# Technical Data Monograph

## V-PRO® 1 Low Temperature Sterilization System
## and
## V-PRO® 1 Plus Low Temperature Sterilization System

STERIS®

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# 1 Introduction

This Technical Data Monograph illustrates the principles of operation and demonstrates the safety and efficacy of the V-PRO® 1 and the V-PRO® 1 Plus Low Temperature Sterilization Systems. The summary test data for microbial efficacy, material compatibility, and biocompatibility testing performed on the V-PRO Sterilization Systems is included.

The V-PRO Sterilizers are intended for use in terminal sterilization of cleaned, rinsed, and dried metal and nonmetal medical devices used in healthcare facilities.

The V-PRO 1 Low Temperature Sterilization System performs one standard, pre-programmed sterilization cycle.

The V-PRO 1 Plus Low Temperature Sterilization System performs two pre-programmed sterilization cycles; the **Lumen and Non Lumen Cycles**.

The Lumen Cycle is identical to the sterilization cycle on the V-PRO 1 Sterilizer. For the purpose of this document:

- "Lumen Cycle" refers to the one standard cycle of the V-PRO 1 Sterilizer and the Lumen Cycle of the V-PRO 1 Plus Sterilizer
- "Non Lumen Cycle" refers to the Non Lumen Cycle of the V-PRO 1 Plus Sterilizer

The **Lumen Cycle** can sterilize[1] instruments/devices with the following features:

- Lumened and non-lumened instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors.
- Medical devices, including single, dual and triple channeled rigid and semi-rigid endoscopes, with the following configurations
  - Single channeled devices with a stainless lumen that is ≥ 0.77mm internal diameter (ID) and ≤ 500mm in length
  - Dual channeled devices with stainless steel lumens that are ≥ 0.77mm ID and ≤ 527mm in length
  - Triple channeled devices with stainless steel lumens that are
    - ≥1.2 mm ID and ≤ 275 mm in length
    - ≥1.8 mm ID and ≤ 310 mm in length

      or
    - ≥2.8 mm ID and ≤ 317 mm in length

The V-PRO 1 Plus Sterilizer's **Non Lumen Cycle** can sterilize[2] instruments/devices with the following features:

- Non-lumened instruments including non-lumened general medical instruments, non-lumened rigid, semi-rigid and flexible endoscopes and non-lumened instruments with stainless steel or titanium diffusion-restricted areas such as the hinged portion of forceps or scissors.

The principle features of the V-PRO Low Temperature Sterilization Systems include:

- Easy to use touch screen control panel that is used to initiate and monitor the validated sterilization cycles
- Proprietary hydrogen peroxide based sterilant which is provided in a multi-cycle container
- Process monitoring and cycle documentation
- Automatic load aeration
- System designed for ease of use and maintenance
- Easy installation – no utilities other than electricity required; no special venting required
- Specially designed conditioning phase that aids in removal of residual moisture. All loads should be thoroughly dried before packaging and placing into the sterilizer.

The V-PRO Low Temperature Sterilization Systems consist of several components. These components include:

- The Sterilizer
- VAPROX® HC Sterilant
- Self-Contained Biological Indicator
- Biological Indicator Test Packs
- Chemical Indicator Tape
- External Process Indicators and Chemical Indicator Strips
- Record Cards and Record Keeping Systems
- Sterilization Trays and Instrument Organizers for V-PRO Sterilizers
- Vis-U-All Low™ Temperature Tyvek®[3] Pouches and Tubing

1. The validation studies for all channel/lumen configurations were conducted using a maximum of twenty (20) lumens per load. Hospital loads should not exceed the maximum number of lumens validated by this testing. The validation studies were performed using a validation load consisting of two instrument trays and two pouches for a total weight of 19.65 lbs.
2. The validation studies were conducted using a validation load consisting of two instrument trays and two pouches for a total weight of 50 lbs.
3. Tyvek® is a registered trademark of DuPont.

# 2 V-PRO 1 and V-PRO 1 Plus Low Temperature Sterilization Systems: Principle of Operation

The V-PRO Low Temperature Sterilization Systems use vaporized hydrogen peroxide to sterilize medical instruments. Prior to sterilization, cleaned and dried instruments are packaged in wrapped trays, rigid containers or Tyvek pouches that are specifically designed for use with the V-PRO Sterilizers. The packaged instruments are placed on the Sterilizer's two shelves and the sterilizer door is shut. The Lumen or Non Lumen Cycle is selected to initiate the sterilization process.

