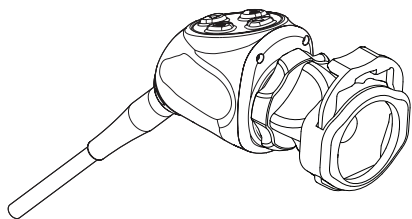
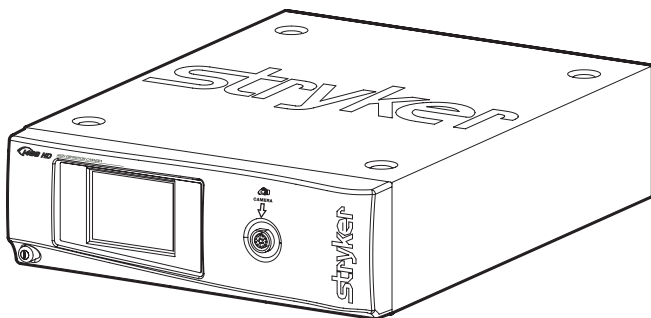


stryker[®]

1488 HD Video Camera



REF	1488010000
	1488010001
	1488210105
	1488610122
	1488710105



CE Rx ONLY

Reprocessing

The camera console is not intended to come into contact with the patient. It may be cleaned, but not sterilized. The camera head and coupler may contact the patient and should both be cleaned and sterilized prior to every use. (Refer to the appropriate coupler user guide—identified in the “Product Description” section of this user guide—for instructions on reprocessing the coupler.)

Cleaning the Console

Should the camera console need cleaning, wipe it down with a sterile cloth and mild cleaning solution.



Disconnect the console from the AC power source before cleaning.

Never immerse or sterilize the camera console as this will damage the camera and void the warranty.

Cleaning, Disinfecting, and Sterilizing the Camera Head

These reprocessing instructions are provided in accordance with ISO 17664, AAMI TIR12, AAMI ST79, and AAMI ST81. While they have been validated by Stryker as being capable of preparing the device for re-use, it remains the responsibility of the processor to ensure that the reprocessing as actually performed, using equipment, materials, and personnel in the reprocessing facility, achieves the desired result. This normally requires validation and routine monitoring of the process. Stryker recommends users observe these standards when reprocessing medical devices.

Warnings

- This device must be cleaned and sterilized prior to the first use and after every subsequent use.
- Use only the sterilization cycles outlined in this document. Using unspecified sterilization cycles may damage the device or result in incomplete sterilization.
- Separate the camera head, coupler (1488210105 and 1488710105 only), and scope prior to cleaning, disinfection, or sterilization. If the coupler and camera head are cleaned, disinfected, or sterilized as a single unit, disconnecting the coupler during use will compromise the sterility of the two products. (Refer to the coupler and scope product manuals for reprocessing instructions.)
- Wear appropriate protective equipment: gloves, eye protection, etc.

- Sterilize only one camera head per tray, or incomplete sterilization may result. Follow any instructions provided with the sterilization tray or system regarding tray setup and other devices that may be sterilized within the same tray.

Cautions

- Always install the soaking cap prior to processing the camera. Failure to properly tighten the soaking cap will corrode the connector pins and void the warranty.
- Inspect the camera cable for cuts and breaks before soaking in any fluid. Return any damaged camera to Stryker for service.
- Never soak the camera in the same tray with sharp instruments.
- Do not use brushes or pads with metal or abrasive tips during manual cleaning, as permanent scoring or damage could result.
- To minimize galvanic corrosion, avoid soaking dissimilar metals in close proximity.
- The 1488 HD camera heads are not autoclavable. Steam sterilizing camera heads that are not marked **AUTOCLAVE** will result in product damage.
- Allow the camera head to cool before connecting it to the console. Connecting the camera head while it is hot may result in system error.
- When sterilizing with Steris® System 1E™, remove the camera head from the chamber once sterilization is complete, or moisture may condense inside the camera head and cause display defects.

Limitations on Reprocessing

- Do not cross-sterilize the device. Using multiple sterilization methods may significantly reduce the performance of the device.
- Prolonged sterilization via Ethylene Oxide or Sterrad® 100NX™ may degrade the product appearance.
- Do not leave the device in solutions longer than necessary. This may accelerate normal product aging.
- Proper processing has a minimal effect on this device. End of life is normally determined by wear and damage due to use.
- Damage caused by improper processing is not covered by the warranty.

Instructions

Point of Use

- Wipe excess soil from the device using disposable paper towels.
- If an automated reprocessing method will be used, rinse any channels in the device with 50 mL of sterile distilled water immediately after use.

