTION: Remove the pressure compensation cap (P/N Z11457) from the vent port prior to SS1E processing.

CAUTION: Processing in the SS1E/SS1 must occur immediately prior to use, since wet devices cannot maintain sterility.

1. Place the Flexible Intubation Video Endoscope into the Universal Flexible Processing Tray C1160E/C1160INT or flexible endoscope Processing Container/Tray C1140E/C1140INT
2. Attach the Quick Connect QKC1694E/QKC1694INT or QKC1705E/QKC1705INT onto the scope and its respective compatible trays C1160E/C1160INT or C1140E/C1140INT.
3. Place the lid on the tray and load the tray into the SS1E/SS1.
4. Start the SS1E/SS1.

Note: Please consult the SS1E/SS1 Operator Manuals and Quick Connects QKC1694E/QKC1694INT and QKC1705E/QKC1705INT Manuals for complete instructions on the proper use of the SS1E/SS1.

Manual High-Level Disinfection

Warning: High-level disinfection (minimum requirement) is recommended ONLY for "semi-critical" instruments which only come into contact with mucous membranes or minor skin breaches.

CAUTION: Remove the pressure compensation cap (P/N Z11457) from the vent port before immersing in liquids.

CAUTION: Place the 8401 YZ protective cap on the video connecting cord prior to immersion in any liquids.

The Flexible Intubation Video Endoscope may be chemically disinfected using CIDEX, a high-level disinfectant containing 2.4% concentration of glutaraldehyde, CIDEX OPA, a 0.55% concentration of *ortho*-phthalaldehyde, or Resert XL HLD, a 2.0% concentration of hydrogen peroxide.

1. Prepare the disinfecting solution for use:
   a. CIDEX: Activate the glutaraldehyde solution by adding the entire contents of activator vial to the solution in the container. Shake well. Activated solution immediately changes color to green, thereby indicating the solution is ready to use. Use CIDEX Solution Test Strips to verify the solution is above the minimum recommended concentration (MRC). Test the solution prior to each use. Do not use activated solution beyond stated 14 day reuse life. Record the date of activation and expiration on the container.
   b. CIDEX OPA: No activation is necessary. Use CIDEX OPA Solution Test Strips to verify the solution is above the minimum recommended concentration (MRC). Test the solution prior to each use. Record the date the solution was poured out of the original container.
   c. Resert XL HLD: No activation is necessary. Use Verify Chemical Monitoring Strip for Resert XL HLD Solution to confirm hydrogen peroxide concentration before each use. Record the date the solution was poured out of the container.
2. Place the Flexible Intubation Video Endoscope into a plastic container containing the disinfection solution. Ensure that the scope is fully immersed and remove any air bubbles adhered onto the surfaces. Fill all working channels with the disinfection solution using a syringe.
3. Use the following KARL STORZ validated conditions to achieve high-level disinfection:
   a. CIDEX: Immerse for 45 minutes at 25° C (77° F)
   b. CIDEX OPA: Immerse for 12 minutes at 20° C (68° F)
   c. Resert XL HLD: Immerse for 8 minutes at 20° C (68° F)
4. After disinfection is complete, remove the flexible intubation video endoscope from the disinfection solution and completely immerse in a large volume of sterile water (e.g. 2 gallons). Flush the channels with water to remove disinfection solution. Keep immersed for one minute. Discard the water and repeat with fresh sterile water for a total of three immersion rinses.

Note: Please refer to the disinfectant manufacturer's instructions-for-use for more detailed information regarding the use of disinfectant solution, including proper rinsing techniques.

5. Dry the scope with a soft, lint-free, sterile cloth or clean, dry, oil-free compressed air (<5 psi). To dry out the channel, flush it with clean, dry, oil-free compressed air (<5 psi).

Automated High-Level Disinfection

KARL STORZ and Medivators have completed a validation of the flow properties of the Medivators Reprocessing Systems with the Flexible Intubation Video Endoscope. The scope is compatible with the following Medivators units provided the correct hookups are used:

Reprocessor Model DSD/SSD and DSD Edge are used with hookup #DSD-110-HU0101 along with cleaning adaptor 11301CD1.

Reprocessor Model CER-1 (MV-1) and CER-2 (MV-2) are used with hookup # CLM-110-HU0080 and CLM-110-HU0137 along with cleaning adaptor 11301CD1.

Reprocessor Model Advantage and Advantage Plus use hookup # 2-8-245HAN along with cleaning adaptor 11301CD1.

