CFlex™

Single-Use Cystoscope

Operations & Maintenance Manual

CFlex™
verathon

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Single-Use Cystoscope

Operations & Maintenance Manual

Effective: 7 May 2026

Caution: Federal (United States) law restricts this device to sale by or on the order of a physician.

Contact Information

To obtain additional information regarding your Verathon system,
please contact Verathon Customer Care or visit verathon.com/service-and-support.

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Table of Contents

Important Information

Product Description

The CFlex cystoscope is a sterile, single-use, flexible cystoscope intended for use in endoscopic access to the lower urinary tract and examination of it through a CystoView monitor. The cystoscope can be used with IEC 60601-2-2–certified monopolar electrocautery tools and with non-powered endoscopic accessories.

Note: This manual covers the single-use cystoscope and the reusable cable. For information about using a video monitor, refer to that monitor's Operations & Maintenance Manual.

Intended Use/Indications for Use

The CFlex Single-Use Cystoscope is a sterile, single-use, flexible cystoscope intended to be used for endoscopic access to and examination of the lower urinary tract. The cystoscope is intended to provide visualization via compatible Verathon monitor and can be used with endoscopic accessories.

The cystoscope is intended for use in adults requiring cystoscopy by qualified urology professionals in a clinic, hospital or ambulatory surgery center (ASC) environment.

The CystoView monitor is intended to display live imaging data from the CFlex Single-Use Cystoscope.

Contraindications

CFlex Cystoscope is not indicated for use with severe urethral stricture, patients with acute infection (acute urethritis, acute prostatitis, acute epididymitis), and on patients on anticoagulants or with coagulopathies.

Statement of Prescription

The system should be used only by individuals who have been trained and authorized by a physician or used by healthcare providers who have been trained and authorized by the institution providing patient care.

Product Compatibility

The CFlex Single-Use Cystoscope has been designed to be used with:

ENDOSCOPIC ACCESSORIES

- Irrigation set (line and sterile water or saline bag) with luer connection
- Syringe and other luer connecting accessories
- Endoscopic accessories labeled for use in a minimum working channel size of (ID) 2.0 mm / 6.0 Fr or less[1]
- Electrocautery tools (monopolar only) used with electrosurgical generators, both of which are certified as compliant with IEC 60601-2-2. To keep high-frequency leakage currents within allowed limits, voltage levels must not exceed the following:
    - Sinusoidal output: 2.2 kV_{pp}
    - Cut: 1.1 kV_{p}
    - Coagulation: 2.4 kV_{p}

[1] *There is no guarantee that instruments selected solely using this minimum working channel size will be compatible in combination. Compatibility of selected instruments should be tested before the procedure.*

Notice to All Users

Verathon recommends that all users do the following:

- Read this manual and the manuals for any applicable accessories or applied parts before use.
- Obtain instruction from a qualified individual.
- Practice using the cystoscope on a mannequin before clinical use.

Warnings & Cautions

Warnings indicate that injury, death, or other serious adverse reactions may result from use or misuse of the device. *Cautions* indicate that use or misuse of the device may cause a problem, such as a malfunction, failure, or damage to the product.

Warnings: Use

WARNING

Before every use, ensure that the instrument is operating correctly and has no sign of damage. Do not use this product if the device appears damaged. Refer servicing to qualified personnel.

Report any suspected defects to Verathon Customer Care. For contact information, visit verathon.com/service-and-support.

WARNING

No modification of this equipment is allowed.

WARNING

Verathon has conducted no analysis to establish the compatibility of the system with environments where magnetic resonance imaging (MRI) equipment is installed. Because of this, the owner of the system must exclude it from any magnetic resonance (MR) environment.

WARNING

Verathon has conducted no analysis to establish the compatibility of the system with environments where shortwave or microwave diathermy equipment is in use. Because of this, the cystoscope should not be used in the presence of shortwave or microwave diathermy.

WARNING

Do not use the cystoscope in conjunction with laser tools. Use of such tools with the cystoscope may cause harm to the patient or damage to the cystoscope.

WARNING

The video signals produced and used by this system are intended for device positioning only. Do not use the system as the sole diagnostic method of any pathology.

WARNING

This instrument and related devices may contain batteries or other environmentally hazardous materials. When the instrument or accessories have reached the end of their useful service life, see the section Device Disposal. Dispose of used, single-use components as infectious waste.

WARNING

Two areas of the cystoscope tip that contact the patient can exceed 41°C (106°F) as part of normal operation:

The first area is the light-emitting area surrounding the camera in the tip. When used as indicated, continuous contact with this area is unlikely because, if tissue were to contact this area, a usable view would be lost. Devices would then need to be adjusted to regain the working distance needed for a usable view.

The second area is the area of the tip that surrounds the camera, but is out of its field of view. Continuous contact with this area is unlikely because the product is typically not held stationary for an extended period of time, and because there is normally a small clearance between the area and the adjacent tissue.

To prevent thermal damage, such as a burn to the mucosal tissue, avoid prolonged, continuous contact with these areas of the cystoscope tip.

WARNING

The high-intensity light emitted by the cystoscope can create high temperatures in front of the distal tip. To avoid heat-related injury, do not view the same area at close range for a long period of time.

WARNING

An insecure or leaky irrigation connection may cause loss of image during electrocautery and injury to the patient. Make sure that irrigation tubing is securely connected to the cystoscope before performing the procedure.

WARNING

Inflow of gas, such as gas supplied by endoscopic accessories or due to over-insufflation, may cause gas embolism leading to stroke or ischemia in tissue.

WARNING

Do not use the cystoscope in conjunction with electrosurgical equipment, such as electrocautery tools, if flammable or explosive gases are present. To avoid risk of gas explosions, ensure adequate patient preparation and gas evacuation before activating any high-frequency surgical equipment.

WARNING

While using sharp or powered endoscopic accessories, be careful not to damage the working channel or the distal tip of the cystoscope. Such damage may result in patient injury.

WARNING

Do not advance the cystoscope while endoscopic accessories extend out of the opening in the distal tip. The resulting accessory movements may result in patient injury.

WARNING

When electrosurgical equipment is being used with the cystoscope, image degradation can occur. If such degradation interferes with the procedure, reposition the electrosurgical equipment before continuing.

WARNING

Before withdrawing the cystoscope, place the distal tip as close to a straight, neutral position as possible. While withdrawing, keep the control lever as close to a neutral position as possible and do not apply excessive force. Any bend in the distal tip, or use of excessive force while withdrawing the cystoscope, may result in patient injury.

WARNING

Do not use excessive force when inserting, positioning, or removing the single-use cystoscope or accessories. Using excessive force against resistance could lead to product damage, including damage to or detachment of the distal tip, and could result in harm to the patient.

WARNING

If a malfunction should occur during use, do not continue the procedure. Place the distal tip into a straight, neutral position, and then slowly withdraw the cystoscope without touching the control lever.

WARNING

Before discarding a cystoscope, ensure that no parts of the camera, distal tip, or insertion tube are missing.

WARNING

To reduce the risk of high-frequency burns to the patient or operator, ensure that the active electrode is at a sufficient distance from the tip of the endoscope and in the correct position for the procedure before activation.

WARNING

Ensure that any lesion being subjected to high-frequency current is not allowed to touch normal mucosa during activation of the electrode.

