

CLEANING AND STERILIZATION GUIDE

EleVision™ HD 2 platform



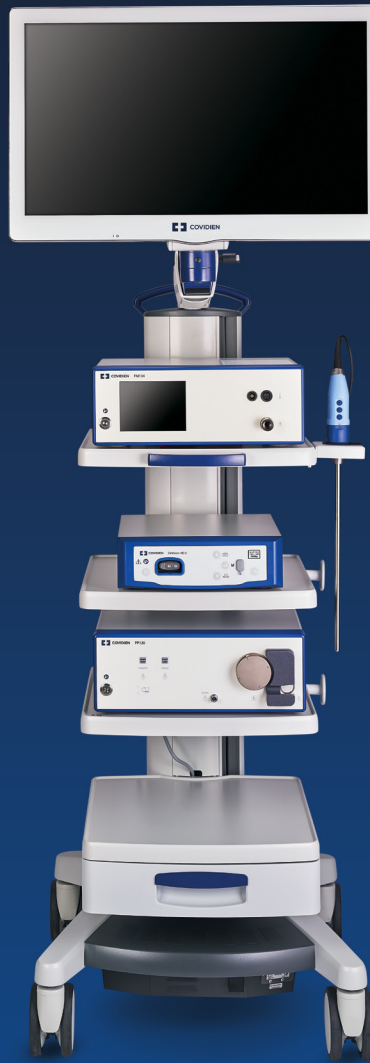
Medtronic
Further. Together

CONTENTS

TipVision™ Videoscope
Camera Heads
Laparoscopes
Light Cables
Insufflator and
Pump Accessories

The EleVision™ HD 2 platform is designed to provide clear, consistent visualization in the OR.

This guide explains how to care for, clean, and sterilize the EleVision™ HD 2 platform and get the most out of your procedures.



PRECAUTION

This guide is a supplement to the approved user manual supplied with the system. Always refer to the applicable version of the user manual.

Before use, read the user manual information carefully and follow the specifications regarding concentration, temperature, usage time, water quantities, and contact time.

NOTE

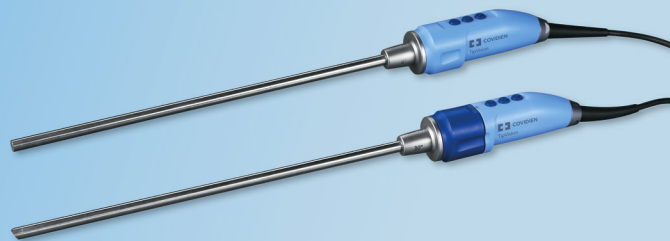
The **manual cleaning process** was validated using:
Cidezyme™/Enzol™*

The **manual disinfection process** was validated using:
Cidex™ OPA

The **automated cleaning process** was validated using:
neodisher™ MediClean forte 0.5 %

Wherever possible, use the above cleaning and disinfecting agents only.

TipVision™ Videoscope



CONTENTS

TipVision™ Videoscope
Camera Heads
Laparoscopes
Light Cables
Insufflator and
Pump Accessories

CLEANING

Manual cleaning (OUS):

Stage	Action	Temperature (°C/°F)	Time (min)	Water quality	Cleaning/disinfectant solution
I	Cleaning	Per manufacturer's instructions	2–5	Tap water	Enzymatic cleaning solution, e.g. Cidezyme™/Enzol™*
II	Intermediate rinsing 3x	20–30 / 68–86	3 x ≥ 2	Tap water	---
III	Disinfection	Per manufacturer's instructions	12	---	0.55 % ortho-phthalaldehyde solution, e.g. Cidex™* OPA
IV	Rinsing 3x	20–30 / 68–86	3 x ≥ 2	Deionized† water	---
V	Drying	---	---	---	---

Manual cleaning (US only):