Recommended high-level disinfection agents for Medivators Reprocessing Systems:

Use CIDEX, CIDEX OPA, or Rapicide, or Rapicide OPA/28 for reprocessor models CER-1 (MV-1), CER-2 (MV-2), and DSD/SSD.

Use Rapicide PA for reprocessor models DSD Edge and Advantage Plus.

Use only Rapicide for reprocessor model Advantage.

Reference for Cleaning and Sterilization

American National Standards Institute/Association for the Advancement of Medical Instrumentation: Flexible and Semi-Rigid Endoscope Processing in Health Care Facilities: ANSI/AAMI ST91:2015.

Storage

CAUTION: To prevent biofilm formation within the endoscope channel it is critical that the scope channels be thoroughly dried prior to storage.

CAUTION: Care must be taken during handling to prevent contact with other objects and the distal end from swinging freely. The distal end must be under control at all times.

Note: To ensure the channels are not wet during storage, the use of a “channel-purge” endoscope storage cabinet (i.e. medical grade filtered air is flushed through every channel) is the preferred method of storage. If this is not available adequate manual drying using forced air (< 5 psi) must be performed for **at least 10 minutes** prior to storage.

1. When handling the flexible endoscope, make certain the shaft is loosely coiled to avoid possible damage.

2. Support the flexible endoscope with both hands when holding it.

3. Do not expose flexible endoscopes to direct sunlight or excessive heat.

4. Store the flexible endoscope either in the sterilization tray specific to that flexible endoscope (for EtO or STERRAD sterilization).

5. For storage of endoscopes post manual or automated HLD or post-SS1E, a channel-purge storage cabinet is preferred. If a channel-purge storage cabinet is not available, hang the endoscope suspended in the appropriate KARL STORZ wall rack. Ensure it is absolutely dry before placing in storage (see Note above).

Endoscope Return Instructions

CAUTION: The pressure compensation cap (P/N Z11457) must be in place on the vent port during shipment.

Contact KARL STORZ Customer Support team at 800-421-0837 to obtain a Return Material Authorization (RMA). Returns will not be accepted by KARL STORZ without issuance of an RMA.

Perform a leak test. If no leaks are detected, clean and sterilize or high-level disinfect the flexible endoscope per the instructions in this manual. Return the flexible endoscope to KARL STORZ for service.

Warning: Leaking flexible endoscopes cannot be effectively cleaned, high-level disinfected or sterilized and should never be used on a patient.

If the leak is detected and found on the exterior of the flexible endoscope and can be sealed with waterproof tape, do so and submit the flexible endoscope to a full manual cleaning and high-level disinfection or sterilization.

If the leak cannot be sealed with waterproof tape, do not submerge flexible endoscope. Instead, wipe down the flexible endoscope with diluted neutral/mild pH enzymatic cleaning solution to remove all visible debris. Then, brush the channel with the channel cleaning brush.

Warning: Since leaking flexible endoscopes cannot be effectively cleaned, high-level disinfected or sterilized,they must be handled and shipped as a contaminated device following your institution's policies.

System Description

The Flexible Intubation Video Endoscope from KARL STORZ has a 650 mm pellethane working shaft, 4.1 mm in diameter and an instrument channel 1.5 mm in diameter. The PEEK (polyetheretherketone) distal tip is 4.00 mm in diameter and houses the CMOS video module. The distal tip of the Flexible Intubation Video Endoscope can be deflected 140° up or 140° down. The handle houses the deflection lever and the LED light source.

The Flexible Intubation Video Endoscope from KARL STORZ is connected to the recommended monitor 8403 ZX using the integrated 2 m supply cable. If an SD memory card is inserted in the monitor 8403 ZX, images and videos can be saved using the function buttons on the videoscope and monitor assigned to the video and image registration functions.

Technical Data

Flexible Intubation Video Endoscope 11302 BDX

Direction of view:	0°
Angle of view:	100° (8403 ZX)
Deflection:	up 140°, down 140°
Working length:	650 mm
Outside diameter:	4.1 mm
Working channel:	1.5 mm
Illumination:	integrated LED light source
Electrical power consumption:	1W
Sensor:	CMOS technology
Weight	385 g
Drip water protection:	IPX8
Classification:	IIa
Applied part:	Type BF

Operating/storage conditions

Operating conditions:	15° C–37° C (59° F–98.6° F) 15%–80% relative humidity
Storage conditions:	0° C–55° C (32° F–131° F) 15%–90% relative humidity

Servicing and Repair

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

Maintenance

Preventive maintenance is not essential. Regular maintenance can help identify potential problems before they become serious, enhancing the instrument's reliability and extending its useful operating life.