Warnings: Reprocessing

WARNING

Do not reuse, reprocess, or resterilize single-use components. Reuse, reprocessing, or resterilization may create a risk of contamination of the device.

Warnings: Electrical

WARNING

When using powered endoscopic accessories, patient leakage currents may combine and exceed safe limits, resulting in patient injury. To prevent this, use only powered endoscopic accessories classified as having type CF or type BF applied parts with the cystoscope.

WARNING

Electric shock hazard. Do not attempt to open the system components. This may cause serious injury to the operator or damage to the instrument and voids the warranty. Contact Verathon Customer Care for all servicing needs.

WARNING

Use of accessories and cables other than those specified or provided by Verathon may cause this system to experience electromagnetic malfunctions, including increased emissions or decreased immunity. This may cause improper operation, procedure delays, or both.

WARNING

Portable radio frequency communications equipment (including peripherals such as antenna cables and external antennas) may not be used within 30 cm (12 inches) of any part of the CFlex Single-Use Cystoscope system, including cables that Verathon specifies or provides for use with the system. If this distance is not maintained, performance of the system may be degraded and image display may be compromised.

WARNING

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

WARNING

Do not activate any energized tool unless it is visible within the image displayed on the monitor. Activating energized tools within the working channel may harm the patient.

WARNING

There are risks associated with the application of electrocautery, including the risk of burning the patient and operator. Ensure all equipment (including the high frequency surgical equipment, the electrocautery tool, the adapter cables and the neutral electrodes) are used in accordance with the manufacturers' instructions for use.

Cautions: Use

CAUTION

Do not use a knife or other sharp instrument to open the packaging containing the cystoscope, and do not use the cystoscope if its packaging is damaged.

CAUTION

When using this system, make sure another single-use cystoscope and monitor are readily available as a backup in case a malfunction occurs.

Cautions: Electrical

CAUTION

Select only equipment and applications that are compatible for use with the cystoscope. For more information, refer to the "Product Compatibility" section of this manual.

CAUTION

Ensure that the high-frequency surgical equipment used is compatible with all accessories and applied parts selected for use. To confirm compatibility, follow the guidance in the instructions for use provided by the manufacturer of the high-frequency surgical equipment.

CAUTION

Do not activate any energized tool unless it is visible within the image displayed on the monitor. Activating energized tools within the working channel may damage the cystoscope.

Introduction

This manual discusses the following components of the CFlex Single-Use Cystoscope system:

- CFlex cystoscope (single-use)
- 2m QuickConnect Cable (reusable)

Note: This manual covers the single-use cystoscope and the reusable cables. For information about using a video monitor, refer to that monitor's Operations & Maintenance Manual.

Figure 1. CFlex Single-Use Cystoscope and Cable

Parts & Accessories

Table 1. System Components

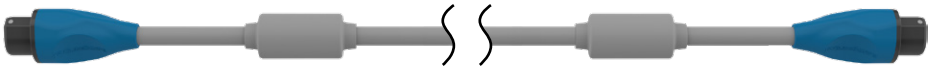
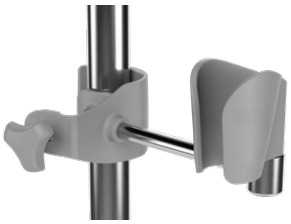
CYSTOSCOPES
CFlex
CFlex 5.0 Standard Deflection Single-Use cystoscope 
CFlex 5.0 Reverse Deflection Single-Use cystoscope 
Accessories
2m QuickConnect Cable 
CystoView monitor 

Table 2. Optional System Components

OPTIONAL PARTS & ACCESSORIES	
Verathon Essential Workstation 	
Endoscope holder for Verathon Essential Workstation 	Endoscope holder for IV pole 

Cystoscope Components

The CFlex cystoscope is a single-use device. The main components of the cystoscope are shown in the following figure.

Figure 2. Cystoscope Components

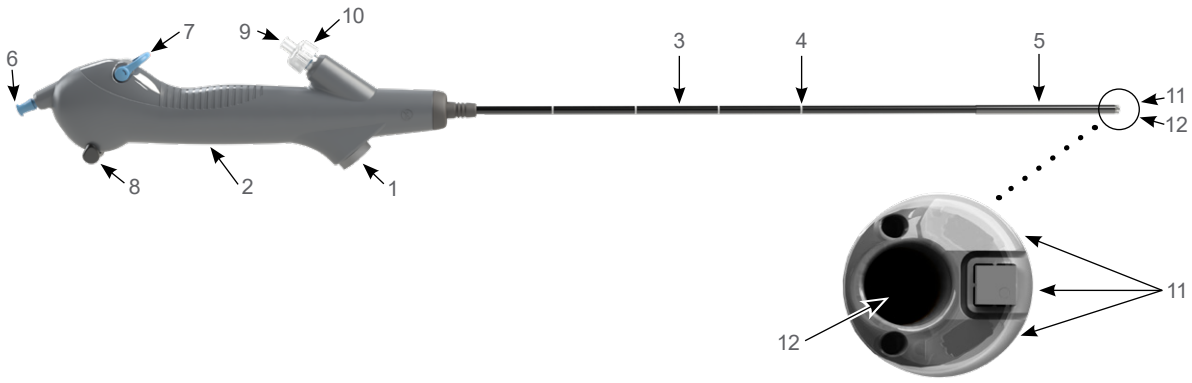


Table 3. Cystoscope Component Descriptions

FIGURE KEY	COMPONENT	NOTES
1	Cable connector	Includes magnetic quick release.
2	Handle	—
3	Insertion tube	—
4	Positioning marks	Includes marks at 5 cm (50 mm) intervals to assist in measuring prostatic length.
5	Articulating distal tip	—
6	Irrigation port	Includes fitting for attachment of irrigation tubing using either a luer connection or a standard connection.
7	Irrigation lever	Switches irrigation fluid supply on and off, and controls irrigation flow rate.
8	Control lever	Controls the deflection angle of the distal tip.
9	Accessory port	Enables introduction of accessories, liquids, or aspiration. Includes luer fitting for attachment of syringes.
10	Accessory port valve	Tuohy-Borst hemostatic valve allows placement and positioning of accessories without fluid leaks.
11	Camera and light	High-resolution, full-color camera with integrated LED light source and anti-fog protection.
12	Working channel	—

Setting Up

Before you can use the system for the first time, you must inspect the components, set up the system, and perform a functional test as recommended by Verathon. Complete the following tasks:

1. Perform Initial Inspection—Inspect the system for any obvious physical damage that may have occurred during shipment.
2. Attach the Video Cable to the Monitor—Connect the QuickConnect cable to the monitor.
3. Attach the Cystoscope to the Video Cable—Connect the cystoscope to the cable.
4. Perform a Functional Check—Before you use the device for the first time, perform a functional check to ensure that the system is working properly.

