Instruction manual for “Flexible endoscopes”

*GAFLEX02

English

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2 Applicability

This instruction manual applies to the product group of flexible naso-pharyngo-laryngoscopes, ureterorenoscopes, bronchoscopes, cystoscopes from EMOS Technology GmbH.
This instruction manual contains important information for the safe and effective use of these instruments. Prior to use, read the instructions for all devices employed during the procedure and use them accordingly. If you have questions or comments on the contents of this instruction manual, please contact EMOS Technology GmbH.
This instruction manual also contains processing instructions for flexible endoscopes.

2.1 Product numbers

This instruction manual applies to the following article numbers:

FNS2200.X*

FNS2800.X*

FNS2812.X*

FNS3200.X*

FNS3400.X*

FNS3814.X*

FURS2812.X*

FBS5223.X*

FBS6028.X*

FCS5523.X*

X* = Placeholder for colour variant of the endoscope

3 Symbols

MD	Is a medical device	WL	Working length
	Observe instruction manual		Not sterile
	Information for proper handling		Protect from sunlight
	Date of manufacture		Store dry
	Manufacturer		Caution!
LOT	Production lot number, batch	CE	CE mark
SN	Serial number	0483	Identification number of the Notified Body
REF	Article number		Latex-free

4 Warnings

⚠ The instructions for use and processing as well as the specifications regarding accessories or medical devices used in combination should be carefully read, observed, and stored.

⚠ The endoscopes are not supplied sterile and must be cleaned, disinfected, and sterilised prior to first use as well as before every further use.

⚠ Endoscopes may not be cleaned in an ultrasonic bath.

⚠ The endoscopes may not be exposed to gamma rays.

⚠ Flexible endoscopes may not be autoclaved/steam-sterilised. Do not exceed temperatures of > 60°C.
If there are signs of damage, the endoscope may not continue to be used in any case.

⚠ If an unsuitable light source is selected, the light may be emitted from the light window with a high level of radiation energy and the temperature in the tissue may increase (> 41°C). Only light sources with max. 300 W (xenon) or 250 W (halogen) may be used. Overheated endoscopes may continue to be used only after

adequate cooling.

Failure to comply with this may lead to the death or a severe injury of the patient or to irreparable damage to the device.

5 General application instructions

The instruction manual contains important information for the operation and proper function of the flexible endoscopes. These instructions do not serve as a guide for or explanation of relevant surgical and/or examination techniques.
Every individual endoscope of EMOS Technology GmbH was developed for a particular area of application and may be used only in this area of application.
The flexible endoscopes are to be used exclusively for their intended purpose and by trained and qualified professionals. The surgeon is responsible for the selection and proper application of the endoscopes. These instructions cannot replace the user's training, care, and state of the art. EMOS Technology GmbH can provide training in the safe application of the endoscopes, if needed.

The endoscopes of EMOS Technology GmbH must be used in accordance with recognised medical regulations for endoscopic procedures and endoscopy practices. We therefore assume familiarity with the relevant legal regulations, standards, and recommendations (such as of the RKI (Robert Koch Institute) or also of the AKI (Arbeitskreis Instrumentenaufbereitung (Instrument Reprocessing Working Group))). The applicable country-specific laws and regulations should always be observed.

EMOS Technology GmbH endoscopes are precision instruments.
All metal parts are made of stainless steel. In patients with a hypersensitivity to components of high-alloy steels, it is the responsibility of the attending physician to clarify the patient’s possible allergic tendencies in an information discussion prior to use and to assess the residual risk or find alternatives.
The flexible endoscopes may not be used if, in the opinion of a responsible physician, such use could cause a hazard to the patient.

Please always handle your endoscope with utmost care.

After every cleaning/disinfection and before each use, the endoscopes are to be checked for cleanliness, function, and damage (see section 10).
Damaged or defective endoscopes may not be used. Damaged individual parts must be immediately replaced with original replacement parts. Damaged endoscopes are to be immediately taken out of service.
If a malfunction should occur during application on a patient, the application should be immediately discontinued.

- Protect the endoscope from direct sunlight.
- Protect the endoscope from X-rays.
- Protect the endoscope from vibrations.
- Always handle the endoscope with utmost care (impact).
- Do not strike the distal tip against hard objects.
- Do not kink the insertion tube (max. turning radius of 25 mm).
- Do not use endoscopes during discharge of a defibrillator.

In the event of suspected or diagnosed Creutzfeldt-Jacob syndrome (CJD or vCJD), measures must be taken immediately to prevent transfer to other patients, users, or third parties. The endoscopes may not be reused and are to be disposed of following thorough processing and sterilisation.