Maintenance services can be obtained from your local KARL STORZ representative. Regardless of the accident prevention regulations or testing intervals for medical instruments prescribed in different countries, we recommend a functional or safety test of the unit at least once a year.

Directive Compliance

CE 0123

According to Medical Device Directive (MDD):

This medical product bears the CE mark in accordance with the Medical Device Directive (MDD) 93/42/EEC. A code number after the CE mark indicates the responsible notified body.

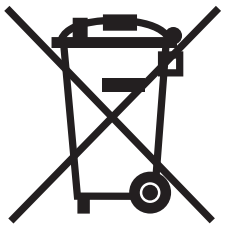
Important Information

To avoid the spread of infectious illnesses among hospital staff or among KARL STORZ employees, telescopes, instruments and equipment must be cleaned and sterilized/disinfected before they are sent for repair. We reserve the right to return contaminated instruments/equipment to the sender.

Repairs, changes or expansions which are not carried out by KARL STORZ or by experts authorized by KARL STORZ will invalidate all warranty rights.

KARL STORZ gives no warranty on the correct functioning of equipment or instruments which have been repaired by unauthorized third parties.

Disposal



This unit has been marked in accordance with the European Directive 2002/96/EC on waste electrical and electronic equipment (WEEE). At the end of its service life, dispose of the device as electronic waste. Please ask either KARL STORZ GmbH & Co. KG, a KARL STORZ subsidiary or your specialist dealer for information about your local collection point. Within the scope of application of this directive, KARL STORZ GmbH & Co. KG is responsible for the proper disposal of this device.

Troubleshooting

Symptom	Possible causes	Remedy
Image unclear	Distal objective lens fogged	Rinse lens
	Dirty lens.	Withdraw Flexible Intubation Video Endoscope and clean distal lens with cotton tip applicator and alcohol.
	Lens water-damaged.	Send Flexible Intubation Video Endoscope to KARL STORZ for repair.
Inadequate lighting	Light conducting fibers damaged.	Send Flexible Intubation Video Endoscope to KARL STORZ for repair.
Light does not function	Not connected to power.	Connect to power.
Complete failure of the unit	No power from power line	Check the electrical supply
Possible lighting up of status display	Power cord connector is not properly connected to power cord receptacle	Push power cord connector firmly into the power cord receptacle
	System error	Carry out reset (see page 24).
No image, TFT screen is dark	Defective camera electronics	Send Flexible Intubation Video Endoscope to KARL STORZ for repair.
	TFT screen defective	Send TFT screen to KARL STORZ for repair.
Color distortions	White balance correct	Carry out new white balance.
	TFT screen defective	Send TFT screen to KARL STORZ for repair.
	Incorrect color setting on the monitor	Set the color on the monitor (see page 17).
Image cannot be saved	No memory card inserted	Insert memory card.
	Memory card full	Change memory card.
Video stream cannot be played back on the PC monitor.	No MPEG-4 codec installed	Install an MPEG-4 codec on the PC

Accessories

8401 YAA

8401 YB

8401 YA

Stand, height 120 cm, star-foot roller stand with antistatic castors, crossbar 25 cm x diameter 25 mm for positioning the monitor, including storage tray for laryngoscopes, measurements (w x d x h): 30 x 20 x 10 cm — 8401 YA (US 9700GCX)

Crossbar, for stands 8401 YA, 50 cm x diameter 25 mm, for positioning the monitor 8403 ZX — 8401 YAA

Multifunctional clamp with VESA 75 standard holder. Suitable for securing rods with a max. diameter of 24 mm and rails with a max. height of 25 mm — 8401 YB (US 9700 CLP)

8401 YZ

Cleaning cap to protect contacts during reprocessing. The cap is reusable. — 8401 YZ

Holder for flexible endoscopes for mounting to standard tubes, including installation accessories — 29005 IFH

29005 IFH

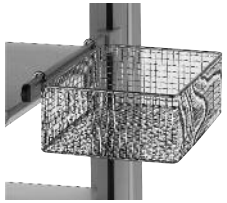
ProShield Protection Tube, for flexible telescopes, for single use, unsterile, distal closed, package of 10, for use with Holder for flexible endoscopes 29005 IFH — 11301 BC