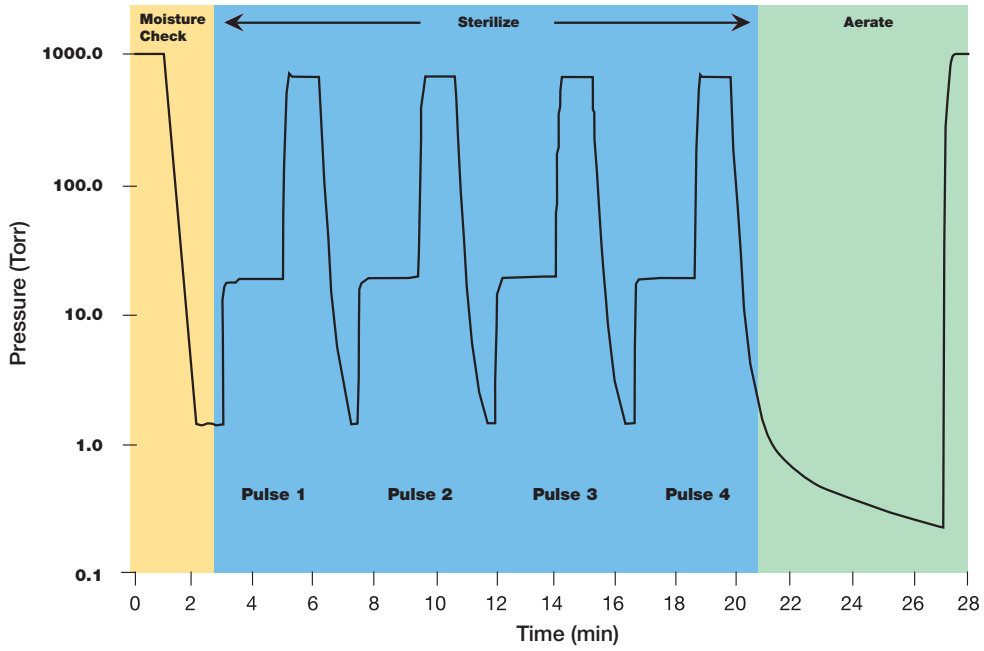
For the V-PRO 1 Plus Sterilizer, the Non Lumen Cycle is selected if the load contains instruments without a lumen and/or instruments with only a stainless steel or titanium diffusion-restricted space (mated surface). If the load includes either a stainless steel lumened instrument or a mated surface of material other than stainless steel or titanium, the Lumen Cycle must be selected.[4]

## Non Lumen Cycle

The approximately 28-minute Non Lumen Cycle is used to sterilize instruments without lumens (i.e. surface sterilization) such as defibrillator paddles, cables, cords, non lumened rigid endoscopes (telescopes), batteries and cameras. The Non Lumen Cycle can be used to sterilize instruments with stainless steel or titanium mated surfaces such as the hinged portion of forceps or scissors. The prepared and packaged load is processed through a short moisture check phase during which the chamber pressure is reduced to 1 Torr (or 0.13 kPa) and the moisture content of the load is verified to be acceptable. If the moisture content is not acceptable, a short conditioning phase is initiated during which the chamber is evacuated to less than 1 Torr (0.13 kPa) to aid in removal of excess moisture. After the optional conditioning phase, the moisture content of the load is verified to be acceptable. The pressure in the sterilizer chamber is then reduced to 1 Torr (0.013 kPa) in preparation for injection of the vaporized hydrogen peroxide or VHP. The sterilizer automatically vaporizes the correct amount of liquid hydrogen peroxide from the multiple-cycle VAPROX HC cartridge. After a two-minute hold segment, filtered air enters the sterilization chamber, increasing the chamber pressure to 500 Torr (or 66 kPa). After an additional one-minute hold phase, the chamber pressure is again reduced to 1 Torr (0.013 kPa) in preparation for the next injection of VHP. VHP is injected four times during each sterilization cycle. After completion of the last VHP injection hold period, the load is automatically aerated in the sterilizer. The chamber VHP is exhausted through a catalytic converter that decomposes the VHP to water and oxygen. No special venting is required for operation of the V-PRO Sterilizers. At completion of the sterilization cycle, the load is removed and can be immediately used or stored prior to use. The cycle is presented graphically in Figure 1.

[4] Only stainless steel lumen configurations identified on page 3 can be sterilized in the Lumen Cycle.

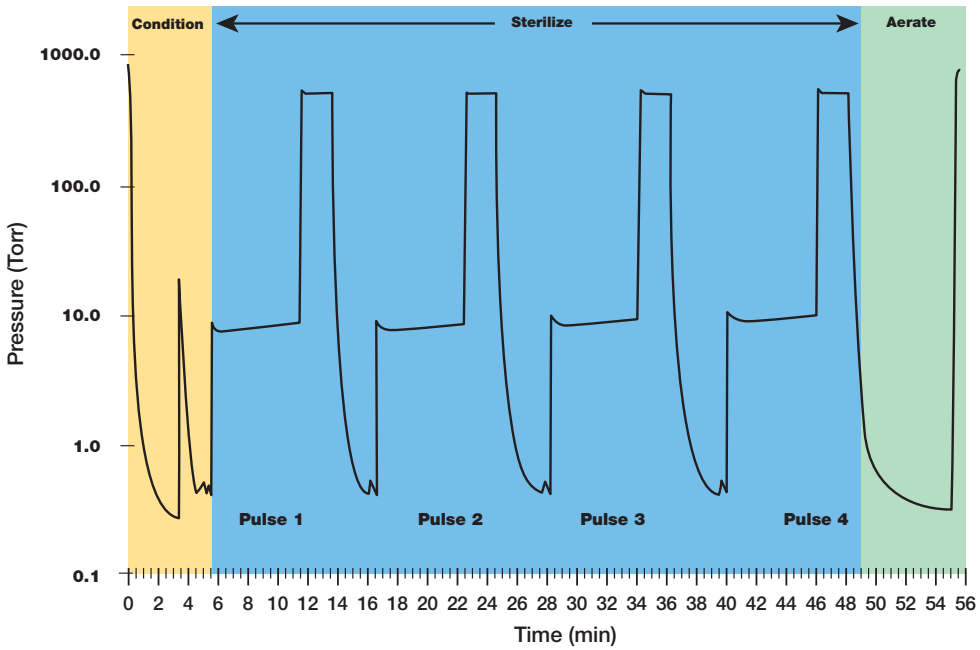
Figure 1. Pressure Graph of the V-PRO 1 Plus Sterilizer's Non Lumen Cycle.