For reasons of infection prevention, shipping contaminated medical devices should on principle be strictly refused. The medical devices should therefore be decontaminated directly on site in order to avoid contact and airborne infections in staff.
EMOS Technology GmbH, as the company placing these devices on the market, does not assume any liability for direct damage or consequential damage that occurs due to improper use or handling, in particular due to a failure to observe

the enclosed instruction manual or due to improper care or maintenance.

The applicable country-specific laws and regulations should always be observed.

6 Intended use

Flexible endoscopes are used in diagnostic and surgical endoscopy. They are used for examination, diagnosis, and/or therapy in connection with endoscopic accessories, including within the framework of the product-specific intended purposes listed below.

6.1 Intended purpose

Flexible naso-pharyngo-laryngoscope:

During examination, diagnosis, and/or in connection with accessories for treatment that can be used endoscopically, flexible naso-pharyngo-laryngoscopes are used exclusively to visualise the nasopharyngeal region, including the trachea.

Flexible ureterorenoscope:

During examination, diagnosis, and/or in connection with accessories for treatment that can be used endoscopically, flexible ureterorenoscopes are used exclusively to visualise the upper urinary tract, including the ureters and renal pelvis.

Flexible bronchoscope:

During examination, diagnosis, and/or in connection with accessories for treatment that can be used endoscopically, flexible bronchoscopes are used exclusively to visualise the trachea and bronchi.

Flexible cystoscope:

During examination, diagnosis, and/or in connection with accessories for treatment that can be used endoscopically, flexible cystoscopes are used exclusively to visualise the lower urinary tract, including the urethra and urinary bladder.

6.2 Medical indication

Flexible naso-pharyngo-laryngoscope:

Flexible naso-pharyngo-laryngoscopes are indicated as an aid during examinations and for visualisation of the upper respiratory tract, among other things for the diagnosis of respiratory diseases, laryngeal disorders, throat pain, or swallowing problems, for the diagnosis of structural anomalies and possibly faulty functioning of the various structures or for therapeutic purposes, for microsurgical procedures or biopsies.

Flexible ureterorenoscope:

Flexible ureterenoscopes are indicated as an aid during examinations and for visualisation of the upper urinary tract, including the ureters and renal pelvis, among other things in the case of ureteral constriction, for the diagnosis of ureteral and renal pelvis tumours, for the clarification of unclear haematuria, and for the removal of urinary and renal calculi or calculus fragments following intra- or extracorporeal shock wave lithotripsy.

Flexible bronchoscope:

Flexible bronchoscopes are indicated as an aid during examinations and for visualisation of the trachea and the bronchi, among other things for the diagnosis of lung tumours, foreign bodies or constriction of the airways, to perform bronchial lavage, for biopsies or in the case of local radiation therapy.

Flexible cystoscope:

Flexible cystoscopes are indicated as an aid during examinations and for visualisation of the lower urinary tract including the urethra and urinary bladder, among other things for the diagnosis of and in the case of suspected tumours, foreign bodies, urinary calculi, fistula formation, urethral narrowing, in the event of recurrent or chronic bladder inflammation or urinary tract infections, haematuria, unclear urinary incontinence, or for tumour aftercare.

6.3 Contraindication

The use of flexible endoscopes is generally contraindicated if the use of other surgical techniques is indicated.
In addition, the following represent contraindications in general:

- general inoperability
- a lack of willingness on the part of the patient
- if the technical preconditions are not met
- applications outside of the intended purpose
- Not for use at the central circulatory and nervous system within the meaning of the Medical Device Regulation

6.4 Specific contraindications:

Flexible nasopharyngolaryngoscopy

- Acute epiglottitis
- Croup

Flexible ureterorenoscopy:

- Urinary tract infection, urosepsis
- Contraindications for the lithotomy position
- Anticoagulation or coagulation disorders:
    - No contraindication in the case of a diagnostic URS
    - A relative contraindication in the case of stone therapy
    - An absolute contraindication in the case of a planned biopsy (tissue removal)

Flexible bronchoscopy:

- Acute myocardial infarct
- Unstable haemodynamics with arrhythmia
- Severe blood clotting disorder
- Inadequate oxygenation during the examination / severe respiratory insufficiency
- Severe tracheal stenosis
- Massive endobronchial bleeding

Flexible cystoscopy:

- Acute infection or inflammation of the urinary tracts
- Severe blood clotting disorders

6.5 Target group (intended user group)

The flexible endoscopes may be used exclusively for their intended use in medical fields, only in medical facilities, and by medical professionals trained and qualified to do so (physician, medical assistants under the supervision of a physician). The attending physician or the user/operator is responsible for selecting the instruments for certain applications or surgical use, the appropriate training and information, and sufficient experience in handling the instruments.
The processing and sterilisation of the endoscopes and accessories is permitted only by professionals with qualified training.