Stage	Action	Temperature (°C/°F)	Time (min)	Water quality	Cleaning solution
I	Cleaning	Per manufacturer's instructions	2–5	Tap water	Enzymatic cleaning solution, e.g. Cidezyme™/Enzol™*
II	Rinsing 2x	20–30 / 68–86	2 x ≥ 2	Tap water	---
III	Final rinsing	20–30 / 68–86	1 x ≥ 2	Critical water	---
IV	Drying	---	---	---	---

Automated cleaning:

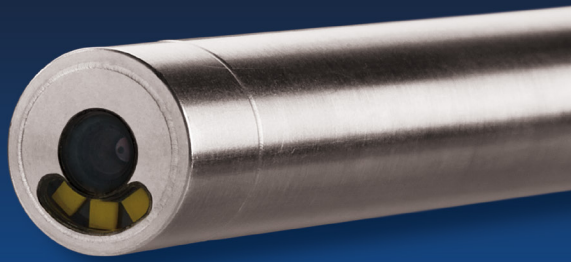
Stage	Action	Temperature (°C/°F)	Time (min)	Water quality	Cleaning/disinfectant solution
I	Prerinsing	< 25 / 77	2	Tap water	---
II	Cleaning	55 / 131	10	---	Alkaline cleaning solution, e.g. 0.5 % neodisher™** MediClean forte, prepared per the manufacturer's instructions
III	Rinsing I	Per the equipment manufacturer's standard cycle	1	Tap water	---
IV	Rinsing II	Per the equipment manufacturer's standard cycle	1	Tap water	---
V [‡]	Thermal disinfection	> 90 / 194	5	Deionized [†] water	A ₀ value > 3000
V [§]	Final rinsing	> 90 / 194	5	Critical water	---
VI	Drying	99 / 210	30	---	---

[†]Deionized water (demineralized, low-germ, max. 10 germs/ml, as well as low endotoxin contaminated, max. 0.25 endotoxin units/ml).

[‡]OUS only.

[§]US only.

TipVision™ Videoscope



CONTENTS

TipVision™ Videoscope
Camera Heads
Laparoscopes
Light Cables
Insufflator and
Pump Accessories

STERILIZATION

To sterilize the TipVision™ videoscope:

WARNING

Steam sterilization should be performed only for products labeled as autoclavable. Use fully desalinated drinking water that meets the requirements of European Standard EN 285.

1. Make sure that manual or automated cleaning and disinfection is complete.
2. Place the videoscope in the reprocessing tray (ELEVTVTRAY) as per the subsequent loading plan. First, place the videoscope in the intended holder first, then wind the cable around the cable guides. The cable shouldn't be tightened too much. Then place the plug in the dedicated holder and seal the reprocessing tray.
3. Pack the tray with two single layers of sterile wrap — use legally marketed products only.
4. Load the sterilizer as per the validated loading plan. Follow the manufacturer's instructions and instructions for use for the device.
5. Start the sterilization cycle in accordance with the manufacturer's instructions, and instructions for use for the sterilizer and the parameters appropriate to the institutional, local and national requirements.

NOTE

Reprocessing results are achieved using the steam sterilization process with the following validated parameters:

- Cycle type pre-vacuum process
- Temperature 134 C (273 F)
- Holding time at least 3 min (effective sterilization time)
- Drying time at least 30 min

6. Remove the sterilized products from the sterilizer. Ensure that the products remain sterile after reprocessing. This concludes sterilization.

Camera Heads



CONTENTS

TipVision™ Videoscope
Camera Heads
Laparoscopes
Light Cables
Insufflator and
Pump Accessories

CLEANING

To manually clean the 1CMOS product code: 95-3901 (US only) (product code: 95-3906):

Stage	Action	Temperature (°C/°F)	Time (min)	Water quality	Cleaning/disinfectant solution
I	Cleaning	Per manufacturer's instructions	2-5	Tap water	Enzymatic cleaning agent: Cidezyme™™/Enzol™™, prepared per manufacturer's instructions
II	Intermediate rinsing 2x	< 45 / 113	2 x ≥ 1	Tap water	---
III	Final rinsing	< 45 / 113	≥ 1	Deionized water†	---
IV	Drying	---	---	---	---

