Thank you for purchasing our product. Read this manual carefully before use to avoid unexpected accidents and to take full advantage of the product's capabilities. Please refer to separate operation manuals regarding detailed instructions for the preparation, operation and use of these endoscopes.
Important Safety Information

1. Safety

Prior to use carefully review this manual. Use this product following all the provided instructions (“Preparation and Operation”, “Cleaning, Disinfection and Storage” and “Electrosurgical Instruments”). The items important for the safe use of this product are summarized in Chapter 1 “Safety” in the preparations and operations section. Safety precautions associated with individual operations and/or reprocessing procedures are provided separately marked by “WARNING” or “CAUTION.”

2. Warning

The items that must be observed for safety when performing endoscopy or electrosurgery are identified by “WARNING” or “CAUTION” comments in our three operation manuals describing “Preparation and Operation”, “Cleaning, Disinfection and Storage” and “Electrosurgical Instruments.” Follow all caution and warning statements in our operation manuals.

**WARNING**

Read this manual and the Operation Manual (Preparation and Operation) thoroughly and carefully before use.

Improper use or operation of this product may injure patients, physicians, or individuals within the immediate procedure environment.

Failure to adhere to all reprocessing instructions could compromise patient safety and present infection control risks.

Improper operations that will damage the equipment only are identified by “CAUTION.”

3. First Time Use

This product has not been cleaned, disinfected or sterilized. It must be reprocessed for the first time prior to use and after any subsequent use as per instructions provided - Chapter 7 “Cleaning,” Chapter 8 “High-Level Disinfection,” or Chapter 9 “ETO Gas Sterilization.”

4. Single Patient Use Only

**⚠️** DO NOT reuse the forceps valve and cleaning brush WB1318DE as their reuse may pose an infection risk. Each of these products is intended for single use only.

5. Annual Return and Inspection

All duodenoscopes must be returned to your local FUJIFILM dealer or authorized service representative for inspection of the forceps elevator seal once a year to maintain safe use of the device.
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Preface

This manual describes how to clean, disinfect, sterilize and store ED-530XT duodenoscope.  

This model is a fully immersible, single-instrument channel flexible endoscope. Carefully follow the instructions in this manual as well as recommendations for ancillary equipment before using other accessories. This endoscope is heat-sensitive and should not be exposed to high temperatures associated with sterilization processes such as steam autoclaving. Handle this product with care since the insertion portion is pliable and acute bending, excessive twisting and/or force can damage the insertion tube as well as underlying internal components.

[Note] FUJIFILM cannot assure the successful reprocessing (cleaning, high-level disinfection and sterilization) of the endoscope and/or accessories if reprocessing methods, chemicals, packaging and/or conditions other than those described in this manual are used. Users are responsible to ensure that if any alternative reprocessing methods, chemicals, packaging and/or conditions are used, appropriate efficacy validation studies have been performed.
[Note] The ED-530XT duodenoscope features a distal elevator mechanism with a sealed (fully enclosed) elevator control wire channel. While the enclosed elevator channel itself does not require special reprocessing, the elevator, surrounding recessed surfaces and distal tip still should be manually cleaned and then high-level disinfected.
Conventions Used in This Manual

This manual uses the following conventions for easier understanding.

### General Conventions

<table>
<thead>
<tr>
<th>Convention</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="exclamation_mark" alt="" /></td>
<td>Indicates a potential danger that may cause harm to people.</td>
</tr>
<tr>
<td><strong>WARNING</strong></td>
<td>Explains dangerous situations that may cause death or serious injury if not avoided.</td>
</tr>
<tr>
<td><strong>CAUTION</strong></td>
<td>Explains situations that may cause injury if not avoided.</td>
</tr>
<tr>
<td><strong>CAUTION</strong></td>
<td>Explains situations that may cause damage to equipment if not avoided.</td>
</tr>
<tr>
<td>(1), (2), (3), ...</td>
<td>Indicates consecutive numbers in operating procedures for the order in which successive steps in the procedure should be taken.</td>
</tr>
<tr>
<td>[Note]</td>
<td>Indicates a comment or supplementary information.</td>
</tr>
<tr>
<td>➡️</td>
<td>Indicates a reference.</td>
</tr>
</tbody>
</table>
Chapter 7 Cleaning

This chapter describes FUJIFILM recommended manual cleaning procedures. Carry out pre-cleaning at the bedside immediately after completion of endoscopic procedure.

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7.1 Methods of Cleaning

**CAUTION**

Clean this product before first time use and after subsequent use following the instructions provided in this manual. Improper cleaning can negatively affect the functionality of this product and/or result in incomplete high-level disinfection or sterilization.

Cleaning is a crucial first step in reprocessing, which if not properly performed, can result in incomplete or inadequate high-level disinfection or sterilization.

Use potable water or filtered water for rinsing after exposure to a detergent solution. Low foaming neutral pH enzymatic detergents are recommended for cleaning flexible endoscopes.

For specific names of compatible detergents, contact your local FUJIFILM dealer.

| Table 7.1 Compatible methods of cleaning for endoscope and accessories |
|--------------------------|-----------------|-------------------|
| Endoscope                | Detergent cleaning | Ultrasonic cleaning |
| Air/Water button         | Yes             | Yes [Note 1]      |
| Suction button           | Yes             | Yes [Note 1]      |
| Cleaning brush [Note 2]  | Yes             | Yes [Note 1]      |
| Carrying case            | No              | No                |
| Cleaning adapter kit [Note 3] | Yes             | No                |

[Note 1] Use an ultrasonic cleaning unit specialized for medical accessories.

[Note 2] FUJINON/FUJIFILM cleaning brushes only are recommended. For non-FUJINON/FUJIFILM brushes, contact the original manufacturer.

[Note 3] Applies to all components of the cleaning adapter kit excluding a 30 mL syringe.
7.2 Preparation for Cleaning

Low foaming, neutral pH, enzymatic detergents are recommended for cleaning flexible endoscopes. For specific names of compatible detergents, contact your local FUJIFILM dealer.

Refer to the detergent manufacturer’s instructions for preparation and use. Personal protective equipment should be worn by end-users during all reprocessing procedures.
7.3 Equipment and Materials

Prepare the necessary equipment used in Chapters 7 and 8.

- **Cleaning adapter kit CA-503/A** (Standard accessory)
  Consists of:
  - Tube for air/water supply channel
  - Tube for suction channel
  - 30 mL syringe [Note 1]
  - Valve adapter CA-503S/A
  - Forceps inlet cleaning adapter CA-503B/C (with a cap)
  - Tank receiving cap
  [Note 1] The supplied 30 mL syringe is intended for cleaning process. Use a sterile syringe for high-level disinfection process.

- **Cleaning brushes** (Standard accessories)
  Consists of:
  - Cleaning brush WB11002FW2
  - Cleaning brush WB4321FW2
  - Cleaning brush WB1318DE

- **Air leak tester LT-7F** (Required accessory)
  [Note] LT-7F is a required accessory and leak testing procedures must be performed prior to cleaning.

- High-level disinfectant solution and enzymatic detergent solution
- Soaking basin for high-level disinfectant solution and detergent solution
- Clean lint-free cloth/sterile gauze
- Toothbrush (soft type) for cleaning of accessories
- Magnifying glass or loupe
- Personal protective equipment
  - For example: Rubber gloves
  - Goggle
  - Facemask
  - Protective clothing

[Note] Prepare spare consumable items such as cleaning brushes, sterile gauze, toothbrush, 30 mL syringe, etc. since they may be damaged or consumed.

[Note] Use potable, filtered and/or sterile water as described in these operation manuals.