Accessories

200220 85

200220 86

200220 47



29005 AK

8401 XA

Airway TROLL-E, rides on 4 antistatic dual wheels, 2 equipped with locking brakes, for mounting monitors with VESA 75/100 connection,integrated cable conduit in vertical beam and cable manager, load capacity for monitor: maximum 15kg.
Dimensions mobile stand: 670 x 1660 x 670 mm (w x h x d),
Caster diameter: 100 mm Trolley is delivered unassembled. — 200220 85

C-MAC® TROLL-E, rides on 4 antistatic dual wheels, 2 equipped with locking brakes and stainless steel tube,
Dimensions mobile stand: 670 x 1500 x 670 mm (w x h x d),
Caster diameter: 100 mm, Trolley is delivered unassembled, — 200200 86

Wire Basket, for accessories, for mounting to equipment rail 29003 GS. Dimensions (w x h x d): 300 x 200 x 100 mm
For usage with equipment carts 29005 — 29005 AK

Shelf, including installation accessories, max. capacity 12 kg,
Dimensions: 455 x 350 mm (w x d),
For use with subracks for Mobile Stands 20020060 and 20020061 — 200200 47

Cable Adaptor for C-MAC®, 6-pin to 8-pin adaptor, dustproof according to IP50, for connecting 8-pin instruments to C-MAC® Monitor 8401 ZX, For use with: — 8401 XA

8401 ZX	Monitor, for CMOS endoscopes
11301BNX	Flexible Intubation Video Endoscope
8402 XS	C-MAC® S Imager
202901 32	C-CAM® Camera Head

Electromagnetic Compatibility (EMC) Information

Warning: Medical electrical equipment needs special precautions regarding Electromagnetic Compatibility (EMC). Observe the EMC instructions in this Appendix during installation and commissioning.

The Flexible Intubation Video Endoscope 11302 BDX in conjunction with monitor 8403 ZX corresponds to EN/IEC 60601-1-2 [CISPR 11 Class B] and therefore meets the EMC requirements of the Medical Device Directive (MDD) 93/42/EEC.

These limits are designed to provide reasonable protection against the typical electromagnetic interference to be expected in a medical environment. The Flexible Intubation Video Endoscope 11302 BDX in conjunction with monitor 8403 ZX is a Group 1 unit (as per CISPR 11).

Group 1 contains all the 'equipment and systems which generate or use RF energy only for their internal functioning'.

Note: The tables and guidelines that are included in this Appendix provide information to the customer or user that is essential in determining the suitability of the equipment or system for the electromagnetic environment of use, and in managing the electromagnetic environment of use to permit the equipment or system to perform its intended use without disturbing other equipment and systems or non-medical electrical equipment. If this equipment does cause harmful interference with other devices, the user is encouraged to try to correct the interference by one or more of the following measures:

- reorient or relocate the receiving device
- increase the separation between the equipment
- connect the equipment into an outlet on a circuit different from that to which the other device(s) is connected.

Warning: The use of portable and mobile RF equipment may have an impact on this and other pieces of medical equipment.

Warning: The use of accessories other than those specified in the KARL STORZ instruction manual may result in increased emissions or decreased immunity of the Flexible Intubation Video Endoscope 11302 BDX in conjunction with monitor 8403 ZX. The accessories listed below have been shown to comply with the requirements of EN/IEC 60601-1-2. When using accessories other than those specified here, it is the responsibility of the user to ensure that they comply with EN/IEC 60601-1 2.

Table 200

Accessories and cables which have been shown to comply with EN/IEC 60601-1-2:

Cable type	Shielded	Length (m)	Ferrite	Used for
Charger ET27-30-0004515	No	2.0	No	Charging the internal battery of C-MAC® monitor 8403 ZX

Table 201/Table 1

Guidance and manufacturer's declaration – electromagnetic emissions

The Flexible Intubation Video Endoscope 11302 BDX in conjunction with monitor 8403 ZX is intended for use in the electromagnetic environment specified below. The customer or user of the system should ensure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Complies Class 1	The Flexible Intubation Video Endoscope 11302 BDX in conjunction with monitor 8403 ZX uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause interference in nearby electronic equipment.
RF emissions CISPR 11	Complies Class B	The Flexible Intubation Video Endoscope 11302 BDX in conjunction with monitor 8403 ZX is suitable for use in all establishments other than domestic and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes
Harmonic emissions IEC 61000-3-2	Class A. Not applicable	
Voltage fluctuations/flicker emissions IEC 61000- 3-3	Complies	

Table 202 /Table 2
Guidance and manufacturer's declaration–electromagnetic immunity

The Flexible Intubation Video Endoscope 11302 BDX in conjunction with monitor 8403 ZX is intended for use in the electromagnetic environment specified below. The customer or user of the system should ensure that it is used in such an environment.

