Technical Data Monograph

V-PRO® 60 Low Temperature Sterilization System

STERIS

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1 Introduction

This Technical Data Monograph illustrates the principles of operation, demonstrates the safety and efficacy of the V-PRO 60 Low Temperature Sterilization System, and summarizes test data for microbicidal efficacy, material compatibility, and biocompatibility testing performed.

The V-PRO 60 Sterilization System is intended for use in terminal sterilization of cleaned, rinsed, and dried, reusable metal and non-metal medical devices used in healthcare facilities. The V-PRO 60 Low Temperature Sterilization System performs three pre-programmed sterilization cycles; the **Non Lumen Cycle**, the **Lumen Cycle** and the **Flexible Cycle**.

Cycles:

The V-PRO 60 Sterilizer's **Non Lumen Cycle** can sterilize:[a]

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

[a] The validation studies were performed using a validation load consisting of one instrument tray with instrument organizers and mat and one pouch for a total weight of 12 lbs (5.4 kg).

The V-PRO 60 Sterilizer's **Lumen Cycle** can sterilize:[b]

- Instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors
- Non-lumened devices including non-lumened rigid and semi-rigid endoscopes
- Medical devices, including single, dual and triple channeled rigid and semi-rigid endoscopes, with the following configurations: [a]
  - single or dual lumen devices with stainless steel lumens that are
    - ≥ 0.77 mm (~1/32") internal diameter (ID) and ≤ 410 mm (16-9/64") in length
  - triple lumen devices with stainless steel lumens that are
    - ≥ 1.2 mm (~3/64") ID and ≤ 275 mm (~10-55/64") in length
    - ≥ 1.8 mm (~5/64") ID and ≤ 310 mm (~12-13/64") in length

      or
    - ≥ 2.8 mm (~7/64") ID and ≤ 317 mm (12-31/64") in length

[b] The validation studies for all lumen configurations were conducted using a maximum of twelve (12) 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 one instrument tray with instrument organizers and mat and two pouches for a total weight of 11 lbs (5.0 kg).

The V-PRO 60 Sterilizer's **Flexible Cycle** can sterilize:[c]

- One flexible surgical endoscope or bronchoscope with a light cord (if not integral to endoscope) and mat without any additional load. The flexible endoscope may be a:
  - single or dual lumen device with lumens that are > 1 mm (~3/64") ID and < 990 mm (38-63/64") in length

[c] The validation studies were conducted with one flexible endoscope, packaged into a tray with silicone mat, instrument organizers and light cord (if not integral to scope) and no additional load.

Features:

- Cart mounted or counter top install options
- An 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
- Cycle Pass statement on cycle tape when all critical parameters are met
- Automatic load aeration
- System designed for ease of use and maintenance
- Easy installation – no utilities save 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.
- USB port for cycle downloads

The V-PRO 60 Low Temperature Sterilization System consists of several components. These components include:

- The V-PRO 60 Sterilizer
- VAPROX® HC Sterilant
- Self-Contained Biological Indicator
- Biological Indicator Test Packs
- Chemical Indicator
- External Process Indicators and Chemical Indicator Strips
- Record Cards and Record Keeping Systems
- Sterilization Trays, Instrument Organizers, and Silicone Mats
- Low Temperature Pouches and Tubing

2 V-PRO 60 Low Temperature Sterilization System: Principle of Operation

The V-PRO 60 Low Temperature Sterilization System uses Vaporized Hydrogen Peroxide or VHP to sterilize reusable medical instruments. Prior to sterilization, cleaned and dried instruments are packaged in containers, wrapped trays or Tyvek[1] pouches that are specifically designed and qualified for use with the V-PRO 60 Sterilizer. The packaged instruments are placed on the Sterilizer's two shelves and the sterilizer door is shut. The V-PRO 60 Sterilizer Non Lumen Cycle, Lumen Cycle or Flexible Cycle is selected to initiate the sterilization process.