In addition, note that ventilation adapter AD-7 is necessary for ETO gas sterilization as described in Chapter 9.
Chapter 7  Cleaning

Cleaning Adapter Kit CA-503/A

- Cleaning Brush WB11002FW2
- Cleaning Brush WB4321FW2
- Cleaning Brush WB1318DE
- Toothbrush (Soft Type) for Cleaning of Accessories
- Clean Lint-free Cloth/Sterile Gauze
- Air Leak Tester LT-7F
- Ventilation Adapter AD-7
- Magnifying Glass/Loupe
- High-Level Disinfectant Solution/Detergent Solution
- Soaking Basin for High-Level Disinfectant Solution/Detergent Solution
- Personal Protective Equipment
7.4 Pre-cleaning (performed at bedside immediately after use of endoscope)

**CAUTION**

Immediately upon completion of the procedure, it is imperative that pre-cleaning is performed to begin removal of patient material and ensure that residual debris does not dry and harden.

7.4.1 Wiping

Wipe off the outside of the insertion portion of the endoscope with a clean lint-free cloth soaked with detergent solution.

[Note]
When wiping the insertion portion, do not wipe/slide gross soil/patient material directly onto the forceps elevator/elevator recess at the scope distal tip.

7.4.2 Purging the Air/Water (A/W) Supply Channel

Expel potential body fluids from the A/W supply channel of the endoscope in accordance with the following procedure. Depending upon specific model of light source, set the air setting to its maximum (highest) output pressure to more forcefully expel fluids/materials during pre-cleaning.

1. Provide air for 10 seconds by covering the A/W button with one’s finger.
2. Provide sterile water from the water tank for 10 seconds by depressing the A/W button.
3. Turn the connector of water tank connected to endoscope to remove it. Then cover the feed water connector of endoscope with one’s finger.
(4) Continue pressing the A/W button until the A/W supply channels are completely drained.

7.4.3 Pre-cleaning Suction Channel

(1) Repeat the following steps (2) and (3) at least 3 times to alternately aspirate detergent solution and air.

(2) Immerse the distal end of endoscope in detergent solution and depress the suction button for 10 seconds to aspirate detergent.

(3) Keeping the suction button depressed, pull the distal end of endoscope out from detergent solution to aspirate air.

(4) Pull the distal end of endoscope out from detergent solution and aspirate air until detergent solution in the suction channel is discharged completely.
7.4.4 Cleaning Forceps Elevator

Clean the forceps elevator mechanism and all scope tip areas surrounding and behind the elevator.

Immerse the distal end of the endoscope in the detergent solution and then move the forceps elevator lever back and forth 5 times ensuring that the elevator and all recessed surfaces surrounding the elevator are in contact with the detergent.
While the scope tip remains immersed in detergent, aspirate detergent solution for 10 seconds while the forceps elevator is fully raised, aspirate detergent for 10 seconds while the forceps elevator is fully lowered and aspirate detergent for 15 seconds while moving the forceps elevator back and forth.

7.4.5 Disconnecting Endoscope from Processor

⚠️ CAUTION

Do not touch the tip of LG (Light Guide) connector until it has cooled down (approximately 5 minutes after turning off the power of the light source). Touching the LG connector tip with one’s hand immediately after use of this product may cause a burn.

After the endoscope has been disconnected from the video processor and/or light source, transport the endoscope in a covered tray to the decontamination area/cleaning room.

(1) Turn OFF the processor and the light source.
(2) Detach suction tube and water tank from LG connector of endoscope.

(3) Detach EVE connector from the processor.

(4) Detach LG connector from the light source.

7.4.6 Detaching Endoscope Components (A/W button, suction button, forceps valve, etc.)

**WARNING**

The forceps valve is a single patient use item. DO NOT reuse it as continued reuse presents an infection risk.

(1) Remove the A/W button, suction button and forceps valve from the endoscope.

(2) Place buttons in detergent solution.

(3) Discard removed forceps valve. Do not reuse it.
7.4.7 Transporting Endoscope for Reprocessing

**WARNING**

To protect the endoscope from damage and to prevent spillage, use a covered tray during transportation to the cleaning room.

Transport the endoscope in a covered tray to the decontamination area/cleaning room.

1. Place endoscope in a transport container.

2. Carry it with endoscopic accessories to the decontamination area/cleaning room.
## 7.5 Manual Cleaning (cleaning in basin)

Manual cleaning of endoscope is performed after pre-cleaning at the bed-side in the procedure room. If performed correctly immediately after the procedure, pre-cleaning should prevent drying and hardening of debris on instrument surfaces.

“7.4 Pre-cleaning (performed at bedside immediately after use of endoscope)”

<table>
<thead>
<tr>
<th>CAUTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>It is imperative that patient material is not allowed to dry and/or harden onto scope surfaces, particularly the elevator and elevator recess at the scope distal tip, as doing so will make cleaning more difficult and possibly impede adequate high-level disinfection and/or sterilization. Delayed reprocessing of endoscopes, especially duodenoscopes is not recommended.</td>
</tr>
</tbody>
</table>

Leak testing must be performed prior to immersing the endoscope in any fluid or solution.

[Note] Fresh enzymatic detergent should be prepared for each endoscope. Do not reuse detergent.

<table>
<thead>
<tr>
<th>WARNING</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carefully inspect all cleaning brushes prior to use and check the brushes integrity after use to ensure that the accessories are not damaged and no brush or accessory fragment remains inside the channel. Retained brush/accessory fragments could be a potential source of infection and/or cause patient injury.</td>
</tr>
</tbody>
</table>

Before using any cleaning brush for a valve cylinder or channel port, remove any debris from the bristles on the brush. This will avoid reintroduction of patient material into the channels/lumens.

If the cleaning brush is damaged and possible brush fragments remain inside the channel, use a new cleaning brush to remove the broken fragments and repeat cleaning of the channel.

Do not place endoscopes on top of one another to prevent damage caused by scope-to-scope contact.
7.5.1 Preparation for Cleaning Endoscope

(1) Prepare all items including cleaning brushes WB4321FW2 and WB11002FW2 and cleaning adapter kit.

(2) Attach the waterproof cap to the EVE connector.

(3) Prepare fresh detergent solution (following detergent manufacturer’s instructions for use) in the basin.

7.5.2 Endoscope Components

If not already detached, remove all detachable components including air/water button and suction button from endoscope.
7.5.3 Leak Testing

**CAUTION**

Do not immerse this product in water or any solution if it fails the leak test because it may cause damage to this product.

Perform a leak test to confirm the watertightness of this product. If a leak is detected, do not continue the test and contact your local FUJIFILM dealer.

For details on how to use the LT-7F and inspection before use, refer to the instructions in this manual or the separate operation manual for the LT-7F.

1. Confirm the waterproof cap is connected to the end of the EVE connector. Ensure that the cap and connector, especially the electrical contacts are dry.

2. Align the index of connector of air leak tester with the notch of ventilation connector of endoscope.

3. Push in the connector of air leak tester and rotate it clockwise to connect the air leak tester to the ventilation connector.

4. Depress the trigger of air leak tester to the pressure side as shown in the figure.
(5) Pump the hand bulb of the leak tester to pressurize the endoscope until the meter indicates 20 kPa.

[Note]
During pressurization, remove fingers from the trigger and do not lay trigger onto the hard surface to avoid inadvertent escape of air.

(6) Release gripping the blower and wait for about 30 seconds, and check that the indicator does not fall. If the indicator falls down 5 kPa (10 indications) or more, the endoscope has an air leak.

[Note]
If the indicator drops slowly, apply more air until the indicator points to 20 kPa.

[Note]
In case of air leak, do not clean the endoscope, but immediately contact your local FUJIFILM dealer.

(7) While applying air pressure of at least 20 kPa into the endoscope, completely immerse the entire scope in water for not less than one minute and ensure that a steady stream of air bubbles (indicative of a leak) is not found.

[Note]
Be sure to apply air pressure before immersing the endoscope into water.

[Note]
Do not immerse the meter or blower of air leak tester but only the connector and tube.
(8) Operate the endoscope and move the inserting portion and bending portion every direction in order to check that air bubbles do not come out continuously from endoscope.