## Lumen Cycle

The approximately 55-minute cycle is used to sterilize instruments with lumens[4] and mated surfaces. The prepared and packaged load is processed through a short conditioning phase during which the chamber is evacuated to less than 1 Torr (or 0.13 kPa). After the conditioning phase the moisture content of the load is verified to be acceptable. The pressure in the sterilizer chamber is then reduced to 0.4 Torr (or 0.012 kPa) in preparation for injection of VHP. The sterilizer automatically vaporizes the correct amount of liquid hydrogen peroxide from the multiple-cycle VAPROX HC cartridge. After a six-minute hold segment, filtered air enters the sterilization chamber, increasing the chamber pressure to 500 Torr (or 66 kPa). After an additional two-minute hold phase, the chamber pressure is again reduced to 0.4 Torr (or 0.012 kPa) in preparation for the next injection of VHP. VHP is injected four times during each sterilization cycle. After completion of the last VHP injection hold period, the load is automatically aerated in the sterilizer. The chamber VHP is exhausted through a catalytic converter that decomposes the VHP to water and oxygen. No special venting is required for operation of the V-PRO Sterilizers. At completion of the sterilization cycle, the load is removed and can be immediately used or stored prior to use. The cycle is presented graphically in Figure 2.

Figure 2. Pressure Graph of V-PRO 1 and V-PRO 1 Plus Sterilizer's Lumen Cycle




[4] Only stainless steel lumen configurations identified on page 3 can be sterilized in the Lumen Cycle.

# 3 Consumables

## Sterilant

VAPROX HC Sterilant is a proprietary, 59% liquid hydrogen peroxide sterilant that is contained in a multi-cycle cup. The sealed cup is placed into the sterilizer's cup interface and the door is closed. The sterilizer confirms that the sterilant cup is within its expiration date prior to automatically opening the sterilant cup. The sterilant cup has been engineered for safe and easy handling.

## Sterility Assurance and Sterile Packaging

The VERIFY® biological and chemical indicator products and Vis-U-All Low Temperature Sterilization Pouches have been designed and validated for exclusive use with the V-PRO Low Temperature Sterilization processes. Each product is designed to meet the Association for the Advancement of Medical Instrumentation's (AAMI) guidelines and applicable International Standards. Only use products that have been validated for the V-PRO 1 or V-PRO 1 Plus Low Temperature Systems. Failure to do so may result in a non-sterile device or ineffective monitoring of the load.

## Equipment Control

VERIFY Equipment Control Products monitor the critical performance characteristics of the sterilization process. As part of any Sterility Assurance Program, these products confirm that the equipment used is functioning correctly. Biological indicators such as the VERIFY® V24 Self Contained Biological Indicator offer a fast means of weekly or daily microbial monitoring while test packs such as the VERIFY® V24 Challenge Pack provide assurance following installation, relocation or major repair.

## Load Control

The V-PRO 1 and V-PRO 1 Plus Low Temperature Sterilization Systems provide cycle printouts for verification of critical performance parameters. A place is provided for the cycle reviewer's initials or signature.

Biological indicators such as the VERIFY V24 Self Contained Biological Indicator may also be used to monitor and release loads.

## Pack Control

Chemical indicator strips such as the VERIFY Vaporized VH2O2 Process Indicator confirm that sterilant is able to penetrate the packs to be sterilized. Each indicator provides the last check prior to use of the device. The indicator strips are designed to fit in sterilization pouches or trays.

## Process Control and Record Keeping

A variety of external process indicators, record cards, record envelopes and logs are available for use with the V-PRO 1 and V-PRO 1 Plus Low Temperature Sterilization Systems. These items are used to prevent the mix up of sterilized items by labeling the packs prior to processing and to ensure complete documentation of sterilization processes.

# 4 Performance Evaluation

## Microbicidal Efficacy Testing

STERIS Corporation conducted tests to validate the microbial efficacy of the V-PRO 1 Low Temperature Sterilization System's cycle and the V-PRO 1 Plus Low Temperature Sterilization System's two cycles. The following summarizes the test data demonstrating that the V-PRO Sterilizers' cycles and VAPROX HC Sterilant are effective.