Immunity test	EN IEC 60601 test level	Compliance level	Electromagnetic environment–guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	Complies ± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile.If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	Complies ± 2 kV for power supply lines ± 1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge 61000-4-5	± 1 kV differential mode ± 2 kV common mode	Complies ± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of IEC a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T* (>95% dip in U_T) for 0.5 cycle	Complies <5% U_T* (>95% dip in U_T) for.5 cycle.	Mains power quality should be that of a typical commercial or hospital environment.
	40% U_T (60% dip in U_T) for 5 cycles	Complies 40% U_T (60% dip in UT) for 5 cycles	If the user of the equipment or system requires continued operation during power main interruptions, it is recommended that the equipment or system be powered from an uninterruptible power supply
	70% U_T (30% dip in U_T) for 25 cycles	Complies 70% UT (30% dip in U_T) for 25 cycles	
	<5% U_T (>95% dip in U_T) for 5 sec	Complies <5% U_T (>95% dip in U_T) for 5 sec	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3A/m	Complies 3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

* NOTE: U_T is the a.c. mains voltage prior to application of the test level.

Table 204/Table 4
Guidance and manufacturer's declaration – electromagnetic immunity – for equipment and systems that are not life-supporting

The Flexible Intubation Video Endoscope 11302 BNX in conjunction with monitor 8403 ZX is intended for use in the electromagnetic environment specified below. The customer or user of the system should ensure that it is used in such an environment.

Immunity test	EN IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Flexible Intubation Video Endoscope 11302 BNX in conjunction with monitor 8403 ZX, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance:
Conducted RF IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	3 volts	$d=[3.5/3]\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d=[3.5/3]\sqrt{P}$ 80 MHz to 800 MHz $d=[7/3]\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts [W] according to the transmitter manufacturer and d is the recommended separation in meters [m]. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with this symbol: 

Note: 1: At 80 MHz and 800 MHz, the higher frequency range applies

Note: 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection by structures, objects and people.

[a]Field strengths from fixed transmitters, such as 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 RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the unit is used exceeds the applicable RF compliance level above, the unit should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the unit.

[b]Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 206 /Table 6

Recommended separation distances between portable and mobile RF communications equipment and the KARL STORZ Flexible Intubation Video Endoscope 11302 BDX in conjunction with monitor 8403 ZX

The Flexible Intubation Video Endoscope 11302 BDX in conjunction with monitor 8403 ZX is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled.

The customer or user of the unit can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the unit as recommended below, according to the maximum output power of the communications equipment.

	Separation distance d [m] according to frequency of transmitter		
Rated maximum output power of transmitter [W]	150 kHz to 80 MHz $d=[3.5/3]\sqrt{P}$	80 MHz to 800 MHz $d=[3.5/3]\sqrt{P}$	800 MHz to 2.5 GHz $d=[7/3]\sqrt{P}$
0.01	0.1	0.1	0.2
0.1	0.4	0.4	0.7
1	1.2	1.2	2.3
10	3.7	3.7	7.4

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note: 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note: 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Shipping

Although KARL STORZ products are carefully packed to minimize in-transit damage, all shipments should be carefully examined upon receipt and if a product is damaged, Customer must document the nature and extent of the damage and immediately contact KSEA. If concealed loss or damage is discovered, Customer must retain all packing materials and immediately notify KSEA, requesting an inspection. If shipments are received short, Customer must contact KSEA's Customer Support Department at once. KSEA reserves the right to make partial shipments on any Order. Invoices for partial shipments are payable upon receipt. KSEA is not liable for any damages caused by or attributable to delays and/or non-delivery due to any cause whatsoever.