6.6 Intended patient population

With regard to flexible naso-pharyngo-laryngoscopes, ureterorenoscopes, bronchoscopes and cystoscopes, there are no limitations or restrictions with regard to the patient population unless there is at least one contraindication. The attending physician or the user/operator is responsible for selecting the instruments for certain applications or surgical use, the appropriate training and information, and sufficient experience in handling the instruments.

7 Scope of delivery

Name	Image	Article number
Flexible naso-pharyngo-laryngoscope, ureterorenoscope, bronchoscope, cystoscope		See section 2.1
Leak tester complete with silicone tube and adapter		200.00040.02
Pressure compensation cap / ETO cap		200.02421.00
Wolf adapter		470.00049.00
Storz adapter		470.00882.00
Packaging / carton		270.00053.00
Instruction manual		GAFLEX02
Guarantee certificate		ZERT01

8 Combination

When combined with electrically operated accessories that can be used endoscopically, there is a possible hazard due to excessively high voltages and currents.
Ensure that patient leakage currents are minimised in the case of combinations.
To avoid an electrical coupling between the patient and the device, EMOS Technology GmbH recommends using EMOS Technology GmbH devices and accessories.
Combine flexible endoscopes with other medical devices only if:

- the intended use in the user and operating instructions permits this
- the technical data in the user and operating instructions permit this
- the standard of the TV lenses or cameras corresponds to the general standard

8.1 Accessories / Replacement parts

Article number	Name
220.00003.00	Stopcock bridge
200.00040.02	Leak tester complete with EMOS adapter, including silicone tube
200.02531.00	Mobile light source
LC35XX* - LC48XX*	Light guide cable (various)
LCXX*	Light guide adapter

All accessories and replacement parts are to be obtained exclusively from the manufacturer. Only the accessories recommended by EMOS Technology GmbH may be used together with the flexible naso-pharyngo-laryngoscopes, ureterorenoscopes, bronchoscopes and cystoscopes.

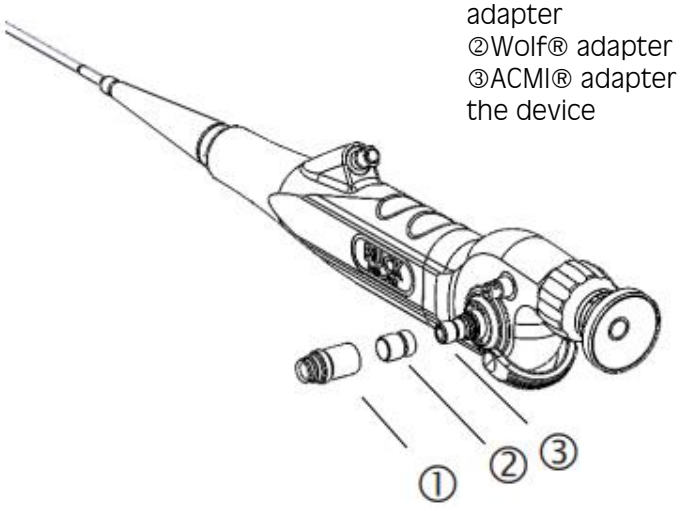
9 Assembly / Disassembly

- Assemble and disassemble the light guide connection according to the figure.
- Ensure that the adapters of the light guide cables correspond to the adapters of the flexible endoscopes (see figure). Corresponding connection systems only fit into the intended adapters.
- Adapters for Storz®/Aesculap®/Olympus® ① and Wolf® ② light guide connections are included in the scope of delivery as standard parts.
- To prevent the endoscope from becoming fogged during the surgery, the proximal end of the lens must be completely dry before attaching the camera or the camera adapter. To ensure a firm and secure connection of the individual components, ensure that the fastener of the endoscope and that of the adapter are not soiled or damaged.
- Always hold the flexible endoscope by the main body or the eyepiece. In doing so, handle the insertion tube carefully, that is, do not compress or squeeze it.
- Ensure that glass surfaces are not touched by other instruments.

Disassembly	**Assembly**
Light guide connection: - Unscrew the adapter ① or ② from the endoscope.	Light guide connection: - Screw on adapter ① or ②.
In the case of working channels – if present –: - Remove sealing cap. - Unscrew valve body. - Remove valve.	In the case of working channels – if present –: - Insert new valve. - Screw on valve body. - Put on sealing cap.

When disassembling contaminated endoscopes, there is a risk of infection

9.1 Assembly



①Storz®/Aesculap®/Olympus® adapter
②Wolf® adapter
③ACMI® adapter firmly mounted on the device

10 Inspection and maintenance

Before each testing and maintenance, allow endoscopes and accessories to cool to room temperature. Assemble detachable endoscopes and accessories.

