Technical Data Monograph

V-PRO® maX 2
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 VPRO maX 2 Low Temperature Sterilization System. The sterilizer's preprogrammed sterilization cycles operate at low pressure and temperature, suitable for processing medical devices without leaving toxic residues. The summary test data for microbicidal efficacy, material compatibility, and biocompatibility testing performed on the VPRO maX 2 Sterilizer are included.

The V-PRO maX 2 Sterilizer is designed for maximizing productivity, ease of use, and also providing maximum flexibility to the user.

- **Innovation**: The V-PRO maX 2 Sterilizer offers the Fast Non Lumen Cycle, smart cup technology, and also an ergonomical hands free door opening option to help with the fast paced work environment of today. These features set the sterilizer apart from other sterilizers offered in the market today.
- **Assurance**: The V-PRO maX 2 Sterilizer has been specifically designed to provide effective and safe sterilization of a wide array of medical device technology. Utilizing vaporized hydrogen peroxide in a highly controlled and proprietary system, the sterilizer is engineered to be safe on the high technology substrates used in medical devices by using and maintaining hydrogen peroxide concentration below 60%. Additionally, it is not necessary to incorporate additional energy into this unit, such as plasma, to reduce residual hydrogen peroxide because of the unique engineering and software features incorporated into this system.
- **Compliance**: The V-PRO maX 2 Sterilizer is specifically designed to meet the infection control, operational and quality needs of healthcare providers by maximizing throughput, compatibility and ease of use. By combining the needs of the healthcare provider and those of the medical device manufacturer, the VPRO maX 2 Sterilizer provides highest standards and requirements validation assurance.

STERIS combines the benefits of the V-PRO maX 2 Sterilizer with validation testing done in specific and direct collaboration with medical device manufacturers. While the V-PRO maX 2 Sterilizer can always be used safely and effectively within the claims, collaborative validation between STERIS and medical device manufacturer provides additional assurance for the healthcare facility and the medical device manufacturer.

Indications for Use

The V-PRO maX 2 Low Temperature Sterilization System using VAPROX HC Sterilant is intended for use in the terminal sterilization of properly prepared (cleaned, rinsed and dried) medical devices in Healthcare Facilities. The preprogrammed sterilization cycles operate at low pressure and temperature, suitable for processing medical devices without leaving toxic residues.

Each Cycle can sterilize non-lumened instruments with diffusion-restricted spaces such as the hinged portion of forceps and scssors. Only stainless steel or titanium diffusion-restricted spaces should be processed in the Non Lumen Cycle and Fast Non Lumen Cycle.

The **Non Lumen Cycle** can sterilize:‡

- Non-lumened instruments including non-lumened general medical instruments, non-lumened rigid, semi-rigid and flexible endoscopes.

‡ Validation studies were conducted using a validation load consisting of two instrument trays and two pouches for a total weight of 50 lbs (22.7 kg).

The **Fast Non Lumen Cycle** can sterilize:*

- Non-lumened instruments including non-lumened general medical instruments, non-lumened rigid, semi-rigid and flexible endoscopes.

* The validation studies were conducted using a validation load consisting of one pouched instrument tray for a total weight of 11 lbs (5 kg).

The **Flexible Cycle** can sterilize:

- Single or dual lumen surgical flexible endoscopes (such as those used in ENT, Urology and Surgical Care) and bronchoscopes in either of the two configurations:
  1. Two flexible endoscopes with a light cord (if not integral to endoscope) and mat with no additional load.* The flexible endoscopes may contain either:
     - A single lumen that is ≥ 1 mm internal diameter (ID) and ≤ 1050 mm in length
     - Or two lumens with:
       - One lumen that is ≥ 1 mm ID and ≤ 990 mm in length
       - And the other lumen that is ≥ 1 mm ID and ≤ 850 mm in length

* The validation studies were conducted with two flexible endoscopes, each packaged into a tray with silicone mat and light cord (if not integral to endoscope).

  2. One flexible endoscope with a light cord (if not integral to endoscope) and mat and additional non-lumened instruments. ‡The flexible endoscope may contain either:
     - A single lumen that is ≥ 1 mm ID and ≤ 1050 mm in length
     - Or two lumens with:
       - One lumen that is ≥ 1 mm ID and ≤ 990 mm in length
       - And the other lumen is ≥ 1 mm ID and ≤ 850 mm in length.