[Note]
If the indicator falls down slowly, squeeze the blower to blow air until the indicator points to 20 kPa.

[Note]
If a stream of air bubbles comes out from the endoscope while it is completely immersed in water for at least one minute, the endoscope has a leak.

[Note]
In case of air leak, do not clean the endoscope, but immediately contact your local FUJIFILM dealer.

(9) Remove the endoscope from water and wipe around the ventilation connector and air leak tester connector.

(10) Depress the trigger of air leak tester to release air pressure from endoscope.

[Note]
Discharge air until the indicator falls and stops at the bottom.

(11) Push in the connector of air leak tester and rotate it counterclockwise to remove the air leak tester. Do not detach the leak tester connector from the endoscope when fully immersed.
7.5.4 Inspecting Cleaning Brushes

**WARNING**

The cleaning brush WB1318DE is a single use item. DO NOT reuse it as continued reuse may present an infection risk.

Check that all cleaning brushes are free from deterioration or damage before using them. If any abnormality is found, replace the brush with a new one.

1. Confirm that the metal tip and/or distal bristles are securely in place for each cleaning brush.
2. Check for loose or missing bristles.
3. Check for bends, scratches and other damage to the shaft.
4. Check for debris on shaft and/or in the bristles of brush.
7.5.5 Cleaning Surface of Endoscope

Check that all cleaning brushes are free from deterioration or damage before using them. If any abnormality is found, replace the brush with a new one.

(1) Fully immerse endoscope in fresh detergent solution.

(2) Wipe the entire surface of endoscope with a clean lint-free cloth in the detergent solution.

[Note] Perform all cleaning procedures including wiping, brushing, attachment of adapters, channel flushing, etc. while the entire endoscope remains fully immersed in detergent solution.

(3) Brush the distal end of endoscope including the air/water nozzle, the objective lens and light guide, the forceps channel, the front surface side of the forceps elevator with the elevator lowered and the reverse (back) side of the forceps elevator and the bottom recessed area in the distal end with the elevator raised with the WB11002FW2 cleaning brush for 10 strokes, respectively per site.

[Note] One stroke equals one complete back and forth scrubbing motion on a surface with brush. For 3 sites (instrument channel outlet, front elevator surface and back elevator surface), apply a twisting (rotating) motion as the brush is stroked back and forth onto these surfaces.

[Note] During brushing of the scope’s distal end minimize/avoid direct contact of the brush’s metal tip and shaft with scope surfaces, especially the objective lens and light guide.
(4) Brush the distal end of endoscope including air/water nozzle, the objective lens and light guide, the forceps channel, the front surface side of the forceps elevator with the elevator lowered, and the reverse side of the forceps elevator with the elevator raised with WB1318DE cleaning brush for 10 strokes, respectively.
[Note]

For the A/W nozzle and objective lens/light guide areas apply the shorter, firmer bristles of the WB1318DE cleaning brush while brushing these areas. When using the WB1318DE cleaning brush for the forceps elevator and surrounding recessed surfaces, apply the longer, most distal bristles while brushing.
(5) Using the WB1318DE cleaning brush, brush surfaces including crevices on both sides of the forceps elevator mechanism. Apply the longer, distal bristles of the brush to the sides of the elevator and to the side walls of the distal body next to the elevator.

(6) With the forceps elevator raised, flush at least 60 mL of detergent solution forcefully onto the reverse side of the elevator using a 30 mL syringe.

[Note]
Ensure that any crevices and/or recessed surfaces at the base, front, back and sides of the forceps elevator and surrounding areas are forcefully flushed with detergent during steps (6) and (7).

(7) With the forceps elevator lowered, flush at least 60 mL of detergent solution forcefully onto the front surface side of the elevator using a 30 mL syringe.

(8) Move the forceps elevator lever to raise and lower the elevator five times, while keeping the distal end of the endoscope immersed in the detergent solution.

(9) In a brightly lit cleaning room and utilizing some means of magnification (ex. magnifying glass, loupe, etc.) carefully check the scope’s distal end, especially the forceps elevator and elevator recess to ensure that no patient debris or material remains. If any debris is found, completely remove by brushing, flushing with detergent and thorough cleaning of these distal surfaces.
7.5.6 Brushing Suction Channel and Channel Ports

All subsequent cleaning procedures including brushing steps should be performed when the endoscope is fully immersed in detergent solution.

[Note] Only FUJINON/FUJIFILM-brand cleaning brushes are recommended because non-FUJINON/FUJIFILM brushes have not been validated by FUJIFILM for their effectiveness.

(1) Insert the WB11002FW2 cleaning brush back and forth five times while rotating (twisting) the brush into the A/W valve cylinder until it can advance no further. Afterwards, pull it out carefully, and clean bristles with one’s fingertips in the detergent solution. Perform this step twice.

(2) Insert the WB11002FW2 cleaning brush back and forth five times while rotating (twisting) the brush into the suction valve cylinder until it can advance no further. Afterwards, pull it out carefully, and clean bristles with one’s fingertips in the detergent solution. Perform this step twice.

(3) Insert the WB11002FW2 cleaning brush into the forceps inlet until it can advance no further, and rotate the inserted brush back and forth five times. Afterwards, pull it out carefully, and clean bristles with one’s fingertips in the detergent solution. Perform this step twice.

(4) Insert the WB4321FW2 cleaning brush from the suction valve cylinder to the distal end of endoscope in the detergent solution.

(5) When the bristles emerge from the distal end, clean them with fingertips in the detergent solution before withdrawing the brush back into the channel. Then carefully pull it out of the suction valve cylinder.

(6) Clean bristles of the WB4321FW2 cleaning brush in the detergent solution again.

(7) Insert the WB4321FW2 cleaning brush from the suction valve cylinder to the suction connector.
(8) When the bristles emerge from the suction connector, clean them with fingertips in the detergent solution before withdrawing the brush back into the channel. Then carefully pull it out of the suction valve cylinder.

(9) Clean bristles in the detergent solution again.

(10) Perform the steps (4) to (9) three times.

(11) Reprocess the used cleaning brush according to Section 10.3 “Cleaning and Disinfecting Cleaning Brushes.”

7.5.7 Connecting Cleaning Adapter Kit

(1) Ensure that the cleaning adapter kit is fully assembled by connecting the tube unit (which consists of tube for A/W supply channel, tube for suction channel, 3 way valve and weight), 30 mL syringe, and valve adapter as shown in the right figure.

[Note] Before using cleaning adapter kit, be sure there is no abnormality including deterioration, breakage, uncoupled channel tube, leak from channel tube or injection failure due to clogging. If any abnormality is found, replace it with a new one.
(2) Attach the valve adapter to the valve cylinders of endoscope by aligning the same color indicators of adapters to the cylinders as shown in the figure.

[Note]
Hold the valve adapter as shown in the figure, push in the inside plate and push the whole valve adapter in the direction of the arrow (at lower right). Let go of valve adapter from your hand and confirm that it is securely attached to endoscope. Connect the adapters to the endoscope while fully immersed.

(3) Install the forceps inlet cleaning adapter. Handle the forceps inlet cleaning adapter as shown in the right figure.

Set the forceps inlet cleaning adapter to forceps inlet of endoscope, and slide from “a” to “b” while pushing the adapter as the right figure. Confirm that the attachment is secure after releasing the forceps inlet cleaning adapter.

[Note]
If the forceps inlet cleaning adapter cannot be installed, check if it is as follows; confirm the pins on the backside of forceps inlet cleaning adapter are in position shown in the right figure. If not, change the position of the pins by sliding them with pushing forceps inlet joint.

(4) Close the cap of forceps inlet cleaning adapter.
(5) Attach the tank receiving cap to the feed water connector of endoscope.