- After each cleaning and disinfection, check flexible endoscopes and accessories for protein residues and contamination. Clean contaminated endoscopes and accessories once again. The flexible endoscopes may not have any residues of cleaning agents and disinfectants.
- Before every sterilisation and every use, the flexible endoscopes are to be checked for cleanliness, function, and damage.
- The entire endoscope should be free of any damage, such as loose, bent, deformed, fractured, cracked, rough, broken-off parts, worn surfaces, sharp edges, defective insulation, etc.
- Damaged, defective, stained or cloudy endoscopes and accessories should be taken out of service and

replaced. Defective cables must be replaced immediately.

- Ensure that no parts are missing or have become loose (e.g. sealing rings) and that the connection elements between the instruments are working properly.
- Visual inspection of the glass surfaces: The surfaces must be clean and smooth.
- Do not continue to use a device with damaged light guides, damaged glass surfaces or stubborn deposits that cannot be removed by cleaning.

If one of the deviations mentioned occurs, the endoscope may not be used further and must be sent to the manufacturer or an authorised service centre for repair (see section 14) or be properly disposed of (see section 16).

10.1 General inspection (visual inspection)

10.2 (Manual) leak test

A leak test is absolutely mandatory before each use, cleaning, disinfection, and sterilisation or other immersion processes.

It is performed using a leak tester with manometer.

- Prepare container with clean water or cleaning solution.
- The test connection and test connection tube must be dry.
- Place the connection cap firmly on the valve and turn it 90° counterclockwise. The tester is then securely connected to the endoscope and cannot come off.
- Generate a test pressure at the leak tester of max. 160 mm/Hg by pumping, visible by slight swelling of the angulation rubber at the distal angulation part.
- If the manometer indicator continuously falls, do not place the endoscope in liquid since the device is leaky. Please send the device in to be repaired.
- If there is no leak, the indicator must continue to be connected to the endoscope. The leak tester should not be placed in the water. Immerse the endoscope in the liquid and observe the rising bubbles. If bubbles (or streams of bubbles) rise evenly over a period of more than 1 minute, this is a sign of a leak. Please send the endoscope in to be repaired.
- Bubble formation at the start comes from external recesses and is not important.
- Pay attention to the manometer of the leak tester at all times. If the pressure falls, build up pressure once again, if necessary, otherwise there is a risk of water damage.
- After a successful test, take the endoscope out of the water, vent the system, and disconnect the leak tester.
- If the leak test is positive (= proven perforation):
  - Take device out of the solution under pressure.
  - Wipe outer casing with disinfectant solution (Mikrozid wipes).
  - Dry the channel system and contacts using compressed air.
  - Wrap endoscope in a protective film covering and send in for repair packed in a shipping box and labelled with the comment “leaky, not disinfected”.

i Never connect or disconnect the tester under water!

i Never immerse the endoscope in liquids while a drop in pressure is present!

10.3 Testing the patency

Before each use, cleaning, disinfection, and sterilisation, the working channel is to be checked for patency.

- The working channel is to be flushed with water using a disposable syringe.
- Ensure patency and leak tightness.
- The test can be combined with the manual leak test (see section 11.2).

10.4 Testing the angulation mechanism

- Slowly operate the angulation lever to test the function.
- Check whether complete angulation is achieved.

i Any limitations in the angulation possibilities may indicate a defect of the endoscope. To avoid greater damage to the endoscope in this case, use the endoscope only if the angulation functions smoothly.

10.5 Testing the fibre optics

Before every use, image quality (clear and free of distortion) and the light transmission through the glass fibres should be checked.

- Direct the distal end of the endoscope against glare-free light, e.g. before a bright ceiling light (no cold light source), hold the light guide connection near the eye (10 cm distance) and move it back and forth.
- The brightness of the fibres changes. If the glass fibres at the distal end appear as dark dots, glass fibres are broken and adequate illumination may no longer be ensured. It is not a problem if individual fibres remain dark. Starting at a breakage rate of approx. 10-20%, it is recommended to send the endoscope in for repair.

10.6 Maintenance and servicing

Flexible endoscopes and accessories are maintenance-free. They do not contain any components that need to be maintained by the user or manufacturer.

11 Processing and disinfection

⚠ The flexible endoscopes are not supplied sterile and must be cleaned, disinfected, and sterilised prior to first use as well as before every further use.

⚠ Flexible endoscopes may not be cleaned in an ultrasonic bath.

⚠ Flexible endoscopes may not be exposed to gamma rays.