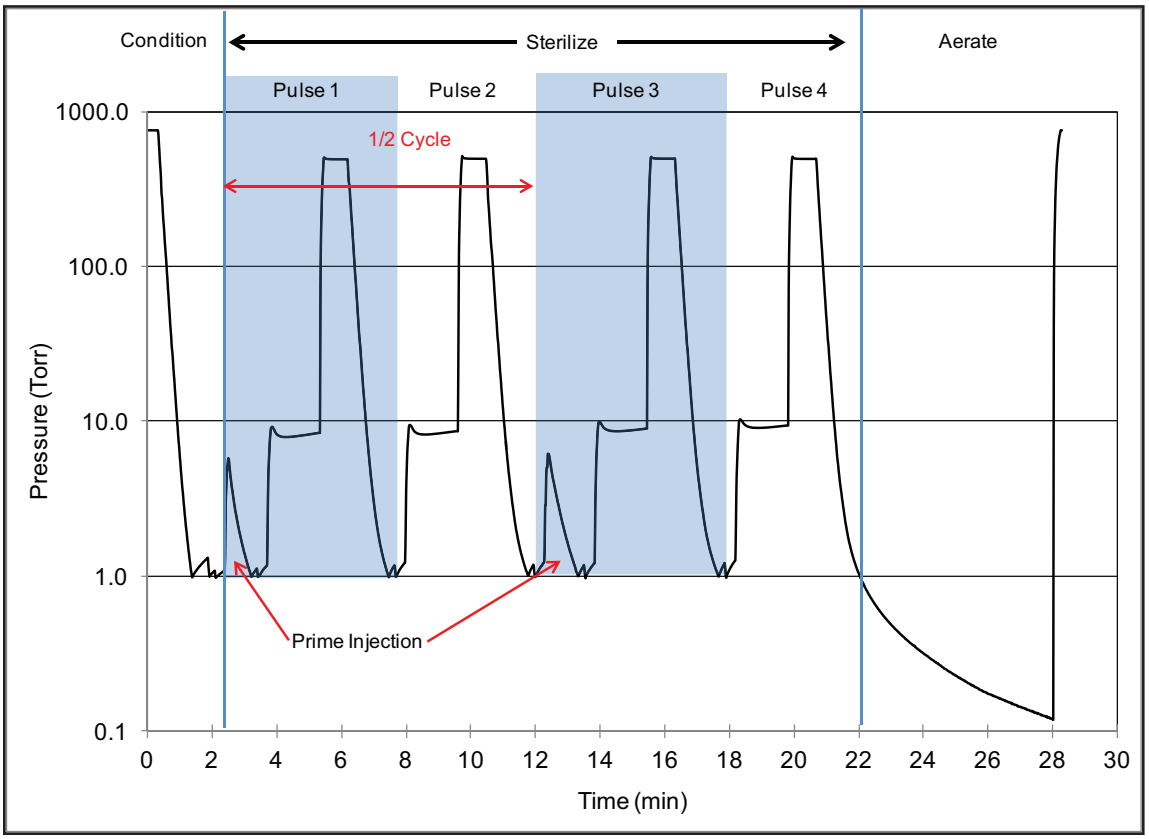
V-PRO 60 Sterilizer Non Lumen Cycle

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. If the load contains a stainless steel lumened instrument and/or a mated surface other than stainless steel or titanium, the Lumen Cycle must be selected.[2] If the load contains a lumened flexible endoscope, the Flexible Cycle must be selected.[3] The prepared and packaged load is processed through a short Condition 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, the chamber is evacuated to less than 1 Torr (0.13 kPa) to aid in removal of excess moisture. After the moisture removal (if needed), the moisture content of the load is verified

1 Tyvek® is a registered trademark of E.I. du Pont de Nemours and Company
2 Only stainless steel lumen configurations identified on page 3 can be sterilized using the Lumen Cycle.
3 Only flexible lumens identified on page 3 can be processed in the Flexible Cycle.

to be acceptable. The pressure in the sterilizer chamber is then reduced to 1 Torr (0.13 kPa) in preparation for the Sterilize Phase, which consists of four sterilization pulses. For the first and third sterilization pulses two injections of hydrogen peroxide occur. For all injections, the sterilizer automatically vaporizes the correct amount of liquid hydrogen peroxide from the multiple-cycle VAPROX HC Sterilant cup. For the first injection, called the prime injection, the VHP is introduced with the vacuum pump actively evacuating the chamber. Once the chamber again achieves a pressure of 1 Torr (0.13 kPa) the second injection of hydrogen peroxide occurs but this time the chamber is not being evacuated. After a 1.75-minute hold segment, filtered air enters the sterilization chamber, increasing the chamber pressure to 500 Torr (or 66.7 kPa). After an additional 30-second hold segment, the chamber pressure is again reduced to 1 Torr (0.13 kPa) in preparation for the next injection of VHP. The second and fourth sterilization pulses consist of a single injection of sterilant identical to the second injection of the first and third sterilization pulses. After completion of the fourth sterilization pulse, the load is automatically aerated (Aerate Phase) 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 60 Sterilizer. 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.