[Note] Align the notch of the tank receiving cap to the pin of the feed water connector on endoscope, and then, push and rotate the cap to secure it onto the connector.

7.5.8 Cleaning of Endoscope

[Note] As an alternate to manual flushing via a 30 mL syringe, portable flushing devices intended for endoscope channel purging may be available. Follow the manufacturer’s instructions for set-up, channel connections/adaptations and recommended flushing times to deliver desired flushing volumes of fluid.

(1) Attach a 30 mL syringe to the A/W channel side of 3 way valve.

All channel flushing steps with detergent should be performed while the endoscope remains immersed in detergent solution.

(2) Immerse the weight for the cleaning adapter in the detergent solution. Inject the detergent solution forcefully, at least 180 mL, into the A/W channel side of the cleaning adapter with a 30 mL syringe until no air bubbles come out from the distal end and LG connector.

(3) Attach a 30 mL syringe to suction channel side of the 3 way valve.

(4) Make sure the cap is securely attached to and seals the luer port of the CA-503B/C forceps inlet cleaning adapter while flushing/filling of the instrument/suction channel.
(5) Inject at least 180 mL of detergent solution into the suction channel side of the cleaning adapter until no air bubbles come out from the distal end and LG connector.

(6) Open the cap of the CA-503B/C forceps inlet cleaning adapter and inject at least 90 mL of detergent solution into the instrument/suction channel with a 30 mL syringe forcefully.

(7) While the endoscope remains completely immersed, detach all components of the cleaning adapter from the endoscope to better ensure exposure of detergent with channels and channel ports.

(8) Inject the detergent solution into all openings, internal structures and gaps/crevices of the endoscope and cleaning adapter kit to eliminate air bubbles completely. Inspect all movable areas and confirm that no air bubbles come out. Specifically, inject at least 30 mL of detergent solution onto each of the following areas - the angle knobs, the distal scope tip, the feed water connector and the external surfaces of the forceps inlet.

(9) While all endoscope channels remain filled, keep the endoscope and the cleaning adapter kit immersed in the detergent solution in accordance with the temperature, concentration and time recommended by the detergent solution’s manufacturer, and cover the basin to prevent the vaporization of detergent solution.

(10) After soaking for an appropriate time period but before removing the entire scope from detergent solution, air purge all channels. Reattach all channel cleaning adapters and using a 30 mL syringe inject air into/through all channels to expel residual detergent from the channel systems. Make sure the cap is securely attached to and seals the luer port of the CA-503B/C forceps inlet cleaning adapter while flushing of the suction channel. Flush at least 90 mL of air into the suction channel and at least 60 mL of air into the A/W channels. Open the cap of the CA-503B/C forceps inlet cleaning adapter and inject at least 90 mL of air into the instrument channel with a 30 mL syringe.
Remove the endoscope and the cleaning adapter kit from the basin by grasping the control portion of endoscope and 3 way valve of cleaning adapter kit so that the detergent solution flows out and falls from them. Detach all components of the cleaning adapter kit from the endoscope.

7.5.9 Rinsing Endoscope

**CAUTION**

After cleaning, thoroughly remove all detergent residue as per the provided instructions that follow to prevent the potential for inadvertent dilution or adulteration of the liquid chemical germicide used in subsequent steps.

Thoroughly rinse any remaining detergent with potable water after the cleaning process.

1. Using fresh potable tap water, fill a basin of adequate size to completely immerse the endoscope.

2. Fully immerse the endoscope and the cleaning adapter kit in the potable water, then rinse while gently shaking. Perform subsequent rinsing steps while the endoscope remains fully immersed in water.

3. Inject the potable water with a 30 mL syringe into all openings, internal structures, and gaps/crevices of the endoscope and cleaning adapter kit to completely eliminate air bubbles completely. Ensure that no air bubbles are present on the device surfaces.

4. With the forceps elevator raised, flush at least 60 mL of potable water forcefully onto the reverse side of the elevator with a 30 mL syringe.
(5) With the forceps elevator lowered, flush at least 60 mL of potable water forcefully onto the front surface side of the elevator with a 30 mL syringe.

(6) Move the forceps elevator lever to raise and lower the elevator five times, while keeping the distal end of the endoscope immersed in the potable water.

(7) Attach the cleaning adapter to the endoscope again according to Section 7.5.7 “Connecting Cleaning Adapter Kit.”

(8) Inject at least 180 mL of potable water into the A/W channel side of the cleaning adapter with a 30 mL syringe after immersing the weight of the cleaning adapter in the tap water to rinse the A/W channel.

(9) Make sure the cap is securely attached to and seals the luer port of the CA-503B/C forceps inlet cleaning adapter while flushing of the suction channel. Inject at least 270 mL of potable water into the suction channel side of the cleaning adapter with a 30 mL syringe after immersing the weight in water to rinse the suction channel.

(10) Open the cap of the CA-503B/C forceps inlet cleaning adapter and inject at least 90 mL of potable water into the instrument channel with a 30 mL syringe.

(11) Subsequent steps describe a manual air purge of all channels. An alternate method is recommended using forced/compressed air up to 228 kPa (33 psi or 1707 mmHg) to more forcefully expel residual fluid without the need for repetitive flushing via a 30 mL syringe.
(12) After all channels have been flushed with rinse water, remove the scope with attached adapters from the water and transfer to a clean basin where all channels should be air purged. Cover channel openings to minimize splashing or spraying of fluid from the channels.

(13) Inject at least 60 mL air into the A/W channel side of the cleaning adapter to discharge the water from the A/W channels.

(14) Make sure the cap is securely attached to and seals the luer port of the CA-503B/C forceps inlet cleaning adapter while flushing of the suction channel. Inject at least 90 mL air into the suction channel side of the cleaning adapter to discharge the water from the suction channel system.

(15) Open the cap of the CA-503B/C forceps inlet cleaning adapter and inject at least 90 mL of air into the instrument channel with a 30 mL syringe.

(16) After air purging all channels using forced air or manually via a 30 mL syringe, detach all components of the cleaning adapter including the valve adapter, forceps inlet adapter and tank receiving cap from the endoscope.

(17) Wipe any water remaining on the endoscope and the cleaning adapter kit with a clean lint-free cloth.
In a brightly lit cleaning room and utilizing some means of magnification (ex. magnifying glass, loupe, etc.) carefully check the scope’s distal end, especially the forceps elevator and elevator recess to ensure that no patient debris or material remains. Should visible debris remain, repeat the cleaning process.
Chapter 7 Cleaning

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Chapter 8    High-Level Disinfection

This chapter describes FUJIFILM recommendations for achieving high-level disinfection.
Perform high-level disinfection after endoscope has been thoroughly pre-cleaned and manually cleaned as per instructions provided.

[Note] Flexible GI endoscopes including duodenoscope models identified in this manual are considered semi-critical devices which require at least high-level disinfection.

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Chapter 8  High-Level Disinfection

8.1 Methods of High-Level Disinfection

**CAUTION**

These endoscopes are heat-sensitive devices which cannot withstand high temperatures associated with steam sterilization.

Prior to high-level disinfection, these instruments must be pre-cleaned and manually cleaned in accordance with Sections 7.4 and 7.5.