## Sterility Assurance Level (SAL) Testing

An SAL of $10^{-6}$ was established for the V-PRO Sterilization Systems by performing ½ cycle testing using inoculated test articles to simulate medical devices under worst case sterilization conditions.

## Worst Case Test Conditions - Most Resistant Organism

STERIS conducted vaporized hydrogen peroxide (VHP) resistance testing under greatly reduced exposure conditions with a variety of organisms (Table 1) and bacterial endospores (Table 2) to identify the most resistant organism to VHP.

## Table 1. Microbial Resistance to VHP*

| Organisms | Log of Recovered Population at Exposure Time (min) | | | |
|---|---|---|---|---|
| | 0 | 1 | 2 | 5 |
| ***Geobacillus stearothermophilus* spores, ATCC 7953** | **5.8** | **4.5** | **4.6** | **3.8** |
| ***Mycobacterium terrae*, ATCC 15755** | **5.9** | **5.2** | **4.2** | † |
| ***Staphylococcus aureus*, ATCC 6538** | **5.0** | **4.4** | **2.1** | † |
| ***Pseudomonas aeruginosa*, ATCC 15442** | **5.7** | **3.2** | **0.8** | † |
| ***Salmonella choleraesuis*, ATCC 10708** | **5.3** | **3.4** | **0.8** | † |
| ***Aspergillus niger* spores, ATCC 6275** | **5.1** | **2.6** | † | † |
| ***Klebsiella pneumoniae*, ATCC 4352** | **4.2** | **3.2** | † | † |
| ***Trichophyton mentagrophytes* spores, ATCC 18748** | **5.4** | **2.9** | † | † |

* Exposure to 1.8 g/min VHP in a 0.6m³ Isolator

† No organism recovered

## Table 2. Bacterial Spore D-Values*

| Test Organism | D-Value (seconds) |
|---|---|
| ***Geobacillus stearothermophilus* spores, ATCC 7953** | **42.3** |
| *Bacillus subtilis* spores, ATCC 19659 | 18.7 |
| *Clostridium sporogenes* spores, ATCC 3584 | 15.6 |
| *Bacillus circulans* spores, ATCC 4513 | 14.4 |
| *Bacillus cereus* spores, ATCC 12826 | 9.9 |

* Exposure to 1.8 g/min VHP in a 0.6m³ Isolator

*Conclusion*

*Geobacillus stearothermophilus* endospores are the most resistant organism and therefore were used to validate the V-PRO Low Temperature Sterilization Systems' SAL and microbicidal efficacy.

## Sterilizer Load

The SAL microbial tests were conducted in the presence of a validation load appropriate for the cycle.

## ½ Cycle

For the SAL studies, ½ cycle evaluation was conducted. The ½ cycle consisted of a moisture check/conditioning phase, two sterilization pulses, and an aeration phase. This exposes the test articles to ½ the amount of peroxide (two sterilization pulses vs. four for a full cycle) for ½ of the total sterilant exposure time.

## Test Articles

Medical instrument material coupons (Table 3), mated configuration medical instrument coupons (Table 4) and stainless steel lumens (Table 5) were inoculated with $10^6$ *G. stearothermophilus* spores and dried. The test articles were placed within the validation load and exposed to a V-PRO 1 Sterilizer Lumen ½ cycle (identical to a V-PRO 1 Plus Lumen ½ Cycle) or a V-PRO 1 Plus Non Lumen ½ cycle. After exposure, the test articles were cultured and the number sterile versus number tested determined. All of the medical instrument materials, mated configuration materials and lumens were sterile after exposure to ½ cycles of the V-PRO 1 and V-PRO 1 Plus Sterilizers (Tables 3-5).

## Table 3. ½ Cycle Microbicidal Efficacy Evaluation - Medical Instrument Materials

| Medical Instrument Material | # Sterile/# Tested | |
|---|---|---|
| | Non Lumen Cycle | Lumen Cycle |
| Aluminum | 15/15 | 20/20 |
| Brass | 15/15 | 20/20 |
| Delrin | 15/15 | 20/20 |
| Ethyl vinyl acetate (EVA) | 15/15 | 20/20 |
| Glass | 15/15 | 20/20 |
| Kraton | 15/15 | 20/20 |
| Neoprene | 15/15 | 20/20 |
| Noryl (Polyphenylene Oxide) | 15/15 | 20/20 |
| Nylon | 15/15 | 20/20 |
| Polyether Ether Ketone (PEEK) | 15/15 | ** |
| Polymethyl methacrylate (PMMA) | 15/15 | 20/20 |
| Polycarbonate | 15/15 | 20/20 |
| Polyethylene | 15/15 | 20/20 |
| Polypropylene | 15/15 | 20/20 |
| Polystyrene | 15/15 | 20/20 |
| Polyvinyl chloride (PVC) | 15/15 | 20/20 |
| Polyurethane | 15/15 | 20/20 |
| Radel | 15/15 | 20/20 |
| Silicone | 15/15 | 20/20 |
| Stainless Steel | 15/15 | 20/20 |
| Teflon | 15/15 | 20/20 |
| Titanium | 15/15 | 20/20 |
| Ultem (Polyetherimide) | 15/15 | 20/20 |