Figure 1. Pressure Graph of V-PRO 60 Sterilizer Non Lumen Cycle



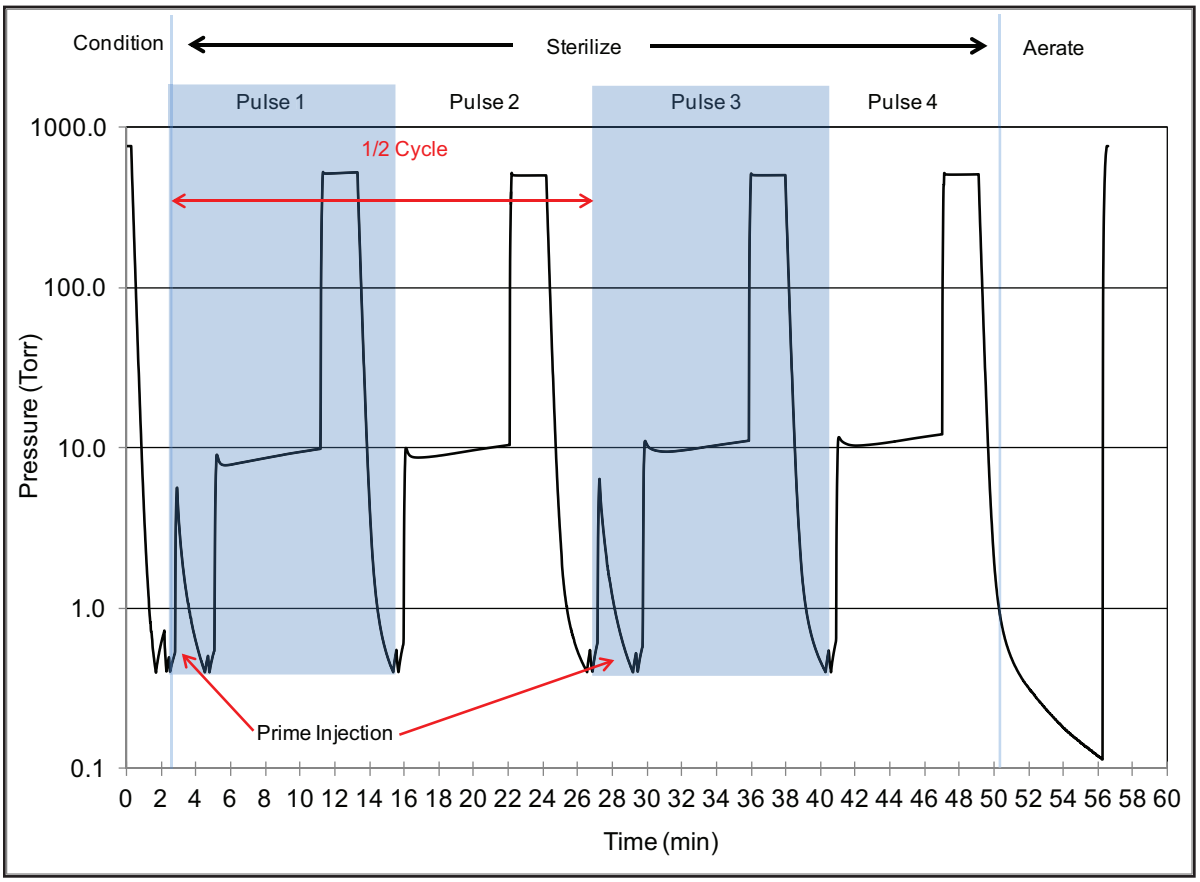
V-PRO 60 Sterilizer Lumen Cycle

The approximately 60-minute cycle is used to sterilize instruments with stainless steel lumens[4] and mated surfaces. The prepared and packaged load is processed through a short moisture check phase during which the chamber pressure is reduced to 0.4 Torr (or 0.05 kPa) and the moisture content of the load is verified to be acceptable. If the moisture content is not acceptable, a short Condition Phase is initiated during which the chamber is evacuated to less than 0.4 Torr (0.05 kPa) to aid in removal of excess moisture. After the moisture removal (if needed), the moisture content of the load is verified to be acceptable. The pressure in the sterilizer chamber is then reduced to 0.4 Torr (0.05 kPa) in preparation for the Sterilize Phase, which consists of four sterilization pulses. For the first and third sterilization pulses, two injections of hydrogen peroxide occur. For all injections, the sterilizer automatically vaporizes the correct amount of liquid hydrogen peroxide from the multiple-cycle VAPROX HC Sterilant cup. For the first injection, called the prime injection, the VHP is introduced with the vacuum pump actively evacuating the chamber. Once the chamber again achieves a pressure of 0.4 Torr (0.05 kPa) the second injection of hydrogen peroxide occurs but this time the chamber is not being evacuated. After a 6-minute hold segment, filtered air enters the sterilization chamber, increasing the chamber pressure to 500 Torr (or 66.7 kPa).