<table>
<thead>
<tr>
<th>Cleaning method</th>
<th>Detergent cleaning</th>
<th>Ultrasonic cleaning</th>
<th>Autoclave</th>
<th>High-level disinfection</th>
<th>ETO gas sterilization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Endoscope</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Yes [Note 1]</td>
<td>Yes [Note 2]</td>
</tr>
<tr>
<td>Air/Water button</td>
<td>Yes</td>
<td>Yes [Note 3]</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Suction button</td>
<td>Yes</td>
<td>Yes [Note 3]</td>
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<td>Yes</td>
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<tr>
<td>Cleaning brush [Note 4]</td>
<td>Yes</td>
<td>Yes [Note 3]</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Carrying case</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Cleaning adapter kit [Note 5]</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

[Note 1] Follow “8.2 Conditions of High-Level Disinfection.”
[Note 2] Follow “9.1 Conditions of Ethylene Oxide (ETO) Gas Sterilization.”
[Note 3] Use an ultrasonic cleaning unit specialized for medical accessories.
[Note 4] FUJINON/FUJIFILM cleaning brushes only are recommended. For non-FUJINON/FUJIFILM brushes, contact the original manufacturer.
[Note 5] Applies to all components of the cleaning adapter kit excluding a 30 mL syringe.
8.2 Conditions of High-Level Disinfection

Legally marketed 2.4 to 3.5% [Note] glutaraldehyde solutions can be used with FUJIFILM endoscopes for high-level disinfection when used in accordance with the manufacturer’s instructions. Contact your local FUJIFILM dealer for names of compatible high-level disinfectant glutaraldehyde solutions. [Note] United States (U.S.A.) only

Refer to the high-level disinfectant solution manufacturer’s instructions regarding preparation, use and exposure conditions.

Check the expiry date of high-level disinfectant solution before use. Do not use a high-level disinfectant solution beyond its expiration date.
Do not use a high-level disinfectant solution whose efficacy is not sufficient. Check the high-level disinfectant solution’s efficacy before use according to the manufacturer’s recommendation (such as using a test strip), referring to the instructions of high-level disinfectant solution.

Ensure that the endoscope, adapters and accessories are completely immersed during high-level disinfection. If the endoscope is connected to the cleaning adapter kit and they are not completely immersed, high-level disinfection of all processed items may not be achieved.
8.3 High-Level Disinfection of Endoscope

8.3.1 High-Level Disinfection of Endoscope

(1) Confirm the waterproof cap is attached securely to the EVE connector.

(2) Fill the high-level disinfectant solution in the basin at the temperature and concentration recommended by the high-level disinfectant solution’s manufacturer.

(3) Fully immerse the endoscope in the high-level disinfectant solution. Perform all disinfecting procedures while the entire endoscope remains fully immersed in high-level disinfectant solution.

(4) With the forceps elevator raised, flush at least 60 mL of high-level disinfectant solution forcefully onto the reverse (back) side of the elevator and interior of the elevator recess with a 30 mL syringe.

(5) With the forceps elevator lowered, flush at least 60 mL of high-level disinfectant solution forcefully onto the front surface side of the elevator and interior elevator recess with a 30 mL syringe.

(6) Move the forceps elevator lever to raise and lower the elevator five times, while ensuring the distal end of the endoscope remains immersed in the high-level disinfectant solution.

(7) Attach the cleaning adapter kit to endoscope according to Section 7.5.7 “Connecting Cleaning Adapter Kit.”

(8) Immerse the weight for the cleaning adapter kit in the high-level disinfectant solution.
(9) Attach a 30 mL syringe to the A/W channel side of the 3 way valve.

[Note] During all channel flushing steps with disinfectant, avoid introduction of air bubbles into the channels.

(10) Inject at least 180 mL high-level disinfectant solution into the A/W supply channel with a 30 mL syringe forcefully. Ensure that no air bubbles come out from the distal end of the endoscope and LG connector during the sixth flush. If bubbles are seen, continue to flush until no bubbles are seen.

(11) Attach a 30 mL syringe to the suction channel side of the 3 way valve.

(12) Make sure the cap is securely attached to and seals the luer port of the CA-503B/C forceps inlet cleaning adapter during flushing/filling of the suction channel.

(13) Inject at least 180 mL high-level disinfectant solution into the suction channel with a 30 mL syringe. Ensure that no air bubbles come out from the distal end of the endoscope and LG connector during the sixth flush.

(14) Open the cap of the CA-503B/C forceps inlet cleaning adapter and inject at least 90 mL of high-level disinfectant solution into the instrument channel with a 30 mL syringe forcefully.
(15) While the endoscope remains completely immersed and all channels are filled with high-level disinfectant solution, detach all components of the cleaning adapter from the endoscope and ensure all items are fully submerged in high-level disinfectant solution.

(16) Using a 30 mL syringe, inject at least 30 mL of high-level disinfectant solution onto the angle knobs, distal end, feed water connector and outside surfaces of the forceps inlet of the endoscope while immersed. Wipe the surface with gauze to remove air bubbles completely. Move any portions (such as angle knobs and forceps elevator lever) that are movable to ensure no air bubbles are trapped.

(17) Ensure that the endoscope and the cleaning adapters remain fully immersed and in contact with the high-level disinfectant solution per recommended usage/exposure conditions described in its product labeling. Cover the basin to minimize personnel exposure to high-level disinfectant vapors.

After soaking for an appropriate time period but before removing the entire endoscope from high-level disinfectant solution, re-attach the cleaning adapter kit again, pull the weight out of the high-level disinfectant solution. Make sure the cap is securely attached to and seals the luer port of the CA-503B/C forceps inlet cleaning adapter while flushing/filling of the suction channel. Using a 30 mL syringe, inject at least 60 mL of air into the A/W channels and at least 90 mL of air into the suction channel in order to discharge remaining high-level disinfectant solution.

(18) Remove the endoscope and the cleaning adapter kit from the basin by grasping the control portion of endoscope and 3 way valve of cleaning adapter kit so that remaining high-level disinfectant solution flows out and falls from them.

Detach the cleaning adapter kit from the endoscope.
8.4 Rinsing Endoscope

CAUTION

After high-level disinfection, thoroughly remove all high-level disinfectant solution residue as per the provided rinsing instructions that follow to prevent patient injury from contact with the residual high-level disinfectant solution.

(1) Fill a basin with sterile water to completely immerse the entire endoscope. (Ensure the basin is large enough to safely accommodate the scope without excessively coiling of the flexible portions.)

(2) Fully immerse the entire endoscope and the cleaning adapter kit in sterile water. Wipe external surfaces of the endoscope with clean gauze in sterile water.

(3) Rinse all items well by gently shaking them in the water for 30 seconds.

(4) While the endoscope and adapter remain submerged, inject sterile water into all openings, internal structures and gaps/crevices of the endoscope. Wipe the surface with gauze to remove air bubbles completely. Move any movable portions to ensure there are no trapped air bubbles.

(5) With the forceps elevator raised, flush at least 30 mL of sterile water forcefully onto the reverse (back) side of the elevator and interior of the elevator recess with a 30 mL syringe.

(6) With the forceps elevator lowered, flush at least 30 mL of sterile water forcefully onto the front surface side of the elevator and interior elevator recess with a 30 mL syringe.

(7) Move the forceps elevator lever to raise and lower the elevator five times, while ensuring the distal end of the endoscope remains immersed in the sterile water.
(8) While the scope and adapter remain submerged in water attach the cleaning adapter kit again to the endoscope.

(9) Attach a 30 mL syringe to the A/W channel side of the 3 way valve.

(10) Inject at least 180 mL of sterile water into the A/W supply channel of the endoscope with a 30 mL syringe after immersing the weight of the cleaning adapter kit in the sterile water to discharge the high-level disinfectant solution in the A/W supply channel.

(11) Attach a 30 mL syringe to the suction channel side of the 3 way valve.

(12) Inject at least 270 mL of sterile water into the suction channel of the endoscope with a 30 mL syringe after immersing the weight in water to discharge the high-level disinfectant solution in the suction channel.

(13) Remove the endoscope with cleaning adapters attached and transfer to a clean basin. Air purge all channels to expel residual water from the channels.

(14) Inject at least 60 mL of air into A/W supply channels and at least 90 mL of air into the suction channel.

After purging water from all channels, perform a final alcohol rinse followed by forced air drying.