‡ The validation studies were conducted with a flexible endoscope in a tray with silicone mat and light cord (if not integral to endoscope). Also included in the load were an additional instrument tray and one pouch for a total weight of 24 lbs (11 kg).

The **Lumen Cycle** can sterilize: †

- 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 ≥ 0.77 mm ID and ≤ 500 mm in length
    - Dual channeled devices with stainless lumens that are ≥ 0.77 mm ID and ≤ 527 mm in length
    - Triple channeled devices with stainless lumens that are either:
      ≥ 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

† Validation testing for all lumen sizes was conducted using a maximum of 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 (8.9 kg).

The principle features of the VPRO maX 2 Low Temperature Sterilization System include:

- Large, 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 VPRO maX 2 Low Temperature Sterilization System consists of several components. These components include:

- The VPRO maX 2 Sterilizer
- VAPROX® HC Sterilant
- Self-Contained Biological Indicator
- Biological Indicator Test Packs
- Chemical Indicator
- External Process Indicators and Chemical Indicator Strips
- Chemical Indicator Tape
- Record Cards and Record Keeping Systems
- V-PRO® PRO-LITE Sterilization Trays, Instrument Organizers, and Silicone Mats
- Vis-U-All Low Temperature Tyvek®[1] Pouches and Tubing

1. Tyvek® is a registered trademark of DuPont

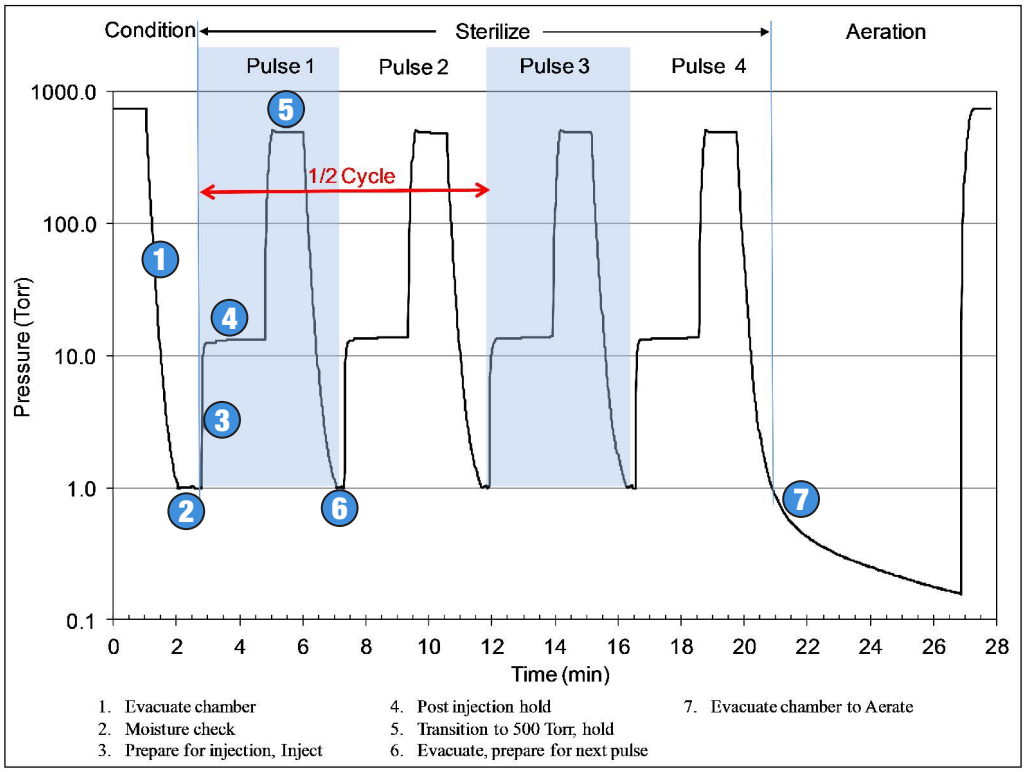
2 V-PRO maX 2 Low Temperature Sterilization System: Principle of Operation

The VPRO maX 2 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 wrapped trays or Tyvek pouches that are specifically designed for use with the VPRO maX 2 Sterilizer. The packaged instruments are placed on the Sterilizer's two shelves and the sterilizer door is shut. The V-PRO maX 2 Sterilizer Non Lumen, Fast Non Lumen, Lumen or Flexible Cycle is selected to initiate the sterilization process.