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

After an additional 2-minute hold segment, the chamber pressure is again reduced to 0.4 Torr (0.05 kPa) in preparation for the next injection of VHP. The second and fourth sterilization pulses consist of a single injection of sterilant identical to the second injection of the first and third sterilization pulses. After completion of the fourth sterilization pulse, the load is automatically aerated (Aerate Phase) 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 V-PRO 60 Sterilizer. 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 60 Sterilizer Lumen Cycle



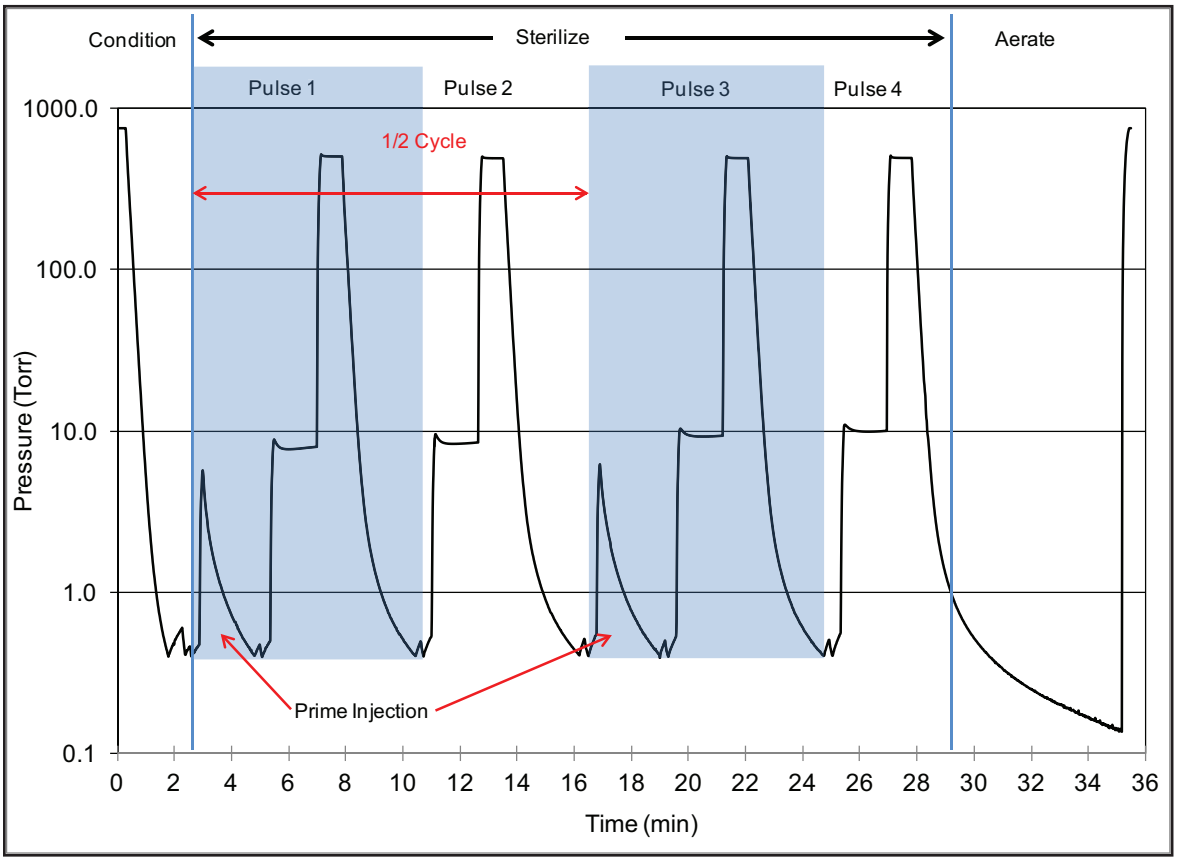
V-PRO 60 Sterilizer Flexible Cycle

The approximately 38-minute Flexible Cycle is used to sterilize flexible surgical endoscopes (such as those used in ENT, Urology and Surgical Care) and bronchoscopes with lumens. The Flexible Cycle can be used to sterilize either a single or dual channel flexible endoscope in a cycle.[5] The prepared and packaged load is processed through a short Condition Phase during which the chamber pressure is reduced to 0.4 Torr (or 0.05 kPa) and the moisture content of the load is verified to be acceptable. If the moisture content is not acceptable, the chamber is evacuated to less than 0.4 Torr (or 0.05 kPa) to aid in removal of excess moisture. After the moisture removal (if needed), the moisture content of the load is verified to be acceptable. The pressure in the sterilizer chamber is then reduced to 0.4 Torr (0.05 kPa) in preparation for the Sterilize Phase, which consists of four sterilization pulses. For the first and third sterilization pulses, two injections of hydrogen peroxide occur. For all injections, the sterilizer automatically vaporizes the correct amount of liquid hydrogen peroxide from the multiple-cycle VAPROX HC Sterilant cup. For the first injection, called the prime injection, the VHP is introduced with the vacuum pump actively evacuating the chamber. Once the chamber again achieves a pressure of 0.4 Torr (0.05 kPa) the second injection of hydrogen peroxide occurs but this time the chamber is not being evacuated. After a 1.75-minute hold segment, filtered air enters the sterilization chamber, increasing the chamber pressure to 500 Torr (or 66.7 kPa). After an additional 30-second hold segment, the chamber pressure is again reduced to 0.4 Torr (0.05 kPa) in preparation for the next injection of VHP.