[Note]
Instead of manually injecting air via a 30 mL syringe through all internal channels as described above, compressed air 200 to 230 kPa (29 to 33.3 psi or 1500 to 1725 mmHg) may be used to purge all channels.
(15) Inject at least 60 mL or more of “70% Ethanol” or “70% Isopropyl Alcohol (IPA)” into the A/W supply channel and at least 90 mL of alcohol into the suction channel with a 30 mL syringe.

The cap should be attached to the forceps inlet during flushing of the suction channel.

[Note]
As with other chemicals, handle Ethanol and IPA with care and use it as per local guidelines.

(16) The flushing of alcohol through all channels should be followed by a forced air purge into the A/W and suction channels to expel alcohol and to enhance evaporation of residual moisture.

It is recommended to use forced/compressed air up to 228 kPa (33 psi or 1707 mmHg) for at least 30 seconds per channel system (A/W and suction/instrument) to more forcefully expel residual fluid and negate the need for repetitive flushing via a 30 mL syringe. Applying forced or compressed air to the channels already flushed with alcohol will facilitate drying of the internal channels of the endoscope.

(17) Detach the cleaning adapter kit from the endoscope.
(18) Detach the waterproof cap from the end of EVE connector.

[Note]
The EVE connector and waterproof cap should be completely dry before use and storage. To prevent residual water from dripping out of the cap onto electrical contacts, position the connector so the electrical contacts face downward and away from potential dripping fluid.

No residual water/fluid should remain inside the connector, near the electrical contacts or within the seam leading to the internal connection mechanism.

(19) Wipe off the end of EVE connector with dry sterile gauze/clean lint-free cloth.

(20) Wipe all external surfaces of the endoscope and the cleaning adapter kit with sterile gauze/clean lint-free cloth.

(21) Ensure that the endoscope is thoroughly dry.

(22) Store it according to Chapter 11 “Storage.”
8.5 Cleaning and/or High-Level Disinfection Using an Automated Endoscope Reprocessor (AER)

**WARNING**

Some legally marketed automated endoscope reprocessors (AERs) may be able to clean and/or disinfect FUJIFILM endoscopes. However, end-users should check with each AER manufacturer to confirm they have validation data to support their reprocessing claims for FUJIFILM endoscopes and removable endoscope components, such as valve mechanisms. Inadequate device-specific instructions and/or non-validated AER recommendations could result in unsuccessful cleaning and/or high-level disinfection which may increase risks to patient safety.

Follow all AER manufacturers’ reprocessing recommendations including for specific endoscope types (ex. duodenoscopes), features (ex. elevators) and/or removable scope components (ex. suction valves).

For information on efficacy of cleaning and high-level disinfection, consult the Automated Endoscope Reprocessor (AER) manufacturer.

Prior to high-level disinfection, all endoscopes must be pre-cleaned and manually cleaned in accordance with Sections 7.4 and 7.5.

8.5.1 Leak Testing

→ “7.5.3 Leak Testing”

[Note] FUJIFILM does not test or validate non-FUJINON/FUJIFILM leak testing devices including those installed in AERs or standalone automated systems. Check with each manufacturer to confirm their specific claims including compatibility with FUJIFILM endoscopes.

8.5.2 Brushing

Applicable channels of FUJIFILM endoscopes should be manually brushed as per the instructions contained in this operation manual.

→ “7.5.5 Cleaning Surface of Endoscope”
→ “7.5.6 Brushing Suction Channel and Channel Ports”
8.5.3 Channel Patency

Prior to automated reprocessing, ensure that all internal endoscope channels are "open" and unclogged. Certain AERs with validated channel monitoring capability may negate this requirement. Check with each AER manufacturer for their specific claims regarding channel monitoring.
Chapter 9   ETO Gas Sterilization

This chapter describes FUJIFILM recommendations for ethylene oxide gas sterilization.

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Chapter 9  ETO Gas Sterilization

**WARNING**
Ensure that all instrument surfaces are dry before attempting ETO gas sterilization. Failure to do so can result in inadequate sterilization.

**CAUTION**
Aeration procedures must be performed immediately after ETO gas sterilization in order to remove potentially harmful gas residuals from contacting patients. No or incomplete aeration can potentially harm patients.

**CAUTION**
These endoscopes are heat-sensitive devices which cannot withstand high temperatures associated with steam sterilization.

Duodenoscope model ED-530XT can be sterilized via ethylene oxide gas per the recommendations that follow.
Prior to sterilization, these instruments must be pre-cleaned and manually cleaned in accordance with Sections 7.4 and 7.5.

9.1 Conditions of Ethylene Oxide (ETO) Gas Sterilization

Efficacy of sterilization is influenced by many factors including but not limited to packaging of non-sterile items, positioning and placing in sterilizer, and load capacity. Check efficacy of sterilization using biological and chemical indicators. Use only legally marketed sterilizers and sterilization accessories.

Also, follow sterilization guideline provided by health service authorities, public institutions and other facilities, and operation manual of sterilizer.

In order to successfully sterilize FUJIFILM endoscopes and accessories by ETO gas sterilization, use the parameters described in Table 9.1.

If chemicals and/or conditions other than those listed in Table 9.1 are used, ensure that appropriate sterilization efficacy validation studies have been performed.
Facilities using ethylene oxide sterilization should note that “the resistance of microorganisms to deactivation by ethylene oxide is affected by their water content. For this reason it is common practice to control and monitor the humidity of the atmosphere to which the product is exposed in order to attempt to equilibrate the water content of the microorganisms with the local conditions. Before commencing the sterilization cycle, it is usual to precondition product at a defined temperature and humidity” (ISO 11135-1, at page 30). Alternatively, facilities may evaluate their sterilization chambers to ensure that they achieve adequate humidity and temperature by conditioning within the sterilization chamber. The validation studies conducted by FUJIFILM and described in this manual used conditioning and sterilization parameter shown in Table 9.1.

| Table 9.1 100% ETO gas |
|-------------------------|------------------|
| **Conditioning**        | **Value**        |
| Temperature             | 55ºC (131ºF)     |
| Humidity                | 60%RH            |
| Time                    | 60 minutes       |

| **Sterilization**       | **Value**        |
| Temperature             | 55ºC (131ºF)     |
| Humidity                | 60%RH            |
| ETO gas concentration   | 0.735 mg/cm³ (735mg/liter) |
| Exposure time           | 90 minutes       |

| **Aeration**            | **Value**        |
| Time                    | 12 hours 55ºC (131ºF) |

Table 9.2 Compatible methods of cleaning, high-level disinfection and sterilization for endoscopes and accessories

<table>
<thead>
<tr>
<th>Cleaning methods</th>
<th>Method of high-level disinfection and sterilization</th>
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</thead>
<tbody>
<tr>
<td>Detergent cleaning</td>
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<tr>
<td>Ultrasonic cleaning</td>
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</tr>
<tr>
<td>Suction button</td>
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</tr>
<tr>
<td>Cleaning brush [Note 4]</td>
<td>Yes [Note 3]</td>
</tr>
<tr>
<td>Carrying case</td>
<td>No</td>
</tr>
<tr>
<td>Cleaning adapter kit [Note 5]</td>
<td>Yes</td>
</tr>
</tbody>
</table>

[Note 1] Follow “8.2 Conditions of High-Level Disinfection.”
[Note 2] Follow “9.1 Conditions of Ethylene Oxide (ETO) Gas Sterilization.”
[Note 3] Use an ultrasonic cleaning unit specialized for medical accessories.
[Note 4] FUJINON/FUJIFILM cleaning brushes only are recommended. For non-FUJINON/FUJIFILM brushes, contact the original manufacturer.
[Note 5] Applies to all components of the cleaning adapter kit excluding syringe.
9.2 ETO Gas Sterilization

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**CAUTION**

Install ventilation adapter before applying ETO gas sterilization. Failure to do so can result in endoscope damage.

Remove ventilation adapter after aeration. Never soak the endoscope with the ventilation adapter attached, or fluid invasion may severely damage the endoscope.