⚠ Flexible endoscopes may not be autoclaved/steam-sterilised. Do not exceed temperatures of > 60°C.

11.1 General application instructions for safe processing

- After every cleaning/disinfection and before each use, the endoscopes are to be checked for cleanliness, function, and damage (see section 10). Damaged or defective endoscopes may not be used. Damaged individual parts must be immediately replaced with original replacement parts. Damaged endoscopes should be immediately taken out of service.
- Process contaminated endoscopes and accessories as quickly as possible.
- Manual or machine (automatic) cleaning and disinfection are to be performed after each use. Observe manufacturer's information (e.g. dosing).
- Do not apply any strong pressure by hand.
- Ensure that endoscopes and accessories do not touch each other during cleaning.
- Use only cleaning agents for the complete dissolution of proteins.
- Avoid any fixation of proteins before and during the processing.
- Do not use any abrasive cleaning agents or metal brushes.
- The parameters indicated by the manufacturer for the cleaning agent and disinfectant with regard to concentration, temperature, service life, and contact time must be observed and automatic metering devices must be controllable.
- If there are elevated chloride concentrations in the water, pitting and stress corrosion on the instruments can occur. Such corrosion can be minimised through the use of demineralised water or alkaline cleaning agents.
- Autoclave only endoscopes and accessories that are marked with "autoclave".
- The selection of the cleaning agent and disinfectant is based on the properties of the instruments and national guidelines and recommendations.
- The applicable country-specific laws and regulations should always be observed.
- Follow instructions for processing and sterilisation.
- Immediately clean with water in the event of contact with corrosive agents. Use demineralised water, if possible.
- Improper cleaning can lead to material damage.
- Autoclave only endoscopes and accessories that are marked with "autoclave".

i Immediately clean with water in the event of contact with corrosive agents. Use demineralised water, if possible.

i Improper cleaning can lead to material damage.

Always perform machine (automatic) cleaning after contact with:

- Blood
- Wounds
- Internal tissue
- Organs

11.2 Preparation of the instruments and precleaning

11.2.1 Preparation of the instruments at the place of use

- Remove visible surgical residues and surface contamination as completely as possible using a clean, damp, lint-free cloth.
- Always perform a leak test before placing in liquids (see section 10.2).

Do not use warm water (> 40°C) or fixing disinfectants since this can lead to fixation of the residues on the device (risk of protein coagulation or denaturing) which can affect the success of the subsequent processing steps.

11.2.2 Transport

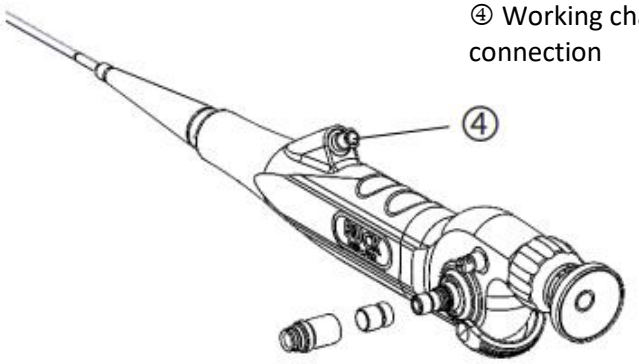
- The instruments can be transported to the respective processing rooms in either wet or dry condition.
- For safe, easy transport for processing, we recommend using the storage systems provided for this (such as disposal containers).

Residues should not be allowed to dry in any case

11.2.3 Manual precleaning

Precleaning must always be performed prior to manual or machine (automatic) cleaning:

1. Disassemble detachable endoscopes and accessories into individual parts. Disassemble the flexible endoscope as much as possible (see section 9). Remove the light guide adapter prior to processing.
2. To remove adhered grime, place the device in cold water (< 40°C) for at least 5 minutes.
3. Using a soft cleaning brush (natural bristles), clean the device under running municipal water (< 40°C) until all visible contamination has been removed.
4. Rinse cavities, lumens, narrow gaps, and slits using a water gun (or syringe) intensively (> 30 seconds) with cold municipal water.



④ Working channel with Luer lock connection

- Insert a long cleaning brush into the working channel (4) only from a proximal to a distal direction, without using any force.
- Guide the cleaning brush through the working channel ⍰ in only one direction and only withdraw it when the head of the brush has exited the distal end. Do not move the cleaning brush back and forth since this can lead to damage.

5. Clean the optical surfaces (proximal eyepiece, distal tip, light guide cable connection) with a lint-free cleaning cloth and carefully rinse them under cold running municipal water (< 40°C). Do not use any cleaning brushes since this can leave scratch marks. Contamination and scratch marks that impair the optical quality can be made visible by reflecting light on the optical surface.