5 Only flexible lumens and load configurations identified on page 3 can be processed in the Flexible Cycle.

The second and fourth sterilization pulses consist of a single injection of sterilant identical to the second injection of the first and third sterilization pulses. After completion of the fourth sterilization pulse, the load is automatically aerated (Aerate Phase) 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 VPRO 60 Sterilizer. 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 3.

Figure 3. Pressure Graph of V-PRO 60 Sterilizer Flexible 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 STERIS Tyvek Packaging have been designed and validated for use with the V-PRO 60 Low Temperature Sterilization processes. Each product is designed to meet applicable International Standards. Only use products that have been validated for the V-PRO 60 Low Temperature Sterilization System. Failure to do so may result in a non-sterile device.

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 Biological Indicator Challenge Pack provide assurance following installation, relocation or major repair.

Load Control

The V-PRO 60 Low Temperature Sterilization System provides 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 HPU Chemical 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 60 Low Temperature Sterilization System. 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 Evaluations

Microbicidal Efficacy Testing

STERIS Corporation conducted tests to validate the microbicidal efficacy of the V-PRO 60 Low Temperature Sterilization System's three sterilization cycles. The following summarizes the test data demonstrating that the V-PRO 60 Sterilizer and VAPROX HC Sterilant are effective.

Sterility Assurance Level (SAL) Testing

An SAL of 10^{-6} was established for the V-PRO 60 Sterilization System by performing ½ cycle testing using inoculated test articles to simulate medical instruments 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. Microbicidal Resistance to VHP*

	Log of Recovered Population			
Organism ↓ 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 0.6 m^3 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 0.6 m^3 Isolator

Conclusion:
Geobacillus stearothermophilus endospores are the most resistant organism and therefore were used to validate the V-PRO 60 Low Temperature Sterilization System's SAL and microbicidal efficacy.

Sterilizer Load

The SAL microbicidal tests were conducted in the presence of a validation load. The load for the Lumen and Non Lumen Cycles was composed of a wrapped tray containing medical instruments and Tyvek pouches. The entire weight of the validation load was 11 lbs (5.0 kg) and 12 lbs (5.4 kg) for the Lumen and Non Lumen Cycles, respectively. For the Flexible Cycle testing the load was composed of one tray, containing a flexible endoscope and light cord (if not integral to the flexible endoscope) with no addition instruments.

V-PRO 60 Sterilizer ½ Cycle

For the SAL studies, ½ cycle evaluation was conducted. The ½ cycle consisted of a moisture check/conditioning phase, 2 sterilization pulses, and an aeration phase. This exposes the test articles to ½ the amount of vaporized hydrogen peroxide (2 sterilization pulses vs. 4 for a full cycle) for ½ of the total sterilant exposure time. (See Figures 1 -3)

Test Articles

Medical instrument worst case material coupons (Table 3), mated configuration medical instrument coupons (Table 4), stainless steel lumens (Table 5), or Teflon lumens (Table 7) were challenged with 10^6 *Geobacillus stearothermophilus* spores and dried. The test articles were placed within the validation load and exposed to a VPRO 60 Sterilizer Lumen ½ Cycle, Non Lumen ½ Cycle or Flexible 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 a V-PRO 60 Sterilizer ½ Cycles (Tables 3-7).

The ability to sterilize medical device surfaces was evaluated using the most resistant material for VHP sterilization. The test articles were exposed to a Non Lumen ½ Cycle. The Non Lumen Cycle is the worst case of the three V-PRO 60 Sterilizer Cycles for device surface sterilization. Testing conducted in the Non Lumen Cycle qualify all three of the V-PRO 60 Sterilizer Cycles for sterilization of compatible device material surfaces.