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Regarding recommended ETO gas sterilization conditions, refer to Table 9.1.

1. Flush and dry all channels of the endoscope according to the “Alcohol flush” instructions in Section 8.4 “Rinsing Endoscope.”

2. Check before use that the ventilation adapter is free from deterioration, breakage, and clogging. If any abnormality is found, replace it with a new ventilation adapter.

3. Connect the ventilation adapter to the ventilation connector on LG connector of endoscope. The ventilation adapter “opens” the endoscope to allow a balance of internal and external pressures.
(4) Place and seal each item (endoscope with ventilation adapter, A/W button, suction button, cleaning adapter kit, etc.) into individual packaging/pouches according to institution protocol consistent with instructions of the sterilizer manufacturer.

(5) Put these packages in ETO gas sterilizer.

(6) Sterilize them according to operating procedure of ETO gas sterilizer.

(7) Follow the ETO gas sterilization parameter as described in Table 9.1.

[Note]
Prior to clinical use, detach the ventilation adapter from the ventilation connector of endoscope.
Chapter 10  Cleaning and High-Level Disinfection/Sterilization of Endoscopic Accessories

This chapter describes the recommendations for cleaning and high-level disinfection/sterilization of endoscopic accessories.

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Chapter 10 Cleaning and High-Level Disinfection/Sterilization of Endoscopic Accessories

**WARNING**

Endoscopic accessories must be completely immersed in a high-level disinfectant solution. Remove air bubbles completely. If any air bubbles remain, effective high-level disinfection may not be achieved and inadequately high-level disinfected accessories may be an infection risk.

Replace any components (air/water button, suction button, etc.) which may be damaged, deteriorated or may have any suspected abnormality with new properly reprocessed components before use. Failure to use an appropriately reprocessed component may pose an infection risk.

**CAUTION**

While brushing the A/W button do not advance the brush so far that the black rubber check valve falls off the bottom of the button. If the check valve is found missing, replace the A/W button with a new one.
10.1 Cleaning, Disinfecting and Sterilizing Air/Water Button and Suction Button

For operational methods of the ultrasonic cleaning unit/autoclaving unit, follow the instructions described in each operation manual for the respective units.

10.1.1 Cleaning Air/Water Button and Suction Button

1. Fill a basin with cleaning fluid at the temperature and concentration recommended by the detergent manufacturer.

2. Fully immerse the air/Water button and the suction button in the cleaning fluid.

3. Brush all surfaces of the buttons soaking in the detergent with a soft toothbrush while the buttons are actuated (depressed and released). Brush inside lumened areas while under cleaning fluid using the WB4321FW2 cleaning brush.

4. Using a 30 mL syringe inject cleaning fluid into all openings, internal areas and gaps/crevices of the buttons to ensure fluid contact with all surfaces and to completely remove all air bubbles. Inspect the movable areas of the buttons to ensure no air bubbles are trapped.

5. Keep the buttons immersed in the detergent solution in accordance with the temperature, concentration and time recommended by the detergent manufacturer, and cover the basin to prevent the evaporation of cleaning fluid.

6. Remove the buttons from the detergent solution and inspect them.

7. Fill a basin with potable water so that the entire buttons can be completely immersed.
(8) Fully immerse the air/water button and the suction button in the potable water and rinse them for a minimum of 1 minute.

(9) Using a 30 mL syringe inject the potable water into all openings, internal areas and gaps/crevices of buttons to ensure fluid contact with all surfaces and to completely remove all air bubbles. Actuate the buttons and inspect their movable areas to ensure no air bubbles are trapped.

(10) Repeat the rinsing procedure two more times for a total of 3 rinses.

(11) Remove the buttons out from the potable water.

(12) Wipe off the remaining water on the buttons with a clean lint free cloth and then inspect the buttons. Repeat these cleaning procedures, until all debris has been removed.

(13) For difficult to remove debris, ultrasonic cleaning may be performed in an ultrasonic cleaning unit intended for medical devices/accessories at a frequency of 33–48kHz for 20 minutes.

(14) After ultrasonic cleaning, thoroughly rinse all accessory surfaces in clean potable water. While soaking and gently agitating the buttons in water for at least 1 minute in duration, inject water onto all surfaces and lumens. Repeat rinsing at least 2 more times.

(15) Inspect the buttons and repeat cleaning until no debris is visible.

10.1.2 Disinfecting Air/Water Button and Suction Button

(1) Fill a basin with high-level disinfectant solution prepared according to the instructions by the high-level disinfectant solution’s manufacturer to completely immerse the air/water and suction buttons.

(2) Immerse the air/water button and suction button in the high-level disinfectant solution.
(3) Inject the high-level disinfectant solution into the all openings, internal areas and gaps of buttons, and wipe the surface with gauze in the high-level disinfectant solution to remove all air bubbles completely. Inspect the movable area of buttons and check if no air bubbles come out.

(4) Keep the buttons immersed in the high-level disinfectant solution in accordance with the temperature, concentration and time recommended by the high-level disinfectant solution’s manufacturer, and cover the basin to prevent the vaporization of high-level disinfectant solution.

(5) Remove the air/water button and the suction button from the high-level disinfectant solution.

(6) Fill a basin with sterile water to completely immerse the buttons.

(7) Soak the buttons in sterile water for a minimum of 1 minute, and rinse well while gently shaking.

(8) Inject sterile water into all openings, internal areas and gaps of buttons with a 30 mL syringe, and wipe the surface with sterile gauze in the sterile water to remove all air bubbles completely. Inspect the movable area of the buttons and confirm that no air bubbles come out.

(9) Repeat the previous rinsing step two more times for a total of 3 rinses using a fresh batch of sterile water each time.

(10) Remove the buttons from the sterile water.

(11) Wipe off the remaining water completely using dry sterile gauze/clean lint-free cloth.

(12) Dry them thoroughly.

(13) Store them according to Chapter 11 “Storage.”
10.1.3 Sterilizing Air/Water Button and Suction Button

(1) Thoroughly dry the air/water button and suction button.

(2) Put them in a sterile pack, and then seal the sterile pack tightly. See the operation manual of sterile pack for proper sealing.

(3) After putting the air/water button and suction button packed inside the sterile pack into the pre-vacuum steam sterilizer, follow the instructions provided by the manufacturer of the pre-vacuum steam sterilizer as well as specific sterilization parameters described in this manual.

For recommended pre-vacuum steam sterilization parameters, refer to Appendix “Autoclaving Conditions” in this operation manual.

(4) Store them according to Chapter 11 “Storage.”
10.2 Cleaning and Disinfecting Cleaning Brushes

Follow the instructions described in operation manual of ultrasonic cleaner.

10.2.1 Cleaning Cleaning Brushes

(1) Fill a basin with detergent solution prepared according to the detergent manufacturer’s recommendations.

(2) Immerse all cleaning brushes in the detergent solution.

(3) Brush the entire cleaning brush(es) in the detergent solution using a soft toothbrush.

(4) Wash the bristles of cleaning brushes with fingertips in the detergent solution.

(5) Inject the detergent solution into all gaps of cleaning brushes with a 30 mL syringe in the detergent solution to completely remove all air bubbles.

(6) Keep the cleaning brushes completely immersed in the detergent solution for the contact conditions recommended by the detergent manufacturer, and cover the basin to prevent the vaporization of detergent solution.

(7) Remove the cleaning brushes from the detergent solution.

(8) Clean the cleaning brushes with the ultrasonic cleaner set at 33-48kHz for 10 minutes in the detergent solution. Use a neutral pH, low-foaming, medical grade non-abrasive detergent solution for ultrasonic cleaning according to the time, temperature, concentration recommended by the detergent solution’s manufacturer.

(9) Fill basin with potable water to completely immerse the cleaning brushes.