If residues remain on the surface of the optical fibres after cleaning, these residues can be burned onto the surface when a light source is used and thus impair the fibre transmission (light transmission)

11.3 Manual processing

11.3.1 Manual cleaning

Validated with the alkaline cleaning agent neodisher® MediClean forte

1. Place the instruments completely in the alkaline cleaning bath (e.g. 0.5% neodisher® MediClean forte for 5 min). Observe the contact time according to the manufacturer's information.
2. It must be ensured that the cleaning solution reaches all areas of the instrument. Movable parts on the instrument must be moved several times (min. 3 x) in the cleaning bath. In the cleaning bath, rinse through and around cavities, lumens, narrow gaps and slits using a syringe (without cannula) several times (min. 3 x 20 ml).
3. After the necessary contact time, the instruments undergo post-cleaning under cold, running municipal water (< 40°C) using a soft brush. Rinse through and around cavities, lumens, narrow gaps, and slits once again using the water gun (or syringe) (min. 30 sec).
4. Then rinse the endoscopes once again under cold, running municipal water (< 40°C) and perform post-cleaning with a brush until the cleaning agent has been completely removed (min. 30 sec).

11.3.2 Manual disinfection

Validated with the aldehyde-free disinfectant Korsolex® plus

1. Immerse instruments in an RKI- or VAH-listed disinfectant (e.g. 3% Korsolex® plus for 15 min). In doing so, follow the instructions of the disinfectant manufacturer.
2. It must be ensured that the disinfectant reaches all areas of the instrument. Movable parts on the instrument must be moved several times (min. 3 x) in the disinfectant bath. In the disinfectant bath, rinse through and around cavities, lumens, narrow gaps and slits using a syringe (without cannula) several times (min. 3 x 20 ml).
3. After the contact time, rinse off the instrument carefully using cold demineralised water (min. 30 sec). Cavities and lumens must be flushed with demineralised water multiple times (min. 3 x 20 ml) using a syringe (without cannula).
4. Dry manually using a disposable, lint-free cloth. To largely prevent water from remaining in cavities, it is recommended to blow out cavities using sterile, oil-free compressed air.

11.4 Machine processing (automatic cleaning and thermal disinfection)

The use of a cleaning and disinfection device for endoscopes in accordance with the recommendations according to standards series ISO 15883 is recommended.

- Instruments must be placed on instrument holders suitable for the machine such that they can be easily rinsed.
- The instrument holders (e.g. mesh baskets) must be designed such that subsequent cleaning in the cleaning and disinfection device is not prevented by "dead zones" that cannot be reached by water.
- The instruments should be secured in the cleaning basket at a minimum distance from each other.
- Overlapping with one another should be avoided to prevent damage to the instruments by the cleaning process.
- Temperatures of 60°C should not be exceeded in order to avoid damaging the flexible endoscope.
- The instructions of the device and cleaning agent manufacturers must always be followed.

Suitable pH-neutral or alkaline cleaners are to be used as cleaning agents for machine cleaning. For this, we recommend the cleaning solution THERMOSHIELD® NR (previously: THERMOTON® NR) from Dr. Schumacher GmbH at a dosage of 0.5%, according to the manufacturer's instructions for endoscope processing.
For chemical disinfection, we recommend the disinfectant THERMOSHIELD® DISINFEKTANT (previously: THERMOTON® DISINFEKTANT) from Dr. Schumacher GmbH.

Automatic processing process validated with cleaning and disinfection device Belimed WD 425, pH-neutral cleaning agent THERMOTON® NR (identical composition and formulation as THERMOSHIELD® NR), disinfectant THERMOTON® DESINFEKTANT (identical composition and formulation as THERMOSHIELD® DESINFEKTANT):

1. Manual precleaning (according to section 11.2.3)

2. Automatic leak testing in the cleaning and disinfection device for endoscopes (also manually, if necessary; see section 10.2)
3. 3 minutes of precleaning with cold municipal water (< 40°C)
4. 5 minutes of cleaning at 55°C ± 2°C 0.6% pH neutral cleaning agent (e.g. THERMOSHIELD® NR)
5. 1 minute of intermediate rinsing with demineralised water (< 40°C)
6. 5 minutes of chemical disinfection with, e.g., 1% THERMOSHIELD® DISINFEKTANT at 55°C ± 2°C, demineralised water
7. 1 minute of final rinsing with demineralised water 55°C ± 2°C
8. 15 minutes of automatic drying according to the automatic drying process of the cleaning and disinfection device at 55°C +/- 2°C
9. Manual drying can then additionally be performed using a lint-free cloth or by blowing out lumens using sterile, oil-free compressed air.

ℹ After machine cleaning, take the endoscopes out of the cleaning device immediately in order to avoid corrosion.