Table 3. V-PRO 60 Sterilizer Non Lumen ½ Cycle Microbicidal Efficacy Evaluation: Worst Case Medical Instrument Material

Trial	# Sterile /# Tested	
	D-value (seconds)	Double Tyvek Pouch
1	3/3	3/3
2	3/3	3/3
3	3/3	3/3

Table 4. V-PRO 60 Sterilizer ½ Cycle Microbicidal Efficacy Evaluation – Mated Instrument Materials

Material	Coupon Pairs Sterile/Pairs Tested	
	Non Lumen Cycle	Lumen Cycle
Stainless Steel	3/3	**
Titanium	3/3	**
Delrin	N/A*	3/3
Ultem		3/3
Radel		3/3
Noryl		3/3

* N/A = Not Applicable. The Non Lumen Cycle is only intended to sterilize stainless steel and titanium mated surfaces.
** Tests conducted in Non Lumen Cycle Qualifies Sterilization in the Lumen Cycle

Table 5. V-PRO 60 Sterilizer Lumen ½ Cycle Microbicidal Efficacy Evaluation for Stainless Steel Lumens

Channel Configuration	Lumen Size (ID x Length mm)	# Sterile/# Tested					
		Wrapped Tray			Double Tyvek Pouch		
		Trial 1	Trial 2	Trial 3	Trial 1	Trial 2	Trial 3
Dual	0.77 x 410	3/3	3/3	3/3	1/1	1/1	1/1
	1.1 x 410	3/3	3/3	3/3	**		
Triple	1.2 x 275	2/2	2/2	2/2	1/1	1/1	1/1
	1.8 x 310	1/1	1/1	1/1	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	1/1	1/1	1/1

* Crescent shaped lumen
** Not evaluated

Table 6. V-PRO 60 Sterilizer Flexible ½ Cycle Microbicidal Efficacy Evaluation with Flexible Lumens

Lumen Size (ID x Length mm)	# Lumens Sterile/# Tested		
	Trial 1	Trial 2	Trial 3
1 x 1000	3/3	3/3	3/3

Conclusion:

The worst case medical device material and lumens challenged with 10^6 *Geobacillus stearothermophilus* spores were sterile in a double wrapped tray or double Tyvek pouch configuration after exposure to a VPRO 60 Sterilizer Lumen ½ Cycle, Non Lumen ½ Cycle, or Flexible ½ Cycle, as applicable, thereby establishing an SAL of 10^{-6} for the VPRO 60 Low Temperature Sterilization System.

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 V-PRO 60 Sterilizer 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 10.4 mg/L VHP as well as at the lower concentration of 7.1 and 6.0 mg/L VHP (Table 7).

Table 7. VHP Dose Evaluation of V-PRO 60 Lumen Cycle

VHP Concentration* (mg/L)	# Sterile Lumens /# Tested
0.6	3/36
2.8	34/36
6.0	36/36
7.1	36/36
10.4	36/36

* Calculated Chamber Concentration

A similar experiment was conducted in the V-PRO 60 Sterilizer Non Lumen Cycle. Tests established the worst case challenge material to the V-PRO 60 Sterilizer 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 10.4 mg/L VHP as well as at the lower concentrations of 6.0 and 2.8 mg/L VHP (Table 8).

Table 8. VHP Dose Evaluation of V-PRO 60 Non Lumen Cycle

VHP Concentration* (mg/L)	# Sterile Coupons /# Tested
0.6	0/9
1.4	1/9
2.8	9/9
6.0	9/9
10.4	9/9

* Calculated Chamber Concentration

A similar test was conducted for the V-PRO 60 Sterilizer Flexible Cycle, 1 flexible endoscope and 3 flexible lumen test articles were exposed to varying concentrations of VHP and the number of sterile articles versus number tested was determined. All lumens were sterile at the normal sterilant concentration of 10.4 mg/L VHP as well as at the lower concentrations of 7.1 and 6.0 mg/L VHP (Table 9).

Table 9. VHP Dose Evaluation of V-PRO 60 Flexible Cycle

VHP Concentration* (mg/L)	# Sterile Lumens/# Tested
0.6	0/9
2.8	8/9
6.0	9/9
7.1	9/9
10.4	9/9

* Calculated Chamber Concentration

Conclusion:

The V-PRO 60 Sterilizer Non Lumen, Lumen and Flexible 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 10.4 mg/L VHP.

AOAC Sporicidal Test Evaluation

AOAC sporicidal carrier testing was performed *in situ* to demonstrate the sporicidal efficacy of the V-PRO 60 Low Temperature Sterilization System. 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, 2013, AOAC Official Method 966.04, "Sporicidal Activity of Disinfectants, Method 1." It is required that a combination of at least 720 carriers are tested and all are required to demonstrate the absence of growth following exposure and incubation. All 720 carriers were confirmed to be sterile following exposure to the V-PRO 60 Sterilizer's Non Lumen Cycle using three separate lots of VAPROX HC Sterilant (Table 10). Sporicidal testing conducted in the V-PRO 60 Sterilizer's Non Lumen Cycle (worst case cycle) verifies efficacy in the V-PRO 60 Sterilizer Flexible and Lumen Cycles.