To manually clean the 1CMOS and 3CMOS cameras (OUS only):

Stage	Action	Temperature (°C/°F)	Time (mins.)	Water Quality	Cleaning Solution
I	Cleaning	Per manufacturer's instructions	2-5	Tap water	Enzymatic cleaning agent, e.g. Cidezyme™™/Enzol™™
II	Intermediate rinse 2x	< 45 / 113	2 x ≥ 1	Tap water	---
III	Disinfection	Per manufacturer's instructions	12	---	0.55% ortho-phthalaldehyde solution, e.g. Cidex™™ OPA
IV	Intermediate rinse 2x	< 45 / 113	2 x ≥ 1	Tap water	---
V	Final rinse	< 45 / 113	≥ 1	DI water	---
VI	Dry	---	---	---	---

Automated cleaning and thermal disinfection‡:

Stage	Action	Temperature (°C/°F)	Time (min)	Water quality	Cleaning solution
I	Prerinsing	Cold	2	Tap water	---
II	Cleaning	55 / 131	10	---	Alkaline cleaner: neodisher™™ MediClean forte, prepared per manufacturer's instructions
III	Intermediate rinsing 1	Per the equipment manufacturer's standard cycle	1	Tap water	---
IV	Intermediate rinsing 2	Per the equipment manufacturer's standard cycle	1	Tap water	---
V	Thermal disinfection	90 / 194	5	Deionized water† (A ₀ value: > 3000)	---
VI	Drying	High (98,8 / 210)	30	---	---

†Deionized water (demineralized, low-germ, max. 10 germs/ml, as well as low endotoxin contaminated, max. 0.25 endotoxin units/ml).

‡Color anodized parts or plastic components may bleach out during automated cleaning.

Camera Heads



CONTENTS

TipVision™ Videoscope
Camera Heads
Laparoscopes
Light Cables
Insufflator and
Pump Accessories

STERILIZATION

To sterilize the 1CMOS and 3CMOS cameras:

NOTE (1CMOS)

STERRAD™† sterilization was validated for the following cycle:
STERRAD™† 100S short cycle.

NOTE (3CMOS)

STERRAD™* sterilization was validated for the following cycles:

- STERRAD™† 100S Short Cycle (top shelf only)
- STERRAD™† NX Standard Cycle (bottom shelf only)
- STERRAD™† 100NX Standard Cycle (top shelf only)

1. Make sure that manual or automated cleaning is complete.
2. Place the product in a sterilization tray. Place a STERRAD™† indicator strip in the tray. Double-wrap the tray in polypropylene wrap.
3. Load the wrapped tray in the sterilizer. Position the tray so that the sterilization medium can act thoroughly on all areas. Do not allow any item to touch the wall of the sterilizer.
4. Start the sterilization cycle in accordance with the manufacturer's instructions and instruction for use for the sterilizer.
5. Remove the sterilized products from the sterilizer. Ensure that the products remain sterile after reprocessing.

Laparoscopes



CONTENTS

TipVision™ Videoscope
Camera Heads
Laparoscopes
Light Cables
Insufflator and
Pump Accessories

CLEANING

To manually clean the laparoscopes (US)†:

Stage	Action	Temperature (°C/°F)	Time (mins.)	Water Quality	Cleaning Solution
I	Cleaning	Per manufacturer's instructions	2-5	Tap water	Enzymatic cleaning solution
II	Rinse 2x	< 45 / 113	2 x ≥ 1	Tap water	---
IV	Final rinse	< 45 / 113	≥ 1	High purity water	---
V	Dry	---	---	---	---

To manually clean the laparoscopes (OUS)†:

Stage	Action	Temperature (°C/°F)	Time (mins.)	Water Quality	Cleaning Solution
I	Cleaning	35-45 / 95-113	5	Tap water	Enzymatic cleaning solution
II	Intermediate rinse	Room temperature	3 x 1	Tap water	---
III	Disinfection	20-25 / 66-77	12	---	Disinfectant solution (undiluted)
IV	Final rinse	Room temperature (cold)	3 x 2	DI water	---
V	Dry	Room temperature	---	---	---
VI	Dry	---	---	---	---