** Tests conducted in the Non Lumen Cycle qualify materials for sterilization in the Lumen Cycle.

## Table 4. ½ Cycle Microbicidal Efficacy Evaluation - Mated Instrument Materials

| Medical Instrument Material | Coupon Pairs Sterile/Pairs Tested | |
|---|---|---|
| | Non Lumen Cycle | Lumen Cycle |
| Stainless Steel | 6/6 | ** |
| Titanium | 6/6 | ** |
| Delrin | N/A* | 20/20 |
| Ultem | N/A | 20/20 |
| Radel | N/A | 20/20 |
| Noryl | N/A | 20/20 |

* N/A = Not Applicable. The Non Lumen Cycle is only intended to sterilize stainless steel or titanium mated surfaces.

** Tests conducted in the Non Lumen Cycle qualify materials for sterilization in the Lumen Cycle.

## Table 5. ½ Cycle Microbicidal Efficacy Evaluation for the V-PRO 1 and V-PRO 1 Plus Lumen Cycle with Stainless Steel Lumens

| Medical Instrument Material | Lumen Size (ID** x Length mm) | # Sterile/# Tested | | |
|---|---|---|---|---|
| | | Trial 1 | Trial 2 | Trial 3 |
| Single | 0.77 x 500 | 12/12 | 12/12 | 12/12 |
| Dual | 0.77 x 527 | 1/1 | 1/1 | 1/1 |
| | 1.17 x 500 | 1/1 | 1/1 | 1/1 |
| Triple | 1.2 x 275 | 1/1 | 1/1 | 1/1 |
| | 1.2 x 275 | 1/1 | 1/1 | 1/1 |
| | 1.8 x 310 | 1/1 | 1/1 | 1/1 |
| Triple | (2x1.5)* x 285 | 1/1 | 1/1 | 1/1 |
| | 1.8 x 300 | 1/1 | 1/1 | 1/1 |
| | 2.8 x 317 | 1/1 | 1/1 | 1/1 |

* Oval channel

** ID=Internal Diameter

*Conclusion*

All of the device materials, mated device materials and lumens challenged with $10^6$ *G. stearothermophilus* spores were sterile after exposure to a V-PRO 1 Lumen ½ Cycle or V-PRO 1 Plus Lumen or Non Lumen ½ Cycle, as applicable, thereby establishing an SAL of $10^{-6}$ for the V-PRO Low Temperature Sterilization Systems.

## Modified Total End Point Kill (VHP Dose Evaluation)

Using the inoculated steel lumen test articles described in Table 5 that had been placed within the validation load, various amounts of hydrogen peroxide were introduced into the chamber under Lumen ½ Cycle conditions. The number of sterile test articles versus number tested was determined. All lumens were sterile at the normal sterilant concentration of 8.6 mg/L VHP as well as at the lower concentration of 6.0 mg/L VHP (Table 6).

## Table 6. VHP Dose Evaluation of Lumen Cycle

| VHP Concentration* (mg/L) | # Sterile Lumens /# Tested |
|---|---|
| 0.5 | 0/60 |
| 2.5 | 50/60 |
| 5.0 | 57/60 |
| 6.0 | 60/60 |
| 8.6 | 60/60 |

* Calculated Chamber Concentration

A similar experiment was conducted in the Non Lumen Cycle. Tests established the worst case challenge material to the Non Lumen Cycle. The inoculated and dried worst case challenge material coupon test articles were placed within the validation load. Various amounts of hydrogen peroxide were introduced into the chamber under Non Lumen ½ cycle conditions. The number of sterile test articles versus number tested was determined. All worst case material coupons were sterile at the normal sterilant concentration of 8.6 mg/L VHP as well as at the lower concentration of 6.0 mg/L VHP (Table 7).

## Table 7. VHP Dose Evaluation of V-PRO 1 Plus Non Lumen Cycle

| VHP Concentration* (mg/L) | # Sterile Coupons /# Tested |
|---|---|
| 2.5 | 9/18 |
| 5.0 | 16/18 |
| 6.0 | 18/18 |
| 8.6 | 18/18 |

* Calculated Chamber Concentration

*Conclusion*

The Lumen and Non Lumen Cycles effectively kill $10^6$ *G. stearothermophilus* spores, the most resistant organism, in a half cycle evaluation at concentrations below the normal minimum injected concentration of 8.6 mg/L VHP.

## AOAC Sporicidal Test Evaluation

AOAC sporicidal carrier testing was performed *in situ* to demonstrate the sporicidal efficacy of the V-PRO 1 and V-PRO 1 Plus Low Temperature Sterilization Systems. The test uses two types of test organisms (spores of *Clostridium* and *Bacillus*), in the presence of test soil, on two different porous surface carrier types (penicylinders and sutures). Testing was performed as defined in the Official Methods of Analysis of the AOAC International Association of Official Analytical Chemists, 17th Edition, 2000/2006, AOAC Official Method 966.04, "Sporicidal Activity of Disinfectants." It is required that a combination of at least 720 carriers are tested and all demonstrate the absence of growth following exposure and incubation. All 720 carriers were confirmed to be sterile following exposure to either the Lumen or Non Lumen Cycles using three separate lots of VAPROX HC Sterilant (Table 8).