Table 10. AOAC Sporicidal Carrier Evaluation in the V-PRO 60 Non Lumen Cycle*

Carrier	#Sterile/#Tested			
	21 Days		≥ 24 Days (post heat-shock)	
	1º Tube	2º Tube	1º Tube	2º 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 60 Low Temperature Sterilization System effectively inactivates bacterial endospores when evaluated by the AOAC carrier method. VAPROX HC Sterilant is sporicidal.

Medical Instrument Testing

STERIS Corporation conducted tests to validate the V-PRO 60 Low Temperature Sterilization System's ability to sterilize medical instruments. The following summarizes the test data demonstrating that the V-PRO 60 Sterilizer 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 with 5% fetal bovine serum and 300 ppm AOAC hard water. The inoculated and dried medical instruments were included as part of worst case validation load and processed through V-PRO 60 Sterilizer Lumen, Non Lumen or Flexible Cycles. After exposure, the medical instrument sites were sampled and evaluated for growth of the test organism. The number of sterile devices tested versus the number of devices tested was determined (Tables 11, 12 and 13). All devices were sterile under worst case simulated use conditions.

Table 11. V-PRO 60 Sterilizer Non Lumen Cycle Simulated Use Evaluation

Medical Instrument	Inoculation Site	# Sterile / # Tested
Cavity Clip	Surface	3/3
Colorectal Intestinal Dilator	Surface	3/3
Surgical Scissors	Hinge (Mated Surface)	3/3
Non-Lumened Flexible Endoscope	Insertion Tube	3/3

Table 12. V-PRO 60 Sterilizer Lumen Cycle Simulated Use Evaluation

Medical Instrument	Inoculation Site	# Sterile / # Tested
Ureteroscope (dual channel)	0.77 x 410 mm lumen	3/3
Hysteroscope (triple channel)	1.2 x 275 mm lumen	3/3
	1.8 x 310 mm lumen	3/3
Sheath (triple channel)	2.8 x 317 mm lumen	3/3

Table 13. V-PRO 60 Sterilizer Flexible Cycle Simulated Use Evaluation

Medical Instrument	Inoculation Site	#Sterile / #Tested
Flexible Dual Channel Ureterorenoscope	1 x 990 mm lumen	3/3
	1 x 850 mm lumen	3/3

Conclusion:
The V-PRO 60 Low Temperature Sterilization Systems utilizing VAPROX HC Sterilant reproducibly sterilize challenging medical instruments challenged with high levels of the most resistant organism, *G. stearothermophilus* spores in the presence of organic and inorganic challenge.

Clinical Use Evaluation
The V-PRO 60 Low Temperature Sterilization System sterilization cycles 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 Non Lumen, Lumen or Flexible 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 18, 19, 20, and 21).

Table 14. V-PRO 60 Sterilizer Clinical Use Evaluation

V-PRO 60 Sterilizer Cycle	Medical Instrument	Selected Site [Outer Surface or Lumen (mm Internal Diameter x mm Length]	# Sterile / # Tested
Non Lumen	Surgical Scissors	Hinge	3/3
	Tourniquet	Surface	3/3
	Syringe Plunger	Tip	3/3
	Flexible Ureteroscope	Outer Surface	3/3
Lumen	Triple Channel Rigid Device	1.2 x 275 lumen, 1.2 x 275 lumen, 1.8 x 310 lumen or 2.8 x 317 lumen 1.8 x 300 lumen (2x1.5) crescent shaped x 285 lumen	9/9
	Dual Channel Ureteroscope	0.77 x 410 lumen 1.1 x 410 lumen	6/6
Flexible	Flexible Ureterorenoscope	1 x 850 lumen 1 x 990 lumen	6/6

Conclusion:
The V-PRO 60 Sterilizer Non Lumen, Lumen and Flexible Cycles utilizing VAPROX HC Sterilant reproducibly sterilize clinically used medical instruments.

Overall Conclusions of Microbicidal Efficacy Evaluations

STERIS Corporation has validated the microbicidal efficacy of the V-PRO 60 Low Temperature Sterilization System:

- An SAL of 10^{-6} has been established through ½ cycle testing and modified total end point kill analysis.
- The system passed the AOAC Sporicidal Test.
- Simulated and Clinical use testing has shown that reusable instruments are sterile when processed in the V-PRO 60 Low Temperature Sterilizer utilizing VAPROX HC Sterilant.

Materials Compatibility

The V-PRO 60 Sterilizer 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 60 Low Temperature Sterilization System is safe for medical instruments. Representative medical instruments composed of a variety of materials were subjected to 50 V-PRO 60 Low Temperature Sterilization Lumen Cycles (worst case, longest sterilant exposure) with functional evaluations performed before and after the tests. Table 15 lists the materials and type of instruments evaluated for material compatibility.