Perform Initial Inspection

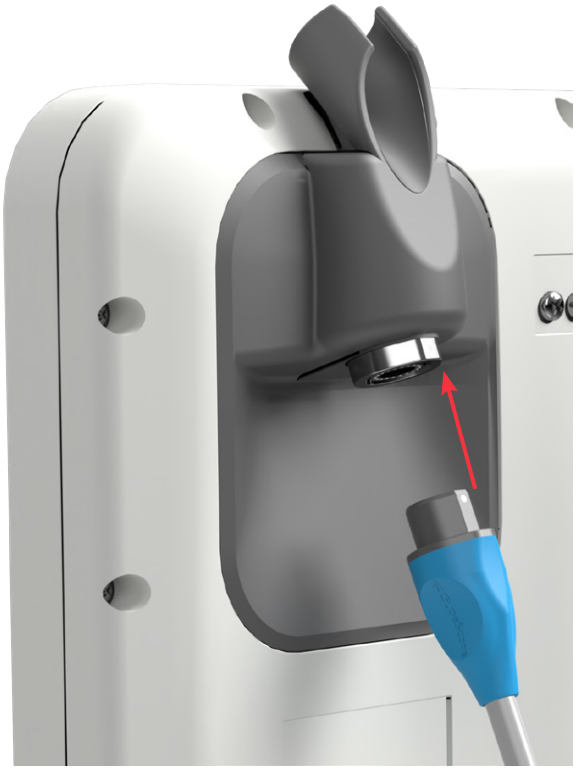
When you receive the system, Verathon recommends that an operator familiar with the instrument perform a full visual inspection of the system for any obvious physical damage that may have occurred during shipment.

1. Verify that you have received the appropriate components for your system by referring to the packing list included with the system.
2. Inspect the components for damage, making sure that there are no rough surfaces, sharp edges, or protrusions that could cause harm to the patient.
3. If any of the components are missing or damaged, notify the carrier and Verathon Customer Care or your local representative. For contact information, visit verathon.com/service-and-support.

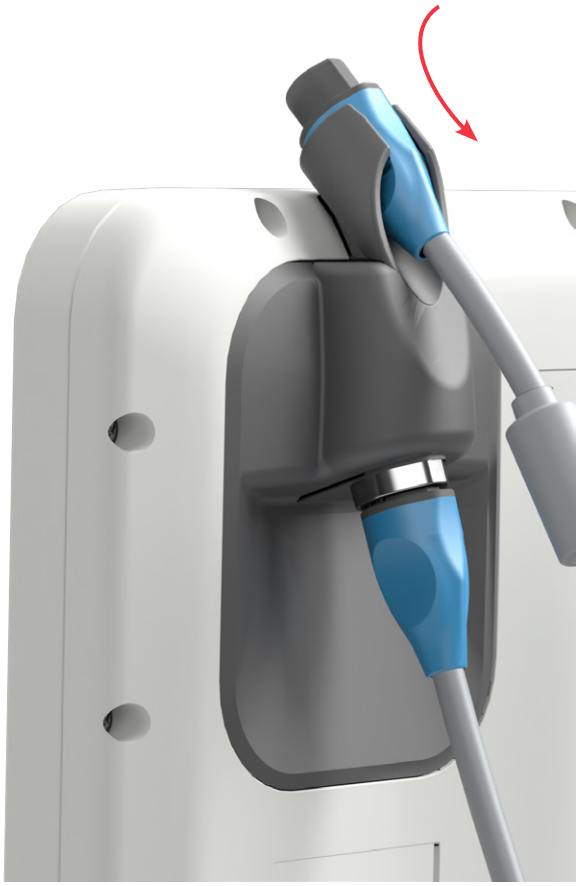
Attach the Video Cable to the Monitor

This procedure provides basic instruction on connecting video cables to a monitor. For information on a specific monitor, please refer to its Operations & Maintenance Manual, or contact Verathon Customer Care.

1. Align the dot on cable connector to the dot on one of the monitor's video connectors, and then fully insert the cable. The connector attaches to the monitor.



2. Place the cable's other connector into the cable rest to store it until it is used.



3. To disconnect the video cable, hold the cable connector in one hand and support the monitor with the other, and then pull. The cable disconnects from the monitor.

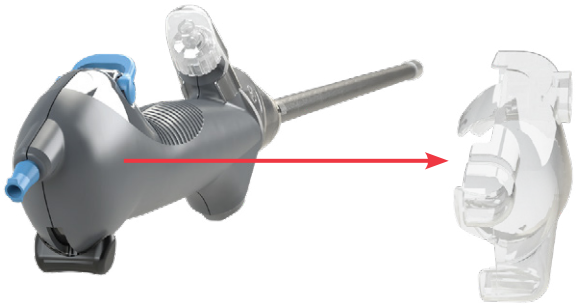
Attach the Cystoscope to the Video Cable

The 2m QuickConnect Cable attaches the cystoscope to the monitor, supplying power to the cystoscope and transmitting video data from the camera to the monitor.

It is recommended that you leave the sterile, single-use cystoscope in its protective sleeve while connecting it, and that you do not remove the cystoscope until you are ready to insert it. This helps ensure that the cystoscope remains as clean as possible.

1. If necessary, connect the cable to the monitor according to the procedure “Attach the Video Cable to the Monitor.”
2. Remove the cystoscope from its pouch, holding it by its protective sleeve.

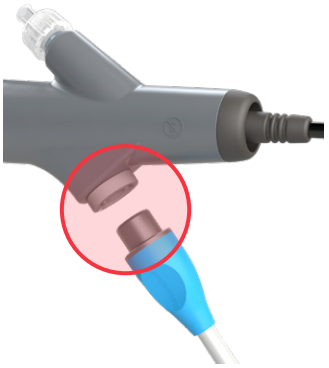
3. Dispose of the pouch as the policy of your hospital or clinic requires.
4. Detach and remove the handle cover.



5. If you are placing the cystoscope into a Verathon endoscope holder for later use, insert the cystoscope with its protective sleeve into the holder.

6. Inspect the cystoscope to ensure that it is functional.

7. Align the white dot on the opposite end of the QuickConnect Cable with the dot on the cystoscope, and then insert the connector into the cystoscope. Magnets in both components hold them in place during use.



8. To disconnect a cystoscope from the QuickConnect Cable, hold the cable connector in one hand and the handle of the cystoscope in the other, and then pull. The cystoscope disconnects from the cable.

RELATED INFORMATION

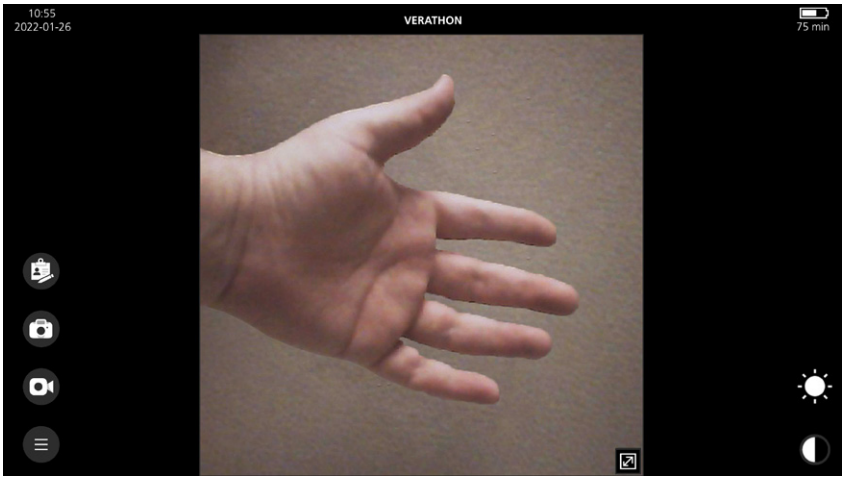
Attach the Video Cable to the Monitor (page 13)

Perform a Functional Check

Before you use the device for the first time, perform the following functional check to ensure that the system is working properly. Please contact your Verathon Customer Care representative if your system does not function as described below.