Return Policy

A return merchandise authorization (RMA) must be obtained from KSEA's Customer Support Department prior to returning any products. When phoning or writing KSEA, for an RMA, the Customer Support Representative must be provided with: (1) Customer name and number, as it appears on the invoice; (2) the telephone number and the person to contact; (3) the applicable P.O. number; (4) the KARL STORZ catalog number and, if applicable, the serial number for each product; and, (5) the reason for the return. KSEA reserves the right to refuse or return any products sent back to KSEA without prior authorization of its Customer Support Department. Returns must be carefully packed and shipped pre-paid to KSEA, attn: RMA number. KSEA's Customer Support Department will provide the return address and the RMA number. When returning products, Customer should include a copy of the original invoice or packing slip to ensure prompt issuing of credit. Full credit will only be issued for products that are returned within 30 days of invoice date and so long as such items are unused, in resalable condition and in their original product container. All products returned after 30 days from the date of invoice are subject to a 15% restocking fee. Shipping charges will be reimbursed, restocking fees will not be charged and full credit will be given if the return was due to an error on the part of KSEA. The following products may not be returned for credit or exchanged: (1) products held longer than 90 days from invoice date; (2) sterile packaged products where the package is opened and/or damaged; (3) discontinued products; (4) instruments that are etched or engraved by Customer; (5) products damaged by the Customer; (6) products purchased "as is" or as demo products; and,(7) used products. In order to prevent the transmission of disease to the medical facilities' and/or KSEA's personnel, all products must be cleaned and then sterilized and/or disinfected before sending such products back to KSEA, who reserves the right to return unclean and contaminated products to the Customer. Additionally, if any product becomes damaged and is not immediately returned, KSEA assumes no responsibility or liability for Customer's continued use of that damaged product. KSEA does not guarantee the performance, and may decline to repair or accept for repair/exchange, any product that has been repaired, modified and/or altered by any person or entity other than KSEA or an authorized repair facility of KSEA.

Repair Program

If repairs become necessary, for other than damages incurred during initial shipment, the Customer must follow the RMA procedure set forth in the “Return Policy”. Warranty repairs will be made without charge (see “Warranty Policy,” for covered repairs). All other repairs are subject to KSEA’s applicable standard repair or exchange charges. If requested, Customer will be advised of the estimated cost of the repair work or a product exchange before it is undertaken. All repairs carry a 90 day warranty. Exchange products carry the applicable KARL STORZ product warranty. If the damaged product is not returned within thirty (30) days of receipt of the replacement product, Customer will be invoiced for the full list price of the replacement. KSEA reserves the right to refuse or return any product sent back without prior authorization of KSEA’s Customer Support Department.

Warranty Policy

Except as otherwise provided herein and/or by the applicable warranty information for a specific product or type of product, all KARL STORZ-branded products are generally warranted to be in good working order at the date of delivery and free from defects in workmanship and materials for one (1) year from date of delivery. However, since some products carry a shorter or a longer warranty period, Customer should check with KSEA’s Customer Support Department or product specific literature, instruction manual and/or labeling for the exact warranty period. Any such product(s) with a defect occurring during the applicable warranty period will be promptly replaced or, at the sole discretion of KSEA, repaired at no charge to Customer. THIS WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESS, IMPLIED AND/OR STATUTORY, INCLUDING, BUT NOT LIMITED TO WARRANTIES OF MERCHANTABILITY, FITNESS AND/OR OF SUITABILITY FOR A PARTICULAR PURPOSE, WITH RESPECT TO ALL KARL STORZ PRODUCTS OR SERVICES. ANY AND ALL OTHER WARRANTIES, REPRESENTATIONS AND/OR GUARANTEES, OF ANY TYPE, NATURE OR EXTENT, BE IT IMPLIED, EXPRESS AND/OR WHETHER ARISING UNDER OR AS A RESULT OF ANY STATUTE, LAW, COMMERCIAL USAGE, CUSTOM, TRADE OR OTHERWISE, ARE HEREBY EXPRESSLY EXCLUDED AND DISCLAIMED. Any contrary course of performance by and between the parties will not modify any representations and/or warranties set forth herein. KSEA neither assumes nor authorizes any person to assume for it any other liabilities in conjunction with and/or related to the sale and/or use of its products. To ensure proper use, handling and care of KARL STORZ products, Customer should consult the product specific literature, instruction manual, and/or labeling included with the product or otherwise available. Repairs, modifications or alterations of KARL STORZ products, performed by any person or entity, other than by KSEA or an authorized repair facility of KSEA, nullifies and otherwise voids all applicable KARL STORZ warranties. Repair or replacement of a KARL STORZ product shall not extend the term of any applicable warranty. The remedies provided herein are Customer’s exclusive remedies under this Warranty Policy.

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