Automated cleaning and thermal disinfection‡:

Stage	Action	Temperature (°C/°F)	Time (mins.)	Cleaning Solution / Water Quality
I	Prerinse	Cold	2	Tap water
II	Cleaning	60 / 140	10	Alkaline detergent
III	Intermediate	per the equipment manufacturer's standard cycle	1	Tap water
IV	Intermediate rinse	per the equipment manufacturer's standard cycle	1	Tap water
V	Final rinse	90 / 194	5	Purified water
VI	Dry	98.8 / 210	30	---

†Outside of the United States, material compatibility releases also exist for Gigasept FF (Schülke & Mayr GmbH) for manual cleaning and disinfection, Lysetol FF (Schülke & Mayr GmbH) for manual cleaning and disinfection, and Helipur HplusN (B. Braun Medical AG) for manual disinfection.

‡Automated reprocessing can cause color-anodized or plastic components (e.g. standard rings and the eyepiece cup) to fade.

Laparoscopes



CONTENTS

TipVision™ Videoscope
Camera Heads
Laparoscopes
Light Cables
Insufflator and
Pump Accessories

STERILIZATION

To sterilize the laparoscopes

NOTE

Reprocessing results are achieved using the fractionated vacuum steam sterilization process at 134 C and with a holding time of 5 minutes.

CAUTION

Risk of scalding when unloading the sterilizer.

1. Make sure that manual or automated cleaning and disinfection is complete.
2. Load the sterilizer as per the validated loading plan. Follow the manufacturer's instructions and instructions for use for the washer/disinfector.
3. Start the sterilization cycle in accordance with the manufacturer's instructions and instruction for use for the sterilizer.
4. Remove the sterilized products from the sterilizer. Ensure that the products remain sterile after reprocessing.

To sterilize using the STERRAD™† Sterilization Procedure (100S, NX, 100NX)

The STERRAD™† sterilization systems, manufactured by Advanced Sterilization Products (ASP), use low-temperature, hydrogen peroxide gas plasma technology for terminal sterilization of properly cleaned, rinsed, and dried reusable medical devices.

1. Double wrap the endoscope with two single layers of FDA-cleared sterilization wrap using a sequential double wrapping technique.
2. Load the wrapped endoscopes in the sterilizer. Devices should be positioned to permit adequate plasma circulation and penetration. Do not allow any item to touch the wall of the sterilizer. Do not stack wrapped devices in the sterilization chamber.
3. Start the sterilization cycle in accordance with the manufacturer's instructions and instructions for use for the steam sterilizer.
4. Remove the sterilized products from the sterilizer. Ensure that the products remain sterile after reprocessing.

†The STERRAD™ Sterilization Systems, manufactured by Advanced Sterilization Products (ASP), use low temperature, hydrogen peroxide gas plasma technology for terminal sterilization of properly cleaned, rinsed, and dried reusable medical devices. Refer to the STERRAD™ Sterilization Systems User Guide for detailed instructions for use of any STERRAD™ unit. ASP's STERRAD™ Sterility Guide (SSG) at www.sterradsterilityguide.com or contact ASP customer service.

Light Cables



CONTENTS

TipVision™ Videoscope
 Camera Heads
 Laparoscopes
 Light Cables
 Insufflator and
 Pump Accessories

CLEANING

Manual cleaning and disinfection:

Stage	Action	Temperature (°C/°F)	Time (min.)	Conc. (%)	Water Quality	Cleaning Solution
I	Cleaning	35–45 / 95–113	5	0.8	Drinking water	Enzymatic cleaning solution, e.g. Cidezyme™*/Enzol™**
II	Rinsing	Room temperature (cold)	2 x 1	---	Drinking water	---
III	Disinfection	20–25 / 68–77	12	---	---	Disinfectant solution (undiluted)
IV	Final rinsing	Room temperature (cold)	3 x 1	---	Deionized water†	---
V	Drying	Room temperature	---	---	---	---