1. Fully charge the monitor battery (this takes approximately 6 hours).
2. Attach a QuickConnect Cable and a cystoscope to the monitor, according to the instructions in the corresponding procedures.
3. Turn the monitor on.
4. Temporarily slide the protective sleeve off the insertion tube of the cystoscope.

5. Look at the monitor screen and verify that the image displayed is being received from the cystoscope.



RELATED INFORMATION

Attach the Video Cable to the Monitor (page 13)

Attach the Cystoscope to the Video Cable (page 15)

Using the Device

Before use, set up the device according to the instructions in the previous chapter, and verify the setup by completing the procedure “Perform a Functional Check.”

IMPORTANT

Please read the “Warnings & Cautions” section before performing the following tasks.

Use of the cystoscope consists of the following tasks:

- Prepare the System
- Connect the Irrigation Fluid Supply
- Control Irrigation
- Position the Handle and Controls
- Insert and Flex the Cystoscope
- Attach a Syringe (Optional)
- Introduce Endoscopic Accessories (Optional)
- Use an Electrocautery Tool with the Cystoscope (Optional)
- Remove the Cystoscope

Note: Follow accepted practices to protect the cystoscope from contamination before insertion.

Procedure 1. Prepare the System

In this procedure, you turn the system on and verify that it is functioning properly.

1. Ensure that each system component has been properly cleaned.
2. Attach the QuickConnect cable and the cystoscope to the monitor, according to the instructions in this manual and in the monitor's Operations & Maintenance Manual.
3. Turn on the monitor.

   Note: If the monitor locks up, becomes unresponsive for any reason, or does not show an image from the cystoscope, consult the monitor's Operations & Maintenance Manual for resetting instructions.
4. Ensure that the battery is sufficiently charged. If necessary, connect the monitor directly to power.
5. On the monitor screen, verify that the image displayed is from the cystoscope camera.

   Note: You do not need to set white balance. The cystoscope and the monitor adjust white balance automatically.
6. Move the control lever back and forth through its range of motion. Make sure that the distal tip moves correctly in response.

RELATED INFORMATION

Attach the Video Cable to the Monitor (page 13)

Connect the Irrigation Fluid Supply (page 20)

Control Irrigation (page 22)

Insert and Flex the Cystoscope (page 24)

Procedure 2. Connect the Irrigation Fluid Supply

Make sure the supply of irrigation fluid is securely connected to the cystoscope before you begin the procedure.

1. Move the irrigation lever all the way down to close the stopcock completely.

2. Turn the accessory port valve clockwise to close it.

3. Position the irrigation fluid bag so that leaked or spilled fluid does not affect other equipment or create a hazard.
4. Seat the irrigation tubing over the flange on the irrigation port.

5. Open the valve on the irrigation fluid bag to allow the fluid to reach the cystoscope.

Procedure 3. Control Irrigation

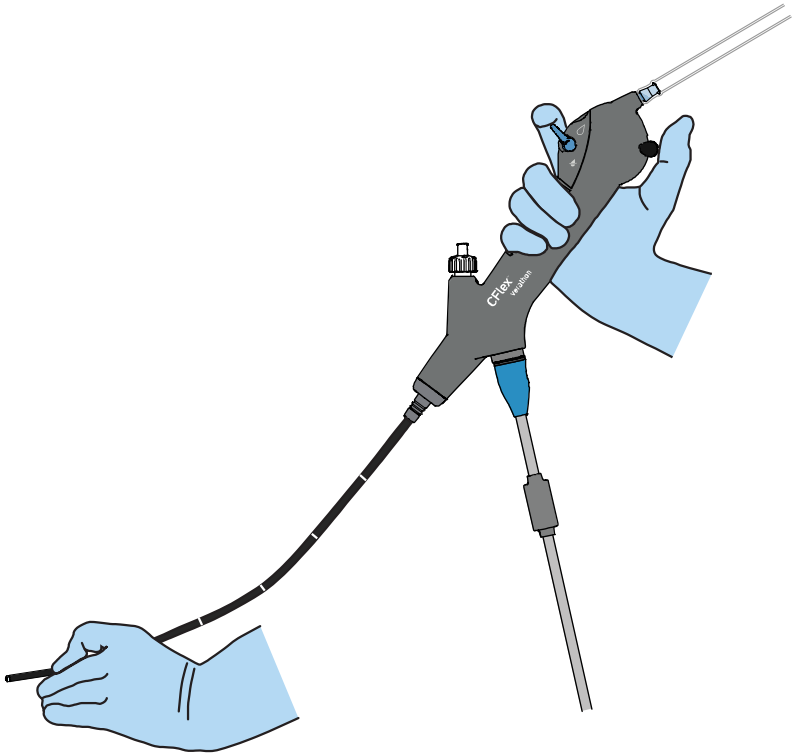
The irrigation port connects to the working channel just inside the accessory port valve. During irrigation, be sure to keep the accessory port valve closed tightly enough to avoid leaks.

1. Move the irrigation lever back and forth. Make sure that the irrigation fluid flows and stops correctly and that moving the lever adjusts the volume of flow.
2. Adjust the irrigation lever to dispense the necessary amount of fluid.

Procedure 4. Position the Handle and Controls

With your hands positioned as described in this procedure, you can regulate irrigation with your index finger and position the distal tip of the cystoscope with your thumb. You can then use your other hand to introduce accessories or liquids through the working channel, to grasp and turn the insertion tube, or to provide additional support as appropriate. If you need to do several of these things at once, you may need a second person to assist.

1. Empty the hand you will use to support and operate the cystoscope. This should normally be your dominant hand.
2. Using that hand, grasp the handle in the center.
3. Place the control lever under your thumb.
4. Make sure your index finger is within easy reach of the irrigation lever.



Procedure 5. Insert and Flex the Cystoscope

IMPORTANT

Verathon has tested compatibility with water based lubricants and common lidocaine-based topical analgesic preparations (1% liquid or 2% jelly) only.

1. Carefully slide the protective sleeve off the insertion tube of the cystoscope.

2. Remove your thumb from the control lever of the cystoscope. Verify that the distal tip is completely straight and in a neutral position.
3. Lubricate the distal tip and insertion tube of the cystoscope, and then slowly insert the distal tip of the cystoscope. While performing the insertion, observe the image on the monitor to verify that the insertion is proceeding normally.

4. Using your thumb, move the control lever to flex the distal tip forward and backward (to flex and retroflex the tip) as needed. The tip flexes with the lever as shown in the accompanying figures.

   Note: The illustrations show the movements of the control lever and distal tip on the standard CFlex cystoscope. A CFlex cystoscope with reversed tip movements (reverse deflection) is also available. For more information, contact Verathon or your Verathon representative.

Flex *Retroflex*

5. If the image on the monitor becomes blurred after the distal tip reaches the bladder, attempt to clear it by rubbing the tip against the mucosal wall. If this is not effective, carefully withdraw the cystoscope and then clean the distal tip.

6. As you carefully advance and flex the distal tip, rotate the handle around its long axis. By combining all three movements, you can direct the tip to any point in the direction of insertion.

Procedure 6. Attach a Syringe (Optional)

IMPORTANT

Please read the “Warnings & Cautions” section before performing the following task.