Containment and Transportation

- Reprocess the device as soon as reasonably practical following use¹.
- Transport the device in a tray to avoid damage.

¹ A 30 minute wait time was used during cleaning validation.

Preparation for Cleaning

1. Disassemble the coupler from the scope and camera head.
2. Prepare an enzymatic detergent according to the manufacturer's recommendations (one ounce per gallon of tap water at 35–40 °C)².
3. Wipe the entire device with the detergent, using a clean cloth.
4. Immerse the device in the detergent. Using a syringe, inject any inside regions of the device with 50 mL of the detergent to ensure all parts of the device are reached.
5. Soak the device in the detergent for a minimum of 15 minutes.

² ENZOL® Enzymatic Detergent is validated for cleaning efficacy.

Cleaning: Manual

1. Brush

- Prepare a fresh solution of enzymatic detergent according to the manufacturer's recommendations (one ounce per gallon of tap water at 35–40 °C).
- Thoroughly brush the exterior of the device with a soft-bristled brush, focusing on any mated or rough surfaces.
- Using a syringe, inject any lumen or mated surface a minimum of five times with 50 mL of the detergent.
- Brush any lumens a minimum of five times from each end, using an appropriate bottle brush.
- Brush any movable parts in all extreme positions.

2. Rinse

- Rinse the device with reverse osmosis/de-ionized (RO/DI) water at ambient temperature until all detergent residue is removed. Flush any lumens or mated surfaces a minimum of five times. Once all detergent residue is removed, continue to rinse for a minimum of 30 seconds.
- Drain excess water from the device and dry it using a clean cloth or pressurized air.
- Visually inspect the device for cleanliness, paying close attention to hard-to-reach areas. If visible soil remains, repeat steps 1 and 2.

3. Soak

- Prepare a non-enzymatic detergent according to the manufacturer's recommendations (0.125 ounces per gallon of tap water at 35–40 °C)³.
- Fully immerse the device and use a syringe to inject any lumens and mated surfaces with 50 mL of the detergent.
- Soak the device for a minimum of 15 minutes.

4. Brush

- Thoroughly brush the exterior of the device using a soft-bristled brush.
- Using a syringe, inject 50 mL of the detergent into any cannulae, lumens, or mated surfaces a minimum of five times.
- Brush any lumens a minimum of five times from each end, using an appropriate bottle brush.
- Actuate the device, brushing around any movable parts in all extreme positions.

5. Rinse

- Thoroughly rinse the device with RO/DI water until all detergent residue is removed. Flush any lumens or crevices a minimum of five times. Once all detergent residue is removed, continue to rinse for a minimum of 30 seconds.
- Drain the excess water from the device and dry it using a clean cloth or pressurized air.

³ Prolystica® 2x Neutral Detergent is validated for cleaning efficacy.

Cleaning: Automated

1. Brush

- Using a syringe, inject 50 mL of the enzymatic detergent (from the “Preparation for Cleaning” section) into any lumen and mated surface a minimum of one time.
- Brush from both ends of any lumens a minimum of five times, using an appropriate bottle brush.

2. Rinse

- Rinse the device with RO/DI water at ambient temperature until there is no visible detergent residue. Continue to rinse for a minimum of 30 seconds after all detergent residue has been removed.
- Place the device in the washer on an incline to facilitate drainage.

3. Automated wash

- Program the washer using the following parameters:

Phase	Recirculation Time	Water Temperature	Detergent Type and Concentration (if applicable)
Pre Wash	2 minutes	Cold tap water	N/A
Enzyme Wash	2 minutes	Hot tap water	Enzymatic Detergent
Wash 1	2 minutes	Set point (66 °C)	Non-enzymatic Detergent ⁴
Rinse 1	2 minutes	Hot tap water	N/A
Dry Phase	7 minutes	115 °C	N/A

- If necessary, use pressurized air to aid in drying. Visually inspect each device for cleanliness.

⁴ Prolystica® 2x Neutral Detergent is validated for cleaning efficacy.

Low Level Disinfection (optional)

1. Clean and prepare the camera head and cable as recommended in this user guide. Ensure the soaking cap is installed.
2. Disinfect the device in a disinfecting solution that has one of the following active Ingredients:
 - $\geq 2.4\%$ glutaraldehyde⁵ with a minimum soaking time of 45 min at 25°C
 - $\geq 3.4\%$ glutaraldehyde⁶ with a minimum soaking time of 20 min at 25°C
 - $\geq 0.55\%$ ortho-phthalaldehyde⁷ with a minimum soaking time of 12 min at 25°C.
3. Prepare the disinfecting solution according to the manufacturer's instructions.
4. Thoroughly rinse and flush all parts and lumens with running, demineralized water to remove the disinfectant.
5. Dry all parts with a lint-free towel immediately after rinsing.