## Table 8. AOAC Sporicidal Carrier Evaluation

| Carrier | #Sterile/#Tested | | | |
|---|---|---|---|---|
| | 21 Days | | 24 Days (post heat-shock) | |
| | 1° Tube | 2° Tube | 1° Tube | 2° Tube |
| *Bacillus subtilis penicylinder* | 180/180 | 180/180 | 180/180 | 180/180 |
| *Bacillus subtilis suture loop* | 180/180 | 180/180 | 180/180 | 180/180 |
| *Clostridium sporogenes penicylinder* | 180/180 | 180/180 | 180/180 | 180/180 |
| *Clostridium sporogenes suture loop* | 180/180 | 180/180 | 180/180 | 180/180 |
| **Total** | **720/720** | **720/720** | **720/720** | **720/720** |

*Conclusion*

The V-PRO 1 and V-PRO 1 Plus Low Temperature Sterilization Systems effectively inactivate bacterial endospores when evaluated by the AOAC carrier method. VAPROX HC Sterilant is sporicidal.

## Medical Instrument Testing

STERIS conducted tests to validate the V-PRO Low Temperature Sterilization Systems' ability to sterilize medical instruments. The following summarizes the test data demonstrating that the V-PRO Sterilizers and VAPROX HC Sterilant are effective under simulated worst case use and clinical use conditions.

## Simulated Use Evaluation

Worst case medical instruments with regard to size and features that are challenging to sterilize, were inoculated with $10^6$ *G. stearothermophilus* spores in 5% fetal bovine serum and 300 ppm AOAC hard water. The inoculated and dried medical instruments were processed through a V-PRO 1 Sterilizer's Lumen Cycle or V-PRO 1 Plus Sterilizer's Lumen or Non Lumen Cycles. After exposure, the medical instrument sites were sampled and evaluated for growth of the test organism. The number of sterile device sites versus the number of devices tested was determined (Tables 9 and 10). All devices were sterile under worst case simulated use conditions.

## Table 9. V-PRO 1 Plus Sterilizer's Non Lumen Cycle Simulated Use Evaluation

| Medical Instrument | Inoculation Site | # Sterile / # Tested |
|---|---|---|
| Cavity Clip | Surface | 3/3 |
| Colorectal Intestinal Dilator | Surface | 3/3 |
| Slide for Cannula Tubing | Surface | 3/3 |
| Defibrillator | Spoon | 3/3 |
| High Frequency Cord | Surface | 3/3 |
| Light Cable | Cable | 3/3 |
| Ocular Lens | Lens | 3/3 |
| Electrosurgical Forceps | Surface | 3/3 |
| Telescope | Ocular Surface | 3/3 |
| Surgical Scissors | Hinge (Mated Surface) | 3/3 |
| Camera | Lens | 3/3 |
| Battery | Housing | 3/3 |
| Non Lumened Flexible Endoscope | Insertion Tube | 3/3 |

## Table 10. V-PRO 1 and V-PRO 1 Plus Sterilizers' Lumen Cycle Simulated Use Evaluation

| Medical Instrument | Inoculation Site | # Sterile / # Tested |
|---|---|---|
| Surgical Scissors | Hinge (Mated Surface) | 3/3 |
| Towel Forceps | Clamp | 3/3 |
| Fixation Hooks/Retractor | Tines | 3/3 |
| Light Cable | Cord | 3/3 |
| Camera | Lens | 3/3 |
| Pacemaker Cables | Lead Connector | 3/3 |
| Batteries | Housing | 3/3 |
| Cystoscope | Contact area with organizer | 3/3 |
| | Ocular | 3/3 |
| Defibrillator Paddles | Handle | 3/3 |
| | Spoons back | 3/3 |
| Ureteroscope (dual channel) | 0.77 ID* x 527 mm lumen | 3/3 |
| | 1.17 ID x 500 mm length lumen | 3/3 |
| Hysteroscope (triple channel) | 1.2 ID x 275 mm length lumen | 3/3 |
| Sheath (triple channel) | 2.8 ID x 317 mm length lumen | 3/3 |

* ID=Internal Diameter

*Conclusion*

The V-PRO Low Temperature Sterilization Systems utilizing VAPROX HC Sterilant reproducibly sterilize challenging medical instruments inoculated with high levels of the most resistant organism, *G. stearothermophilus* spores.

## Clinical Use Evaluation

The V-PRO Low Temperature Sterilization Systems were evaluated in a clinical setting with medical instruments that had been used in clinical procedures. The instruments were cleaned, dried, packaged and exposed to either the Lumen or Non Lumen Cycles. After exposure, selected medical instrument sites were sampled and evaluated for growth of organisms. The number of sterile instrument sites versus the number of instrument sites tested was determined. All instruments were sterile under clinical use conditions (Tables 11 and 12).