The working channel on the cystoscope can support the following tasks:

- Administering a liquid, such as a contrast agent
- Aspirating fluid from the bladder

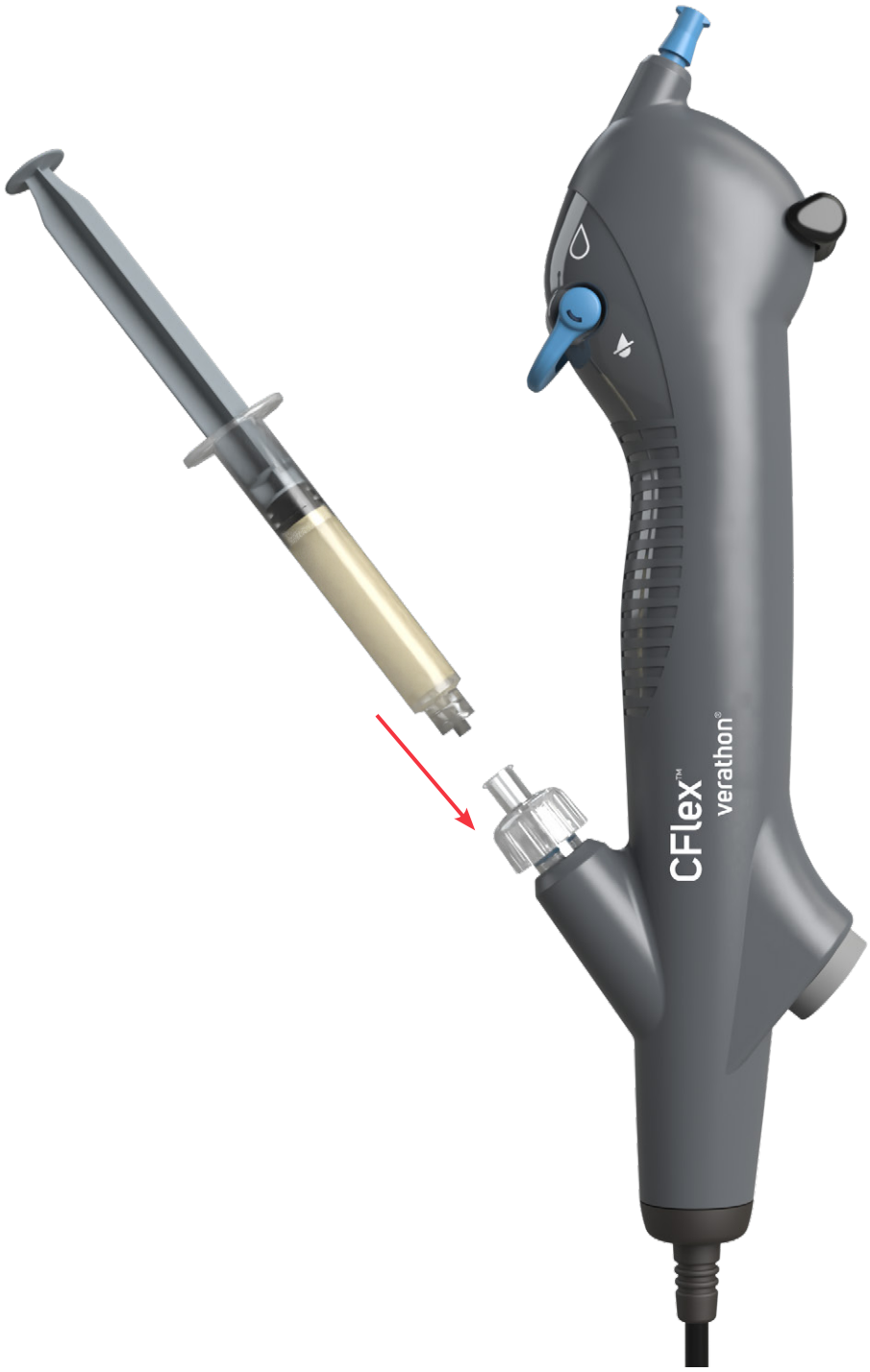
Note: Iohexol-based contrast agents are compatible with the cystoscope.

The accessory port is equipped with a flange for easy attachment of luer lock syringes. You can also attach standard syringes to the port.

1. Move the irrigation lever all the way down to close the stopcock completely.

2. If you are using the syringe to introduce a solution into the bladder, aspirate the solution into the syringe.

3. Insert the tip of the syringe into the accessory port until it is fully engaged. If you are using a standard syringe, make sure its tip is securely seated within the port. If you are using a luer lock syringe, make sure its locking connector is fully seated on the flange of the port.



4. If you are using a luer lock syringe, turn it to lock it into place.

5. Turn the accessory port valve counterclockwise to open the channel.

Note: If you need to aspirate more fluid than the syringe can hold, remove the syringe and empty it. Repeat this procedure to attach the syringe and aspirate the remaining fluid.

Procedure 7. Introduce Endoscopic Accessories (Optional)

The working channel of the cystoscope has a minimum inside diameter of 2.4 mm. For compatibility, please refer to the tool or accessory manufacturer's documentation and make sure that it can operate safely within a channel of that diameter.

1. Inspect the accessory for damage, making sure that there are no rough surfaces, sharp edges, or protrusions that could cause harm to the patient.
2. Move the control lever to return the distal tip as close to a straight position as possible.
3. Move the irrigation lever all the way down to close the stopcock completely.

4. Turn the accessory port valve counterclockwise to expand the valve enough to accommodate the accessory.

5. If appropriate, position the accessory so that its distal end fits through the accessory port and the working channel.

6. Insert the distal end of the accessory through the accessory port and into the working channel.

7. Turn the accessory port valve clockwise until you barely start to feel resistance when moving the accessory through the working channel. This allows you to position the accessory without allowing leaks.
8. Slide the accessory through the working channel until the end of the accessory is just inside the distal tip of the cystoscope.
9. Position the distal tip of the cystoscope near the site of the procedure.
10. Position the end of the accessory as needed to perform the procedure.

Procedure 8. Use an Electrocautery Tool with the Cystoscope (Optional)

WARNING

Do not activate any energized tool unless it is visible within the image displayed on the monitor. Activating energized tools within the working channel may harm the patient.

WARNING

To reduce the risk of high-frequency burns to the patient or operator, ensure that the active electrode is at a sufficient distance from the tip of the endoscope and in the correct position for the procedure before activation.

WARNING

Do not use the cystoscope in conjunction with electrosurgical equipment, such as electrocautery tools, if flammable or explosive gases are present. To avoid risk of gas explosions, ensure adequate patient preparation and gas evacuation before activating any high-frequency surgical equipment.

WARNING

Ensure that any lesion being subjected to high-frequency current is not allowed to touch normal mucosa during activation of the electrode.

WARNING

There are risks associated with the application of electrocautery, including the risk of burning the patient and operator. Ensure all equipment (including the high frequency surgical equipment, the electrocautery tool, the adapter cables and the neutral electrodes) are used in accordance with the manufacturers' instructions for use.

CAUTION

Select only equipment and applications that are compatible for use with the cystoscope. For more information, refer to the "Product Compatibility" section of this manual.

CAUTION

Ensure that the high-frequency surgical equipment used is compatible with all accessories and applied parts selected for use. To confirm compatibility, follow the guidance in the instructions for use provided by the manufacturer of the high-frequency surgical equipment.