V-PRO maX 2 Sterilizer Non Lumen Cycle

The approximately 28-minute Non Lumen Cycle is used to sterilize up to 50 pounds of 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 mated or titanium surfaces such as the hinged portion of forceps or scissors. If the load contains a stainless steel lumened instrument, the Lumen Cycle must be selected[2]. If the load contains a flexible endoscope and/or a mated surface other than stainless steel, the Flexible cycle must be selected[3]. 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 (0.13 kPa) in preparation for injection of the VHP. The sterilizer automatically vaporizes the correct amount of liquid hydrogen peroxide from the multiple-cycle VAPROX HC Sterilant cup. After a two-minute hold segment, filtered air enters the sterilization chamber, increasing the chamber pressure to 500 Torr (or 66.7 kPa). After an additional 1minute hold segment, 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. Each injection is called a sterilization pulse. After completion of the last VHP injection hold segment, 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 VPRO maX 2 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. Non Lumen Cycle Pressure Graph

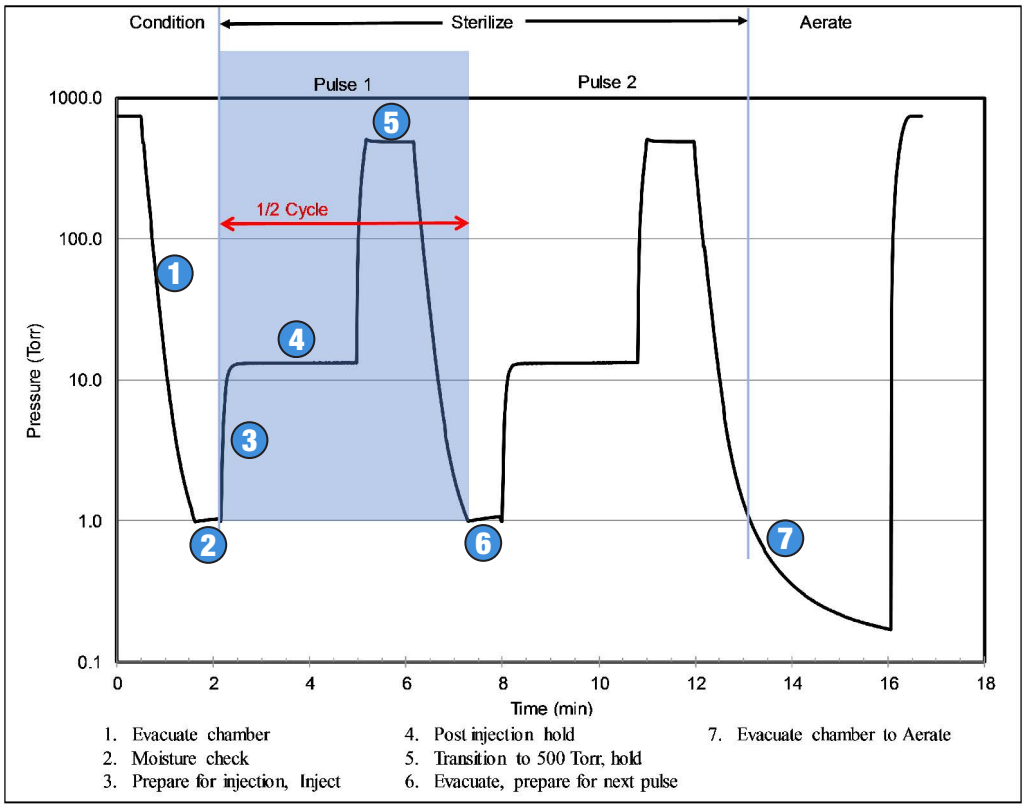


2. Only single stainless steel lumens with dimensions identified on page 3 can be sterilized using the Lumen Cycle.
3. Only flexible lumens and load configurations identified on page 4 can be processed in the Flexible Cycle.

V-PRO maX 2 Sterilizer Fast Non Lumen Cycle

The approximately 17-minute Fast Non Lumen Cycle is used to sterilize up to 11 pounds of instruments without lumens (i.e. surface sterilization) such as defibrillator paddles, cables, cords, non-lumened rigid endoscopes (telescopes), batteries and cameras. The Fast 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, the Lumen Cycle must be selected[4]. If the load contains a flexible endoscope and/or a mated surface other than stainless steel, the Flexible cycle must be selected[5]. The load should be packaged in sterilization pouches or a sterilization tray within a sterilization pouch. 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 (0.13 kPa) in preparation for injection of the VHP. The sterilizer automatically vaporizes the correct amount of liquid hydrogen peroxide from the multiple-cycle VAPROX HC Sterilant cup. After a two-minute 45 second hold segment, filtered air enters the sterilization chamber, increasing the chamber pressure to 500 Torr (or 66.7 kPa). After an additional 1-minute hold segment, the chamber pressure is again reduced to 1 Torr (0.013 kPa) in preparation for the next injection of VHP. VHP is injected two times during each sterilization cycle. Each injection is called a sterilization pulse. After completion of the last VHP injection hold segment, 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 VPRO maX 2 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. Fast Non Lumen Cycle Pressure Graph