Table 15. Material Compatibility*

Material	Device Evaluated	Cosmetic Change	Functionality
Aluminum	Lens	Loss of black color	Pass
Brass	Endoscope	None	Pass
	Resectoscope: Working Element	None	Pass
Delrin	Amalgam Carrier	None	Pass
	Flexible Ureteroscope	None	Pass
EVA	Adult Hose Cuff	None	Pass
Glass	Endoscope	None	Pass
	Rigid Telescope	None	Pass
	Lens	None	Pass
	Flexible Ureteroscope	None	Pass
Kraton Polymers	Reusable Rubber Mouthpiece	None	Pass
Neoprene	Neoprene Cord	None	Pass
Noryl	Bite Block	None	Pass
Nylon	Rigid Telescope	None	Pass
	Nonconductive Retractor	None	Pass
PMMA	Lens	None	Pass
Polycarbonate	Ultrasonic Probe	None	Pass
PEEK	Bipolar Scissors with Guard	None	Pass
	Flexible Ureteroscope	None	Pass
Polyethylene	Adult Hose Cuff	None	Pass
Polypropylene	Ultrasonic Probe	None	Pass
	Defibrillator Paddle	None	Pass
Polystyrene	Vaginal Speculum	None	Pass
Polyurethane	Flexible Ureteroscope	None	Pass
PVC	Ultrasonic Probe	None	Pass
Radel	Resectoscope: Working Element	None	Pass
	Orthopedic Mallet	None	Pass
Silicone	Resectoscope: Working Element	None	Pass
	Amalgam Carrier	None	Pass
	Defibrillator Paddle	None	Pass

Material	Device Evaluated	Cosmetic Change	Functionality
Stainless Steel	Bipolar Scissors with Guard	None	Pass
	Orthopaedic Mallet	None	Pass
	Endoscope	None	Pass
	Amalgam Carrier	None	Pass
	Defibrillator Paddle	None	Pass
	Resectoscope: Working Element	None	Pass
	Hopkins II Telescope	None	Pass
	Nonconductive Retractor	None	Pass
	Flexible Ureteroscope	None	Pass
Teflon	Endoscope	None	Pass
	Resectoscope: Working Element	None	Pass
	Flexible Ureteroscope	None	Pass
Titanium	Titanium Bulldog Spring Clamp	None	Pass
	Resectoscope: Working Element	None	Pass
Ultem Polymers	Endoscope	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 60 Sterilizer does not significantly affect the appearance or functionality of most medical instruments.

Safety

The toxicology of hydrogen peroxide (H_20_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).

$$2\ H_2O_2 \rightarrow 2\ H_2O + O_2$$

These by-products do not present toxicity concerns to the user. There are three conditions under which the V-PRO 60 Sterilizer user or patients could potentially be exposed to hydrogen peroxide. Safeguards are in place to prevent these potential exposures.

Exposure to Liquid Hydrogen 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.

Exposure to Hydrogen Peroxide Vapor

The user places a sealed, vented sterilant cup into the Sterilizer. The Sterilizer automatically dispenses and injects 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.

Exposure to Hydrogen Peroxide on Medical Instruments or Packaging

Biocompatibility testing was conducted for instrument composed of commonly used medical device materials as well as common packaging materials after sterilization in the V-PRO 60 Sterilizer to verify effective removal of residuals. All medical device and packaging extracts were non-cytotoxic when tested in accordance with ISO 10993-5 *Biological Evaluation of Medical Devices—Part 5, Tests for Cytotoxicity: 2009* In addition to cytotoxicity evaluations, ocular irritation, acute systemic toxicology, intracutaneous irritation and blood compatibility evaluations were performed with medical device materials that had been processed in the V-PRO maX Low Temperature Sterilization System. The tests completed in the V-PRO maX System are applicable to the V-PRO 60 Low Temperature Sterilization System based upon the comparable hydrogen peroxide residue (next paragraph) and cytotoxicity results obtained in the two vaporized hydrogen peroxide sterilization systems. The results from the cytotoxicity and other biocompatibility evaluations demonstrate that items processed in the V-PRO 60 Sterilizer retain their innate biocompatible characteristics.

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 VPRO 60 Sterilization System was shown to reduce the levels of residues on representative medical devices (the same devices as used for the cytotoxicity evaluation) and common packaging materials to well below the established residue limits (11 to >65 fold lower than the allowable residue limit for internal tissue contact and > 100 fold lower than the allowable residue limit for dermal contact established in accordance with ISO 10993-17) proving that the V-PRO 60 Sterilizer effectively eliminates toxic process residuals.

Conclusion:

The sterilization process of the V-PRO 60 Sterilizer is safe for the environment, safe for the patient and safe for the user.

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