CAUTION

Do not activate any energized tool unless it is visible within the image displayed on the monitor. Activating energized tools within the working channel may damage the cystoscope.

1. Prepare the electrocautery tool and the patient for the procedure, according to the electrocautery system manufacturer's instructions for use. To avoid the possibility of harm to the patient, be sure to follow the guidelines those instructions provide for correct placement of electrodes, high-frequency cables, and other equipment that may come into contact with the patient.
2. Insert the electrocautery tool into the working channel of the cystoscope, as described in the procedure "Introduce Endoscopic Accessories."
3. Verify that the electrocautery tool is the only tool or accessory in the working channel.
4. Configure the electrocautery system for use.
   - To ensure compatibility with the cystoscope, use the electrocautery system in cut mode or coagulation mode only.
   - Configure the initial output setting according to the clinician's experience based on guidance from appropriate clinical references, training, or both. To ensure compatibility with the cystoscope, do not exceed the voltage levels specified in the "Product Compatibility" section.
5. Position the active electrode of the electrocautery tool so that it is visible on the monitor screen and is separate enough from the distal tip of the cystoscope to allow effective operation. Ensure that the electrode remains visible on the monitor screen during use.
6. Operate the electrocautery tool as specified in its manufacturer's instructions for use.

RELATED INFORMATION

Product Compatibility (page 2)

Introduce Endoscopic Accessories (Optional) (page 29)

Procedure 9. Remove the Cystoscope

If you intend to use the cystoscope with the same patient more than once, prepare a sterile resting area for it. If you are using it with a Verathon endoscope holder, the holder can be used as an intra-operative storage location. Keep the cystoscope in this area when it is not in use.

WARNING

Before discarding a cystoscope, ensure that no parts of the camera, distal tip, or insertion tube are missing.

1. Retract any accessories into the working channel to avoid interference with the distal tip during removal.
2. Return the control lever as close to a neutral position as possible.
3. Carefully withdraw the cystoscope without applying any unnecessary force to the control lever. While you withdraw the cystoscope, observe the image on the monitor to verify that the withdrawal is proceeding normally.
4. As you withdraw the cystoscope, observe the white markings on its insertion tube to determine depth. These markings are spaced at 50 mm intervals. The first mark appears 195 mm from the distal tip.
5. After you have withdrawn the cystoscope completely, examine it thoroughly. Verify that it is not damaged and none of its components are missing. If a component is missing, retrieve it according to the facility's protocols.
6. Disconnect the cable from the cystoscope by holding the cable connector in one hand and the cystoscope handle in the other, and then pulling them straight apart.
7. If you want to disconnect the cable from the monitor, hold the cable connector in one hand and support the monitor with the other, and then pull.
8. When the procedure is complete, dispose of the cystoscope according to your local protocols for biohazard waste.

Troubleshooting

If the system does not function normally, use the suggestions in this table to correct the problem. If none of the suggestions in the table is effective, contact Verathon Customer Care or your local representative. For contact information, visit verathon.com/service-and-support.

PROBLEM	POSSIBLE SOLUTION
The video signal from the cystoscope does not appear on the monitor.	• Make sure both ends of the QuickConnect cable are connected securely. • Tap **Back** until the monitor displays the Home screen. • Restart the monitor. • Try a different CFlex cystoscope.
Image is blurred, distorted, or hard to see	• Gently rub the end of the distal tip against the mucosal wall. • Withdraw the cystoscope, clean the distal tip with gauze, and then reinsert the cystoscope.
Flow of fluid through the working channel is blocked or restricted	• If you are using a syringe to administer or aspirate liquid, make sure the accessory port valve is open. • If you are attempting to irrigate the bladder, make sure the irrigation lever is set to the Open position. • If the distal tip is flexed, try varying its position to open the working channel. • Withdraw the cystoscope and then use a syringe filled with sterile water or saline solution to flush out the working channel. Reinsert the cystoscope once the working channel has been cleared. • Withdraw the cystoscope and then use a brush to scrub the working channel. Reinsert the cystoscope once the working channel has been cleared.

Reprocessing

The CFlex cystoscope is a single-use device and cannot be cleaned, disinfected, or sterilized for reuse. However, some of the other components in this manual may require cleaning, low-level disinfection, high-level disinfection, or sterilization between uses or under specific circumstances. For information about the cleaning, disinfection, and sterilization requirements for these components, refer to the Airway & Urologic Endoscopy Products Reprocessing Manual, which is available at verathon.com/service-and-support/reprocessing-products.

Maintenance & Safety

Periodic Inspections

No periodic inspections, maintenance, or calibrations are required by Verathon.

Report any suspected defects to Verathon Customer Care or your local representative. For contact information, visit verathon.com/service-and-support.

Device Repair

The cables are not user-serviceable. Verathon does not make available any type of circuit diagrams, component parts lists, descriptions, or other information that would be required for repairing the device and related accessories. All service must be performed by a qualified technician.

If you have any questions, contact your local Verathon representative or Verathon Customer Care.

IMPORTANT

Please read the “Warnings & Cautions” section.

Device Disposal

The system and related accessories may contain batteries and other environmentally hazardous materials. When the instrument has reached the end of its useful service life, it must be disposed of in accordance with WEEE requirements. Coordinate disposal through your Verathon Service Center, or alternatively, follow your local protocols for hazardous waste disposal.

Warranty

ORIGINAL FIRST YEAR TOTAL CUSTOMER CARE WARRANTY

Verathon warrants the system against defects in material and workmanship. The limited warranty applies for one (1) year from the date of shipment from Verathon and applies only to the original purchaser of the system. The terms of this warranty are subject to the *Terms and Conditions of Sale* or any other contractual document between the parties.

Verathon's policy is to honor product warranties and to perform services only on products purchased from an authorized Verathon dealer. If you purchase a Verathon product or system components from an unauthorized dealer or if the original factory serial number has been removed, defaced or altered, your Verathon warranty will be void. Purchasing Verathon products from unauthorized entities could result in receipt of product that is counterfeit, stolen, used, defective, or not intended for use in your region.

If a customer's system requires service or repair, Verathon will, at its discretion, either repair or replace the customer's unit and provide a loaner unit. The customer agrees to send the defective unit to Verathon (cleaned and disinfected as appropriate) upon receipt of the loaner unit, and the customer agrees to return the loaner unit within two (2) business days of receipt of the repaired unit. All exchanged parts become property of Verathon.

Each product manufactured by Verathon is warranted to be free from defects in material and workmanship under normal use and services. Verathon's warranty does not cover defects or problems caused by the buyer's acts (or failure to act), the acts of others, or events beyond Verathon's reasonable control. The buyer shall be solely responsible, for any problem, failure, malfunction, defect, claim, damage, liability, or safety issue arising out of the following:

- Accident, theft, misuse, abuse, extraordinary wear and tear, or neglect.
- Misapplication, improper use, or other failure to follow Verathon's product instructions and safety precautions. The system shall be used in accordance with the instructions contained in this manual. This warranty does not apply if there is evidence of the equipment being exposed to temperatures in excess of 60°C (140°F).
- Use of the system in conjunction with hardware, software, components, services, accessories, attachments, interfaces, or consumables, other than those supplied or specified by Verathon.
- Products that have been repaired or maintained by anyone other than a Verathon authorized service provider. Modification, disassembly, rewiring, re-engineering, recalibration, and/or reprogramming of products other than as specifically authorized by Verathon in writing is prohibited and will void all warranties.