## Table 11. V-PRO 1 Plus Sterilizer's Non Lumen Cycle Clinical Use Evaluation

| Medical Instrument | Selected Site | # Sterile / # Tested |
|---|---|---|
| Surgical Scissors | Hinge | 3/3 |
| Colorectal Intestinal Dilators | Surface | 3/3 |
| Syringe Plunger | Tip | 3/3 |
| Defibrillator Paddle | Spoon | 3/3 |
| Light Cord | Cord | 3/3 |
| Bipolar Cable | Cable | 3/3 |
| Electrosurgical Forceps | Surface | 3/3 |
| Camera | Lens | 3/3 |
| Batteries | Housing | 3/3 |
| Telescope | Ocular Surface | 3/3 |

## Table 12. V-PRO 1 and V-PRO 1 Plus Sterilizers' Lumen Cycle Clinical Use Evaluation

| Medical Instrument | Selected Site | # Sterile / # Tested |
|---|---|---|
| Surgical Scissors | Hinge | 3/3 |
| Towel Forceps | Clamp | 3/3 |
| Skin/Fixation Hooks/Retractor, | Tines | 3/3 |
| Defibrillator Paddles | Handle | 3/3 |
| | Spoon back | 3/3 |
| Light Cable | Cord | 3/3 |
| Camera | Lens | 3/3 |
| Pacemaker Cables | Lead Connector | 3/3 |
| Batteries | Housing | 3/3 |
| Telescope | Contact area with organizer | 3/3 |
| | Ocular | 3/3 |
| Ureteroscope (dual channel) | 0.77 ID x 510 mm lumen,<br>1.17 ID x 500 mm length lumens<br>or<br>0.85 ID x 520 mm lumen,<br>1.4 ID x 520 mm length lumens | 6/6 |
| Hysteroscope (triple channel)<br>or<br>Sheath (triple channel) | 1.2 ID x 275 mm lumen,<br>1.2 ID x 275 mm lumen,<br>1.8 ID x 310 mm length lumens<br>or<br>2.8 ID x 317 mm lumen<br>1.8 ID x 300 mm lumen<br>(2x1.5)* ID x 285 mm length lumens | 9/9 |

* Crescent shaped lumen

** ID = Internal Diameter

*Conclusion*

The V-PRO Low Temperature Sterilization Systems utilizing VAPROX HC Sterilant reproducibly sterilize clinically used medical instruments.

## Overall Conclusions of Microbicidal Efficacy Evaluations

STERIS has validated the microbicidal efficacy of the V-PRO 1 and the V-PRO 1 Plus Low Temperature Sterilization Systems:

- An SAL of $10^{-6}$ has been established through ½ cycle testing and modified total end point kill analysis
- The systems passed the AOAC Sporicidal Test
- Simulated and Clinical use testing has shown that instruments are sterile when processed in the V-PRO 1 and V-PRO 1 Plus Sterilizers utilizing VAPROX HC Sterilant

# 5 Materials Compatibility

The V-PRO Sterilization process is compatible with a wide range of medical instruments and materials. STERIS Corporation performed medical instrument materials compatibility evaluations to ensure that the V-PRO Low Temperature Sterilization Systems are safe for medical instruments. Representative medical instruments composed of a variety of materials were subjected to 50 V-PRO Low Temperature Sterilization Cycles with functional evaluations performed before and after the tests. Table 13 lists the materials and type of instruments evaluated for material compatibility.

## Table 13. Material Compatibility

| Materials | Instrument Evaluated | Cosmetic Change | Functionality |
|---|---|---|---|
| Aluminum | Telescope | None | Pass |
| | Wide Field Vitrectomy Lens | Loss of black color | |
| Brass | Resectoscope Working Element | None | Pass |
| | High Frequency Cord | | |
| | Defibrillator | | |
| | Bridge Adapter | | |
| Delrin | High Frequency Cord | None | Pass |
| | Defibrillator | | |
| EVA | Slide for Cannula Tubing | Slight yellowing | Pass |
| Glass | Telescope | None | Pass |
| | Wide Field Vitrectomy Lens | | |
| Kraton | Cavity Clip | None | Pass |
| | Piston Syringe with Thumb Control Ring | | |
| | Non-vented Luer Dispenser Tip Cap | | |
| | Pediatric Tuohy Borst Adapter | | |
| Neoprene | Neoprene Rubber Tubing | None | Pass |
| Noryl | Sterilization Tray | None | Pass |
| Nylon | High Frequency Cord | Yes | Fail after 39th Cycle* |
| | Resectoscope Sheath | Fading | Pass |
| | Resectoscope Obturator | | |
| | Pediatric Tuohy Borst Adapter | None | |
| PEEK | Endoscope | None | Pass |
| PMMA | Contact | None | Pass |