ℹ Accelerated cooling of the instrument should be avoided.

12 Sterilisation

⚠ The flexible endoscopes are not supplied sterile and must be cleaned, disinfected, and sterilised prior to first use as well as before every further use.

ℹ Before each sterilisation, the endoscopes are to be thoroughly cleaned (manual or machine) and disinfected (see section 11)

ℹ Before each sterilisation, the endoscopes should be checked for cleanliness, function and damage (see section 10)

- Sterilise endoscopes individually packed into suitable sterilisation containers.
- Ensure that the entire surface is in contact with sterilisation medium.
- Ensure that the fastening elements securely accommodate the endoscopes.
- The endoscopes may not be exposed to any mechanical stress since this could damage the sensitive lens systems.
- After the end of the sterilisation process, the endoscopes should cool slowly to room temperature. The endoscope may not be rinsed with cold water or other liquids for cooling since this can lead to damage of the lenses.

12.1 Sterilisation methods

Only special methods for thermolabile lenses that are tested and approved for this purpose may be used.

⚠ Flexible endoscopes may not be exposed to gamma rays.

⚠ Flexible endoscopes may not be steam-sterilised or autoclaved. Do not exceed temperatures of 60°C.

Recommended sterilisation methods:
- Gas sterilisation with EtO (validated parameters, see section 12.1.1)
- Gas sterilisation with hydrogen peroxide in the STERIS® V-PRO® method (see section 12.1.2)

Select the suitable sterilisation method for thermally labile instruments according to the national statutory regulations and recommendations.

It is possible that sterilisation methods not listed in these instructions are also compatible with the endoscopes. When using methods other than those listed in these instructions as being validated, the operator is responsible for the sterility.

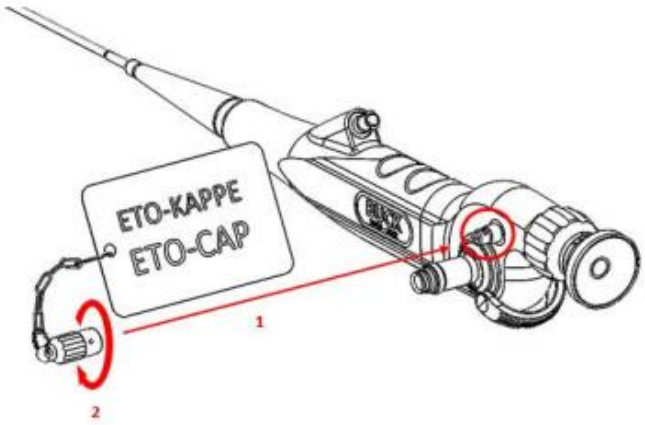
12.1.1 Sterilisation with ethylene oxide (gas sterilisation)

Perform sterilisation with ethylene oxide (gas sterilisation) according to DIN EN ISO 11135. In doing so, take relevant national requirements into account.

EtO devices that operate according to a validated method in accordance with EN 1422 ensure safe sterilisation and desorption, according to manufacturer's information. When performing sterilisation with ethylene oxide gas, follow all processing protocols from national authorities, health authorities, professional associations and from your institution, as well as the instructions of the manufacturer of your sterilisation equipment.
The sterilisation result depends on various factors, such as how the sterilised instrument was packaged or stored or how the instrument is arranged in the steriliser. Check the degree of sterilisation using biological or chemical indicators.

Ethylene oxide gas is toxic and can be harmful to health. Follow the applicable health protection regulations to determine the suitability of the method.

- Thoroughly clean and dry the instructions prior to gas sterilisation. Remaining water can prevent sterilisation or lead to damage to the endoscope.
- Before sterilisation, attach the pressure compensation cap (EtO cap) to the endoscope connection (see figure). If the EtO cap is not attached to the endoscope during sterilisation with ethylene oxide gas, the air in the endoscope expands and the coating of the angulation part can tear and/or the angulation mechanism can be damaged.



- After sterilisation, allow the instruments to sufficiently degas and properly dry in order to eliminate toxic residues of the ethylene oxide gas.

Validated sterilisation parameters:

EtO sterilisation	Temperature	55°C ± 3°C
	Chamber pressure	1.7 bar (0.17 MPa)
	Relative humidity	40 – 100%
	Contact time (duration of exposure)	120 min (2 hours)
	EtO concentration	7 – 8.5% EtO (≥ 260 mg/l) 91.5 – 93% CO_2
Degassing (desorption)	Minimum duration	≥ 6 hours at 52 – 58°C

If the desorption conditions indicated are adhered to in connection with the sterilisation parameters listed, the flexible endoscopes are free of residual gas as established by the limits defined in DIN EN ISO 10993-7.