This warranty provides coverage if the instrument is rendered inoperable as a result of an accidental drop or mishandling after payment by the buyer of the current deductible as determined by Verathon. The deductible charge will be applied on each warranty request and may be applied an unlimited number of times per instrument.

WHAT IS COVERED?

Warranty coverage applies to the following system components:

- 2m QuickConnect Cable

Additional reusable components purchased either singularly or as a part of a system are warranted separately. Consumable items are not covered under this warranty.

PREMIUM CUSTOMER CARE WARRANTY

You may purchase a Premium Total Customer Care warranty that extends the limited warranty. For more information, contact Verathon Customer Care or your local representative.

DISCLAIMER OF ADDITIONAL WARRANTIES

There are no understandings, agreements, representations of warranties expressed or implied (including warranties of merchantability or fitness for a particular purpose) other than those set forth in this chapter and the *Terms and Conditions of Sale*. The contents of this manual do not constitute a warranty.

Some states disallow certain limitations on applied warranties. The purchaser should consult state law if there is a question regarding this disclaimer. The information, descriptions, recommendations, and safety notations in this manual are based upon Verathon experience and judgment. The contents of this manual should not be considered to be all-inclusive or to cover all contingencies.

Product Specifications

Specifications, Standards, and Approvals

Table 4. Specifications

GENERAL SPECIFICATIONS		
Ingress protection against water:	QuickConnect Cable (all)	IPX7
Expected product life:	Single-use cystoscope (all)	Refer to the “use by” date indicated by the ⌛ symbol on the package label.
OPERATING, SHIPPING, & STORAGE SPECIFICATIONS		
Operating Conditions		
Temperature:	Single-Use Cystoscopes	10–40°C (50–104°F)
	QuickConnect Cables	
Relative humidity:	Single-Use Cystoscopes	10–95%
	QuickConnect Cables	
Atmospheric pressure:	Single-Use Cystoscopes	700–1060 hPa
	QuickConnect Cables	
Shipping Conditions		
Temperature:	Single-Use Cystoscopes	-20–45°C (-4–113°F)
	QuickConnect Cables	
Relative humidity:	Single-Use Cystoscopes	10–95%
	QuickConnect Cables	
Atmospheric pressure:	Single-Use Cystoscopes	440–1060 hPa
	QuickConnect Cables	
Storage Conditions		
Temperature:	Single-Use Cystoscopes	18–28°C (64–82°F)
	QuickConnect Cables	-20–45°C (-4–113°F)
Relative humidity:	Single-Use Cystoscopes	40–60%
	QuickConnect Cables	10–95%
Atmospheric pressure:	Single-Use Cystoscopes	1013 hPa
	QuickConnect Cables	440–1060 hPa

IMPORTANT

Please read the “Warnings & Cautions” section.

Component Specifications

Table 5. 2m QuickConnect Cable (0600-0843)

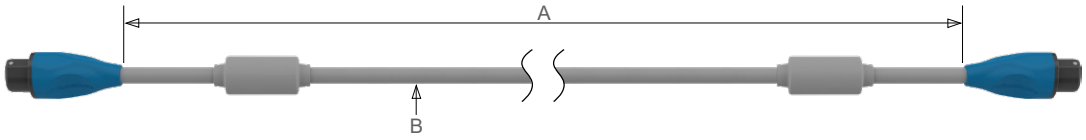
SPECIFICATION	VALUE
Length (A)	1981 ± 50 mm
Diameter (B)	6.8 mm
	

Table 6. Endoscope Holder (0810-0293)

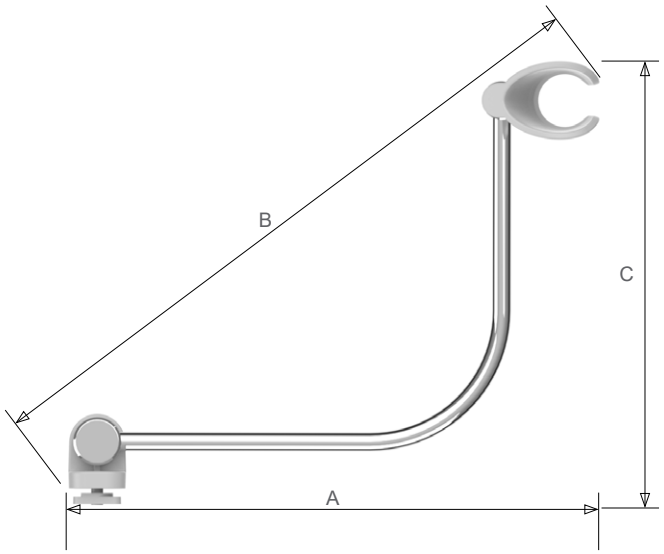
SPECIFICATION	VALUE
Width (A)	220 mm (8.7 in)
Length (B)	281 mm (11.1 in)
Height (C)	182 mm (7.2 in)
Weight	249 g
	

Table 7. Endoscope Holder for IV Pole (0810-0294)

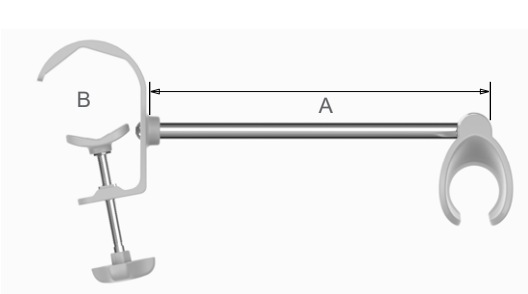
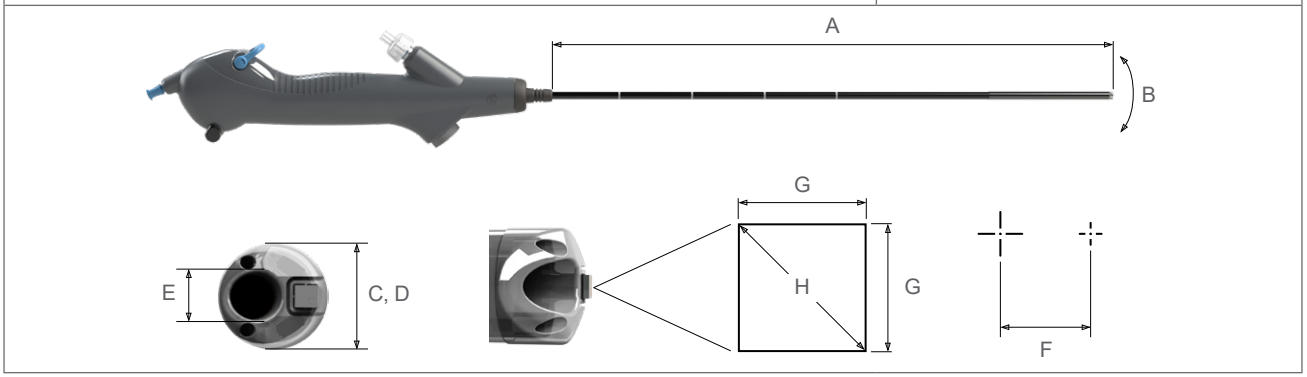
COMPONENT SPECIFICATIONS		
Arm length (A)	152.1 mm (6.0 in)	
Pole width range (B)	19–38 (0.75–1.5 in)	
Weight	0.19 kg	

Table 8. CFlex (0570-0455 standard deflection, 0570-0456 reverse deflection)

SPECIFICATION	VALUE
Length of flexible insertion tube from distal tip (A)	390 mm
Deflection angle (B)	210°
Outside diameter of flexible insertion tube (C)	5.0 mm (15 Fr)
Maximum outside diameter of flexible insertion tube and distal tip (D)	5.7 mm
Inside diameter of working channel (E)	2.4 mm (7.2 Fr)
Depth of field (F)	5–50 mm
Direction of view, relative to center line of distal tip	0°
Field of view, horizontal/vertical (G)	85°
Field of view, diagonal (H)	120°
Illumination method	LED



Electromagnetic Compatibility

The CFlex system is designed to be in compliance with IEC 60601-1-2, which contains electromagnetic compatibility (EMC) requirements for medical electrical equipment. The limits for emissions and immunity specified in this standard are designed to provide reasonable protection against harmful interference in a typical medical installation.