## Table 13. Material Compatibility (Continued)

| Materials | Instrument Evaluated | Cosmetic Change | Functionality |
|---|---|---|---|
| Polycarbonate | Reusable Nebulizer | None | Pass |
| Polyethylene | Piston Syringe with Thumb Control Ring | None | Pass |
| Polypropylene | Defibrillator | None | Pass |
| | Forceps | | |
| | Piston Syringe with Thumb Control Ring | | |
| | Reusable Nebulizer | | |
| | Sterilization Tray | | |
| Polystyrene | Non-vented Luer Dispenser Tip Cap | None | Pass |
| Polyurethane | Flexible Endoscope | None | Pass |
| PTFE | Working Element | None | Pass |
| | High Frequency Cord | | |
| PVC | Pediatric Tuohy Borst Adapter | None | Pass |
| | Reusable Nebulizer | | |
| Radel | Adapter for STERIS SYSTEM 1 | None | Pass |
| Silicone | Resectoscope Working Element | None | Pass |
| | High Frequency Cord | | |
| | Defibrillator | | |
| | Forceps | | |
| | Wide Field Vitrectomy Lens | Slight Discoloration | |
| | Reusable Nebulizer | None | |
| Stainless Steel | Resectoscope Working Element | Slight discoloration | Pass |
| | Microsurgical Scissors | None | |
| | Telescope | | |
| | Resectoscope Sheath | | |
| | Resectoscope Obturator | | |
| | Forceps | | |
| | Bone Chisel | | |
| | Bridge Adapter | | |
| | Probe Tip | | |
| | Sterilization Tray | | |
| Titanium | Bulldog Clamp | None | Pass |
| Ultem | Instrument Tray | None | Pass |

See Operator Manual for specific information on compatible materials. Some grades of Nylon, Delrin and Radel devices may have limited life after repeated sterilization.

*Conclusion*

Exposure to numerous cycles in the V-PRO Sterilizers does not significantly affect the appearance or functionality of most medical instruments.

# 6 Safety

The toxicology of hydrogen peroxide ($H_2O_2$) is well understood in the scientific literature. A thorough risk assessment of hydrogen peroxide was completed in 2003 by the European Union. The by-products from hydrogen peroxide sterilization, formed upon decomposition are water ($H_2O$) and oxygen gas ($O_2$).

$$2\ H_2O_2 \longrightarrow 2\ H_2O + O_2$$

These by-products do not present toxicity concerns to the user. Safeguards are in place to protect against potential exposure to hydrogen peroxide.

## Liquid Peroxide

Under normal conditions of use, the Sterilizer operator is not exposed to the contents of the VAPROX HC Sterilant cup (59% hydrogen peroxide). The sterilant cup is sealed, and the user cannot access the sterilant without physically damaging the cup. A SDS is provided to advise the user on safe handling practices.

## Hydrogen Peroxide Vapors

The user places a sealed, vented sterilant cup into the Sterilizer. The Sterilizer automatically dispenses and injects hydrogen peroxide into the low pressure chamber. At the end of each sterilization pulse, hydrogen peroxide vapor is removed from the chamber through a catalytic converter which converts the hydrogen peroxide into water and oxygen. To confirm this, the environment around the sterilizer was monitored under simulated use conditions for acceptable VHP levels during typical sterilization cycle conditions. The levels were >20 times lower than the OSHA hydrogen peroxide gas Time Weighted Average (TWA) limit of 1 ppm.

## Hydrogen Peroxide on Medical Instruments or Packaging

Biocompatibility testing was conducted for commonly used medical device materials after sterilization in the V-PRO 1 Low Temperature Sterilizer and V-PRO 1 Plus Low Temperature Sterilizer to verify effective removal of residuals. As part of the testing, cytotoxicity screening evaluations were conducted. Cytotoxicity is an extremely sensitive methodology that can identify a material as causing a positive cytotoxic response even though that material has an established history of safe clinical use. Therefore, the results obtained after processing in the V-PRO 1 Low Temperature Sterilizer and V-PRO 1 Plus Low Temperature Sterilizer were compared to those obtained using a similar technology that has been in clinical use for over fifteen years. In addition to cytotoxicity evaluations, ocular irritation, acute systemic toxicology, intracutaneous irritation and blood compatibility evaluations were performed. The results from these tests demonstrate that items processed in the V-PRO 1 Low Temperature Sterilizer and V-PRO 1 Plus Low Temperature Sterilizer do not have their innate biocompatible characteristics altered or compromised.

In accordance with ISO EN 10993-17 Biological Evaluation of Medical Devices- Part 17: Establishment of allowable limits for leachable substances, a risk analysis was conducted and safe levels of residual hydrogen peroxide were established. A risk assessment completed by the European Commission (2003) was used as primary source document for this assessment. The V-PRO 1 Low Temperature Sterilizer and V-PRO 1 Plus Low Temperature Sterilizer were shown to reduce the levels of residues on representative medical devices (12 medical devices including flexible endoscopes, resectoscope and forceps) to well below the established residue limits (greater than 9 to 800 fold lower than the allowable residue limit for internal tissue contact established in accordance with ISO 10993-17) proving that the V-PRO 1 Low Temperature Sterilizer and V-PRO 1 Plus Low Temperature Sterilizer effectively eliminates toxic process residuals.

## 7 Conclusion

The V-PRO 1 and V-PRO 1 PLUS Low Temperature Sterilization Systems can be used to safely and effectively terminally sterilize properly prepared (cleaned, rinsed and dried) metal and nonmetal medical devices used in healthcare facilities.

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