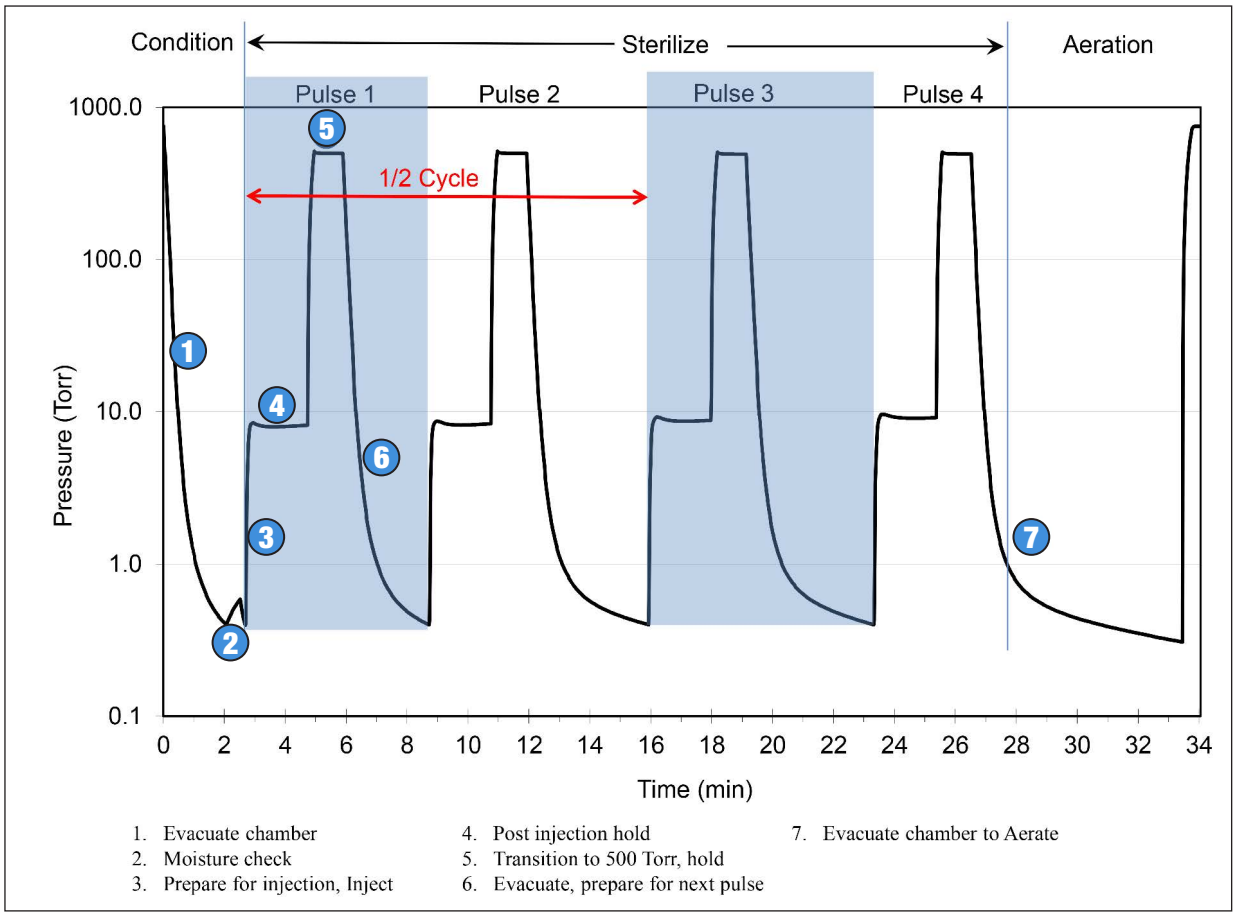
4. Only single stainless steel lumens with dimensions identified on page 3 can be sterilized using the Lumen Cycle.
5. Only flexible lumens and load configurations identified on page 4 can be processed in the Flexible Cycle.