The system complies with the applicable essential performance requirements specified in IEC 60601-1 and IEC 60601-2-18. Results of immunity testing show that the essential performance of the system is not affected under the test conditions described in the following tables.

Note: The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals. If this equipment Is used in a residential environment, it may not offer adequate protection to radio frequency communication services. It is recommended to use the device only in the intended use environment.

Electromagnetic emissions

Table 9. Guidance and Manufacturer's Declaration—Electromagnetic Emissions

The system is intended for use in the electromagnetic environment specified below. The customer or the user of the system should ensure that it is used in such an environment.

EMISSIONS TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT – GUIDANCE
RF emissions CISPR 11	Group 1	The system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The system is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	In compliance	

Electromagnetic immunity

Table 10. Guidance and Manufacturer's Declaration—Electromagnetic Immunity

The system is intended for use in the electromagnetic environment specified below. The customer or the user of the system should ensure that it is used in such an environment.

IMMUNITY TESTS	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT – GUIDANCE
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	In compliance	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst IEC 61000-4-4	± 2 kV for power supply lines 100 kHz repetition frequency	In compliance	Mains power quality should be that of a typical hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	In compliance	Mains power quality should be that of a typical hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T for 0.5 cycle 70% U_T for 25 cycles at 50 Hz, 30 cycles at 60 Hz 0% U_T for 250 cycles at 50 Hz, 300 cycles at 60 Hz	In compliance	Mains power quality should be that of a typical hospital environment. If the user of the system requires continued operation during power mains interruptions, it is recommended that the system be powered from an uninterruptible power supply or a battery.
Rated power frequency magnetic fields IEC 61000-4-8	30 A/m Frequency 50 Hz	In compliance	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical hospital environment.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6Vrms in ISM bands 150 kHz to 80 MHz 80% AM at 1 kHz	In compliance	Portable and mobile RF communications equipment should be used no closer to any part of the system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance d (m)** $d=1.2\sqrt{P}$ (150 kHz to 800 MHz) $d=2.4\sqrt{P}$ (800 MHz to 5.8 GHz) where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Table 10. Guidance and Manufacturer's Declaration—Electromagnetic Immunity

The system is intended for use in the electromagnetic environment specified below. The customer or the user of the system should ensure that it is used in such an environment.

IMMUNITY TESTS	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT – GUIDANCE
Radiated RF IEC 61000-4-3: 2020	3 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	In compliance	Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated immunity to proximity RF fields IEC 61000-4-3: 2020	27 V/m 380 to 390 MHz Pulse modulation, 18 Hz 28 V/m 430 to 470 MHz FM, ± 5 kHz deviation, 1 KHz sine 9 V/m 704 to 787 MHz Pulse modulation, 217 Hz 28 V/m 800 to 960 MHz Pulse modulation, 18 Hz 28 V/m 1700 to 1990 MHz Pulse modulation, 217 Hz 28 V/m 2400 to 2570 MHz Pulse modulation, 217 Hz 9 V/m 5100 to 5800 MHz Pulse modulation, 217 Hz	In compliance	RF wireless communication equipment may interfere with the operation of medical electrical equipment. Avoid placement or use of RF wireless communication equipment near, adjacent to, or stacked with medical electrical equipment.
Immunity to proximity magnetic fields IEC 61000-4-39: 2017	134.2 kHz @ 65 A/m, Pulse modulation 13.56 MHz @ 7.5 A/m, Pulse modulation Additionally, frequency sweep 9kHz to 13.56MHz	In compliance	Proximity magnetic fields should be at levels characteristic of a typical location in a hospital environment.

Note: U_T is the AC mains voltage prior to application of the test level.

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

The presence of electromagnetic disturbances may cause loss or degradation of the image displayed on the monitor. If this occurs, take one or more of the following actions to resolve it:

- Turn devices on and off in the vicinity to determine the source of interference.
- Reorient or relocate this device or other devices.
- Increase the separation between devices.
- Connect the device to an outlet on a circuit different than the other device(s).
- Eliminate or reduce EMI with technical solutions (such as shielding).
- Purchase medical devices that comply with the IEC 60601-1-2 standard.
- Be aware that portable and mobile radio frequency communications equipment (such as cellular telephones) may affect medical electrical equipment; take appropriate precautions during operation.

Accessory Conformance to Standards

To maintain electromagnetic interference (EMI) within certified limits, the system must be used with the cables, components, and accessories specified or supplied by Verathon. The use of accessories or cables other than those specified or supplied may result in increased emissions or decreased immunity of the system.

Table 11. EMC Standards for Accessories

ACCESSORY	MAX LENGTH
AC power cord	4.5 m (15 ft)
DC medical power adapter cable	1.8 m (6 ft)
2m QuickConnect Cable	2.03 m (6.7ft)

RELATED INFORMATION

Parts & Accessories (page 9)

Component Specifications (page 41)

Glossary

The following table provides definitions for specialized terms used in this manual or on the product itself. For a full list of caution, warning, and informational symbols used on this and other Verathon products, please refer to the Verathon Symbol Directory at verathon.com/service-and-support/symbols.

A
Ampere

AC
Alternating current

AER
Automated endoscope reprocessor

C
Celsius

CFR
Code of Federal Regulations (U.S.)

CISPR
International Special Committee on Radio Interference

cm
Centimeter

CSA
Canadian Standards Association

EMI
Electromagnetic interference

ESD
Electrostatic discharge

Essential performance
The system performance necessary to achieve freedom from unacceptable risk

F
Fahrenheit

g
Gram

GHz
Gigahertz

hPa
Hectopascal

Hz
Hertz

IEC
International Electrotechnical Commission

in
Inch

ISM
Industrial, scientific, and medical

ISO
International Standards Organization.

kHz
Kilohertz

kPa
Kilopascal

kV
Kilovolt

L
Liter

m
Meter

mAh
Milliampere-hour

MHz
Megahertz

mm
Millimeter

mmHg
Millimeters of mercury

non-powered accessory
Endoscopic tool that does not require its own source of electrical power

OSHA
Occupational Safety and Health Administration (federal agency in U.S.)

powered accessory
Endoscopic tool that requires its own source of electrical power

QC
QuickConnect

RF
Radio frequency

RH
Relative humidity

SDS
Sodium dodecyl sulphate

V
Volt

Vrms
Voltage root mean squared

W
Watt

WEEE
Waste electrical and electronic equipment

verathon