Automated‡ alkaline cleaning and thermal disinfection:

Stage	Action	Temperature (°C/°F)	Time (min.)	Conc. (%)	Water Quality	Cleaning Solution / Notes
I	Prerinsing	< 25 / 77	2	---	Drinking water	---
II	Cleaning	55 / 131	10	0.5	Drinking water	Alkaline detergent, e.g. neodisher™** MediClean forte (5 ml / L), pH > 10
III	Rinsing I	> 10 / 50	1	---	Drinking water	---
IV	Rinsing II	> 10 / 50	1	---	Deionized water†	---
V	Thermal disinfection	90 / 194	5	---	Deionized water†	---
VI	Drying	---	---	---	---	---

†Deionized water (demineralized, low-germ, max. 10 germs/ml, as well as low endotoxin contaminated, max. 0.25 endotoxin units/ml).

‡Automated reprocessing can cause color-anodized or plastic components (e.g. standard rings and the eyepiece cup) to fade.

STERILIZATION

Steam Sterilization

1. Make sure that manual or automated cleaning and disinfection is complete.
2. Load the sterilizer per the validated loading plan and follow the manufacturer's instructions and instructions for use for the washer/disinfector.
3. Start the sterilization cycle in accordance with the manufacturer's instructions and instruction for use for the sterilizer.
4. Use the following validated parameters for steam sterilization:
Temperature: 134 C (273.2 F)
Holding time: 5 minutes (effective sterilization time)
5. Remove the sterilized products from the sterilizer. Ensure that the products remain sterile after reprocessing.

Low-Temperature Plasma-Based Sterilization (LTP)

Performing LTP

1. Make sure that manual or automated cleaning and disinfection is complete.
2. Double-package the product using transparent Tyvek™* wrappings.
3. Load the sterilizer and follow the manufacturer's instructions and instructions for use for the device.
4. Start the sterilization cycle in accordance with the manufacturer's instructions and instruction for use for the sterilizer.
5. Remove the products from the sterilizer.
6. Continue processing the products as per your validated process — ensure that the products remain sterile after reprocessing.

Insufflator and Pump Accessories



CONTENTS

TipVision™ Videoscope
Camera Heads
Laparoscopes
Light Cables
Insufflator and
Pump Accessories

CLEANING AND STERILIZATION

Insufflator Tubesets (Reusable) — OUS Only

Cleaning and disinfection:

Reusable Insufflation Tubing	Manual cleaning: Neodisher™* Mediclean 2 percent or equivalent Automated cleaning: Vario – Miele or equivalent Disinfection: Lysetol 8 percent or equivalent
Sterilization	Steam Sterilization 132–134 degrees C 5 min

Suction Irrigation Pump Tubesets (Reusable) — OUS Only

Reusable Insufflation Tubing	Neodisher™* Mediclean 2 percent or equivalent Automated cleaning: Vario – Miele or equivalent Disinfection: Lysetol 8% or equivalent
Sterilization method:	Pre-vacuum sterilizer:
Packaging	Packed
Cycle time	5 minutes (273 F/134 C, 3 bar)
Drying time	10 minutes

Contact your local Medtronic sales representative for more information about the EleVision™ HD 2 platform cleaning and sterilization process.



Always refer to the instructions for use included with the product for complete indications, contraindications, warnings, and precautions.

© 2020 Medtronic. All rights reserved. Medtronic, Medtronic logo and Further, Together are trademarks of Medtronic.™* Third party brands are trademarks of their respective owners. All other brands are trademarks of a Medtronic company. 08/2020-US-NI-2000012-[WF# 3943806]

555 Long Wharf Drive 800.722.8772
New Haven, CT 06511 508.261.8000 [medtronic.com/visualizationsystems](https://www.medtronic.com/visualizationsystems)

Medtronic