(10) Immerse the cleaning brushes into the potable water, and rinse it well while gently shaking.
(11) Inject the potable water into all gaps of cleaning brushes with a 30 mL syringe in the potable water to completely remove all air bubbles.

(12) Remove the cleaning brushes from the potable water.

(13) Wipe off the remaining water on the cleaning brushes with a clean lint-free cloth. If you find any debris, repeat these procedures.

10.2.2 Disinfecting Cleaning Brushes

(1) Fill a basin with high-level disinfectant solution prepared according to the instructions by the high-level disinfectant solution’s manufacturer to completely immerse the entire cleaning brushes.

(2) Immerse the entire cleaning brushes in the high-level disinfectant solution.

(3) Inject the high-level disinfectant solution into all gaps with a 30 mL syringe, and wipe the surface with gauze in the high-level disinfectant solution to remove all air bubbles.

(4) Keep the cleaning brushes immersed in the high-level disinfectant solution in accordance with the temperature, concentration and time recommended by the high-level disinfectant solution’s manufacturer, and cover the basin to prevent the vaporization of high-level disinfectant solution.

(5) Remove the cleaning brushes from the high-level disinfectant solution.

(6) Fill a basin with sterile water to completely immerse the cleaning brushes.

(7) Immerse the cleaning brushes into sterile water, and rinse it well while gently shaking. Wipe the surface with sterile gauze in sterile water.

(8) Inject sterile water into all gaps with a 30 mL syringe in sterile water to completely remove all air bubbles.
(9) Repeat step (8) two more times for a total of 3 rinses using a fresh batch of sterile water each time.

(10) Remove the cleaning brushes from the sterile water.

(11) Wipe off the remaining water on the cleaning brushes with sterile gauze.

(12) Dry them thoroughly.

(13) Store them according to Chapter 11 “Storage.”

10.2.3 Sterilizing Cleaning Brushes

(1) Dry the cleaning brushes thoroughly after cleaning.

(2) Carry out the ETO gas sterilization of the cleaning brushes according to the steps (2) to (5) in Section 9.2 “ETO Gas Sterilization.”

(3) Store them according to Chapter 11 “Storage.”
10.3 Autoclaving Cleaning Adapter Kit CA-503/A

(1) Thoroughly dry the cleaning adapter kit.

⇒ “7.5 Manual Cleaning (cleaning in basin)”

(2) Put it in a sterile pack and seal the pack tightly.

(3) Autoclave the cleaning adapter kit according to the instructions provided by the manufacturer of the pre-vacuum steam sterilizer as well as specific sterilization parameters described in this manual.

For recommended pre-vacuum steam sterilization parameters, refer to Appendix “Autoclaving Conditions” in this operation manual.
10.4 High-Level Disinfecting and Sterilizing Forceps Valve (FOV-DV7)

The forceps valve is provided non-sterile and must be high-level disinfected or sterilized prior to use following the instructions below. The forceps valve is a single patient use item. Do not reuse.

10.4.1 High-Level Disinfection of Forceps Valve

**WARNING**

The forceps valve must be completely immersed in a high-level disinfectant solution. Remove air bubbles completely. If any air bubbles remain, effective high-level disinfection cannot be achieved and an inadequately high-level disinfected forceps valve may be an infection risk.

1. Fill a basin with a high-level disinfectant solution prepared according to the recommendations by the high-level disinfectant solution’s manufacturer to completely immerse the forceps valve.

[Note]

When you carry out high-level disinfection using chemical solution, follow the conditions indicated in Section 8.2 “Conditions of High-Level Disinfection” in this operation manual.

2. Ensure that the lid of the forceps valve is removed from the main body and completely immerse the forceps valve in the high-level disinfectant solution.

3. Inject high-level disinfectant solution with a 30 mL syringe into all openings, internal areas and gaps of the forceps valve, and wipe its surfaces with gauze to remove air bubbles completely.

4. Keep the forceps valve immersed in the high-level disinfectant solution in accordance with the temperature, concentration and time recommended by the high-level disinfectant solution’s manufacturer, and cover the basin to prevent the vaporization of the high-level disinfectant solution.
(5) Remove the forceps valve from the high-level disinfectant solution.

(6) Fill the basin with sterile water.

(7) Soak the forceps valve into sterile water, and rinse it well while gently shaking.

(8) Inject sterile water with a 30 mL syringe into all openings, internal areas and gaps of the forceps valve with a 30 mL syringe, and wipe its surfaces with sterile gauze in sterile water to remove air bubbles completely.

(9) Remove the forceps valve from sterile water.

(10) Wipe off the remaining water on the forceps valve with sterile gauze or clean lint-free cloth.

(11) Dry it thoroughly.

10.4.2 Autoclave (Pre-vacuum Steam) Sterilization

(1) Ensure that the forceps valve is thoroughly dry.

(2) Put the forceps valve in a sterile pack, and then seal the sterile pack tightly according to the manufacturer’s instructions.

(3) Follow the operating instructions from the manufacturer of the autoclave equipment including placement of the sterile packs.

For recommended pre-vacuum steam sterilization parameters, refer to Appendix “Autoclaving Conditions” in this operation manual.
Chapter 11  Storage

This chapter describes the recommendations for storage.
Chapter 11 Storage

**WARNING**

Do not store this product in a carrying case. Storage of this product in a carrying case and subsequent clinical use may cause infection.

- Detach removable parts (air/water supply button, suction button and forceps valve) from endoscope.
- Confirm all endoscope and component surfaces are dry.
- Hang endoscope in a storage cabinet with the distal end hanging freely.
- Be sure that the insertion portion hangs freely and as straight as possible.

**CAUTION**

Do not store this product in locations that do not satisfy the storage conditions. Improper storage may cause damage to this product.

Endoscope, air/water supply button, suction button, cleaning brushes and ventilation adapter should be stored in a location that satisfies the following conditions.

<table>
<thead>
<tr>
<th>Storage Conditions</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature</td>
<td>+10 to +40°C (50 to 104°F)</td>
</tr>
<tr>
<td>Humidity</td>
<td>30 to 85%RH (no dew condensation)</td>
</tr>
<tr>
<td>Pressure</td>
<td>70 to 106 kPa (10.2 to 15.4 psia or 525 to 795 mmHg) (within range of atmospheric pressure)</td>
</tr>
<tr>
<td>State of endoscope</td>
<td>Straight, rather than bent, state.</td>
</tr>
<tr>
<td></td>
<td>Condition not subjected to external force.</td>
</tr>
<tr>
<td></td>
<td>Hung with control portion up.</td>
</tr>
</tbody>
</table>
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Appendix-1
Autoclaving Conditions

The efficacy of autoclaving sterilization is influenced by many factors including but not limited to packaging of non-sterile items, positioning and placing in sterilizer, and load capacity. Check the efficacy of sterilization using biological and chemical indicators. Use only legally marketed sterilizers and sterilization accessories. Also, follow the sterilization guideline provided by health service authorities, public institutions and other facilities, and the operation manual of sterilizer. Handling a wet package can compromise sterility of the contents. Ideally, use the autoclave’s drying cycle to allow the packages to dry.

FUJINON/FUJIFILM air/water supply button, suction button and cleaning adapter kit may be sterilized using pre-vacuum steam sterilization by following the parameters described below.

<table>
<thead>
<tr>
<th>Sterilizer type</th>
<th>Pre-vacuum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature</td>
<td>132°C (270°F)</td>
</tr>
<tr>
<td>Exposure time</td>
<td>4 minutes</td>
</tr>
<tr>
<td>Drying time</td>
<td>20 minutes</td>
</tr>
</tbody>
</table>

[Note] The above pre-vacuum steam sterilization (autoclaving) conditions (132°C for 4 minutes) were used in FUJIFILM's validation studies. However, each health care facility should follow the relevant industry standards, facility-specific procedures and sterilizer manufacturer's instructions to ensure the adequacy of its sterilization processes.
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