12.1.2 Gas sterilisation with hydrogen peroxide in the STERIS® V-PRO® method

Gas sterilisation with hydrogen peroxide is another alternative method for the sterilisation of thermolabile flexible endoscopes. For this method, the efficacy was validated and material tolerance was tested over 30 cycles.

The validation of the flexible endoscopes from EMOS is valid for the following STERIS® V-PRO® low-temperature

sterilisation system:

Steriliser (Low Temperature Sterilization System)	Flexible cycle
V-PRO® maX	✓
V-PRO® maX 2	✓
V-PRO® 60	✓
V-PRO® s2	✓

The proof of suitability of the flexible endoscopes for effective sterilisation was provided by an independent, accredited test laboratory. The sterilisation is then considered to be sufficiently effective if a reduction of viable microorganisms by at least a factor of 10^6 is achieved (sterility assurance level (SAL): 10^{-6}).

For information on packaging and weight limits, the information from the steriliser manufacturer should be observed.

13 Storage and packaging

- Flexible endoscopes sterilised with gas or an equivalent method are to be stored after corresponding desorption (see section 12.1) in a closed cabinet, protected from contamination.
- Before storage, flexible endoscopes must be completely dry.
- Store and pack flexible endoscopes only individually.
- Store flexible endoscopes in a dry, clean, dust-free, and well-ventilated environment and in a protected place at room temperature (free of corrosive vapours). To avoid the formation of condensate, major temperature fluctuations should be avoided.
- Flexible endoscopes are to preferably be stored hanging from appropriate holders in a dedicated closed endoscope cabinet.
- The transport packaging of the flexible endoscopes is not intended for cleaning, sterilisation and storage, therefore do not store flexible endoscopes in the transport packaging.
- The flexible endoscopes must be reprocessed no later than after 7 days of storage.
- Before use after storage, wipe the outer casing with a Mikrozid cloth and rinse the channels with 20 ml 70% alcohol.

13.1 Transport

- For transport, the flexible endoscope is to be kept protected from contamination in suitable closed containers, in order to avoid recontamination.
- Transporting endoscopes in transport packaging for examinations at outside facilities is not permissible. The transport packaging may be used only to ship a defective device to the manufacturer for repair (see section 14).

14 Service and repair

To ensure operational safety of the flexible endoscopes:

- Have repairs performed only by the respective dealer or a qualified customer service centre authorised by EMOS Technology GmbH.
- Use only original replacement parts for the repairs.
- The guarantee and warranty claim becomes void in the case of repairs that are not performed by service centres not authorised by EMOS Technology GmbH.
- Information on repairs and guarantees is available from EMOS Technology GmbH representatives or an authorised customer service centre.

14.1 Shipment

- Returning used medical devices is permitted only if the devices are in a cleaned and sterilised condition with documented proof.
- When returning devices, always use the original transport packaging. The packaging must ensure optimal protection of the endoscopes during transport.

15 Service life

Flexible endoscopes are reusable instruments.
The service life of the flexible endoscopes depends on the frequency of use and on maintenance and careful handling.
When used properly, flexible endoscopes can be used and reprocessed for 30 cycles without maintenance/breakage.
Before each use, the flexible endoscope should be checked for cleanliness, function and damage (see section 10).
After the end of the life cycle, dispose of the flexible endoscope properly, if necessary (see section 16).

16 Disposal

When disposing of flexible endoscopes, the following should be observed:

- Before disposal, thoroughly clean and sterilise flexible endoscopes.
- Dispose of packaging and used parts according to country-specific regulations.
- Protect flexible endoscopes from being accessed by unauthorised persons.

17 Loss of warranty

The use of damaged and/or soiled endoscopes is under the sole responsibility of the user. Failure to follow these instructions for use and processing leads to the loss of guarantee and warranty claims. We accept no liability in the event of improper handling, incorrect or deficient processing, or unauthorised repairs.

18 Reporting incidents

In the event of a serious incident that occurs in connection with the device, the user and/or the patient must report this immediately to the manufacturer and the competent authority of the member state in which the user and/or patient is located.

19 Compliance with regulations

This medical device is provided with a CE mark in accordance with Medical Device Regulation (MDR) 2017/745.
If an identification number follows the CE mark, this indicates the competent Notified Body.

The flexible endoscopes correspond to ordinance (EU) 2017/745 (MDR) class IIa.

Devices of class IIa are additionally labelled with the identification of notified body no. 0483 “mdc medical device certification GmbH”. CE 0483

More information on the technical data is available from our service hotline:
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Created by:	DS	Created on:	08.03.2022		
Modified from:	NF	Modified on:	22.01.2024	Revision:	C