⁵ CIDEX Activated® is validated for disinfection efficacy.

⁶ CIDEX Plus® is validated for disinfection efficacy.

⁷ CIDEX® OPA is validated for disinfection efficacy.

Drying

- For automated drying, use the drying cycle provided with the washer/disinfector.
- For manual drying, use a lint-free cloth.
- Dry any lumens with compressed air.

Maintenance, Inspection, and Testing

- Inspect the device on a continual basis. If a problem is observed or suspected, the device should be returned for repair.
- Inspect all components for cleanliness. If fluid or tissue buildup is present, repeat the above cleaning and disinfection procedures.
- Inspect the camera cable for cuts and breaks. Return any damaged camera to Stryker for service.

Packaging

N/A

Sterilization

After performing the cleaning instructions specified above, perform one of the following sterilization cycles.

Ethylene Oxide (EO)

1. Clean and prepare the camera head and cable as recommended in this user guide. Ensure the soaking cap is installed.
2. If using a sterilization tray (optional), follow any additional instructions provided with the tray. Use only trays that are compatible with EO.⁸
3. Double wrap the camera head and cable (or tray) prior to sterilization.
4. Sterilize the camera head and cable using the parameters below.
5. Allow the camera head, cable, coupler, and scope to completely dry before reassembly. Any moisture on the threads will cause the camera and coupler windows to fog during use.

Preconditioning parameters

Temperature	55 °C (131 °F)
Chamber Humidity	70% RH
Vacuum Set Points	1.3 psia
Time	30 minutes

Exposure

Concentration (100% EO)	725 mg/L
Temperature	55 ± 2 °C (131 ± 5 °F)
Time	1 hour
Chamber Humidity	70% RH (50–80%) ± 5%

Aeration parameters

Aeration Time	12 hours
Temperature	35–54 °C (95–129 °F)

Steris System 1E

1. Clean and prepare the camera head and cable as recommended in this user guide. Ensure the soaking cap is installed.
2. Sterilize the camera head and cable using Steris System 1E with S40™ Sterilant. Follow the manufacturer's instructions.
3. Remove the camera head and cable from the Steris chamber once sterilization is complete, or moisture may condense inside the camera head and cause display defects.
4. Allow the camera head, cable, coupler, and scope to completely dry before reassembly. Any moisture on the threads will cause the camera and coupler windows to fog during use.

Steris/Amsco V-PRO

1. Clean and prepare the camera head and cable as recommended in this user guide. Ensure the soaking cap is installed.
2. If using a sterilization tray (optional), follow any additional instructions provided with the tray. Use only trays that are approved for sterilization with Steris/Amsco V-PRO.⁸
3. Double wrap the camera head and cable (or tray) prior to sterilization.
4. Sterilize the device using the V-PRO maX Sterilizer (Non-Lumen or Standard cycle), the V-PRO 1 Plus Sterilizer (Non-Lumen or Standard cycle), or the V-PRO 1 Sterilizer (Standard cycle).
5. Allow the camera head, cable, coupler, and scope to completely dry before reassembly. Any moisture on the threads will cause the camera and coupler windows to fog during use.

Sterrad

1. Clean and prepare the camera head and cable as recommended in this user guide. Ensure the soaking cap is installed.
2. If using a sterilization tray (optional), follow any additional instructions provided with the tray. Use only trays that are compatible with Sterrad.⁸



Not all sterilization trays are compatible with Sterrad systems. Using an incompatible tray may result in incomplete device sterilization. Consult the instructions that came with your sterilization tray to determine which sterilization method is compatible with your tray and devices. If a compatible tray is not available, the devices can be double wrapped prior to using the Sterrad system.

3. Double wrap the camera head and cable (or tray) prior to sterilization.
4. Sterilize the camera head and cable following the instructions of the manufacturer, using the Sterrad 100S, NX™, or 100NX Sterilization System. Select the standard cycle.
5. Allow the camera head, cable, coupler, and scope to completely dry before reassembly. Any moisture on the threads will cause the camera and coupler windows to fog during use.

⁸ Stryker sterilization trays 0233032105 and 0233032107 are validated for sterilizing the camera head using EO, V-PRO, and Sterrad. Consult user guides 1000400907 or 1000400926, respectively, for more information about using the trays.

Storage

Never store the device in a non-ventilated, humid environment such as a carrying case. This may present an infection control risk.

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