V-PRO maX 2 Sterilizer Flexible Cycle

The approximately 35-minute Flexible Cycle is used to sterilize surgical flexible endoscopes (such as those used in ENT, Urology and Surgical Care) and bronchoscopes with lumens and other non-lumened devices (i.e. surface sterilization) such as defibrillator paddles, cables, cords, non-lumened rigid endoscopes (telescopes), batteries and cameras. The Flexible Cycle can be used to sterilize either two single or dual channel flexible endoscopes in a cycle or a single flexible endoscope and non-lumened devices [up to a total of 24 lbs (10.9 kg) per cycle][6]. Stainless steel lumened instruments cannot be processed in the Flexible Cycle.

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 conditioning phase is initiated during which the chamber is evacuated to less than 0.4 Torr (or 0.05 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 0.4 Torr (or 0.05 kPa) in preparation for injection of the VHP. The sterilizer automatically vaporizes the correct amount of liquid hydrogen peroxide from the multiple-cycle VAPROX HC Sterilant cup. After a two-minute hold segment, filtered air enters the sterilization chamber, increasing the chamber pressure to 500 Torr (or 66.7 kPa). After an additional 1minute hold segment, the chamber pressure is again reduced to 0.4 Torr (or 0.05 kPa) in preparation for the next injection of VHP. VHP is injected four times during each sterilization cycle. Each injection is called a sterilization pulse. After completion of the last VHP injection hold segment, 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 VPRO maX 2 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. Flexible Cycle Pressure Graph

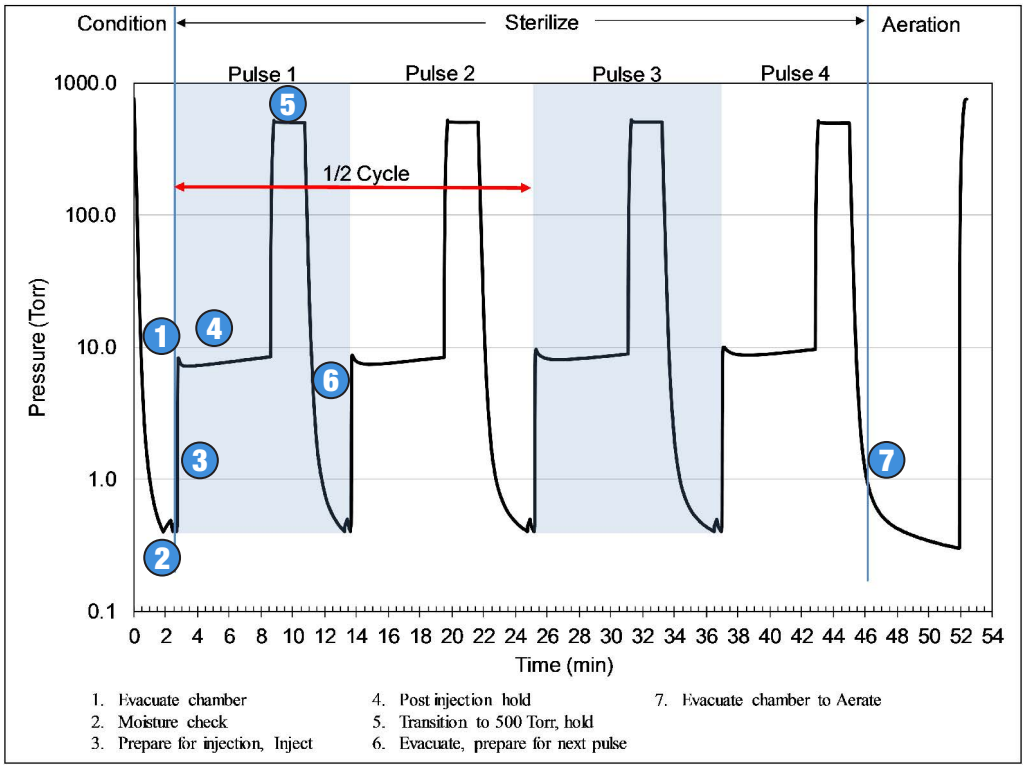


6. Only flexible lumens and load configurations identified on pages 3 and 4 can be processed in the Flexible Cycle.

V-PRO maX 2 Sterilizer Lumen Cycle

The approximately 52-minute cycle is used to sterilize up to 19.65 pounds of instruments including stainless steel lumens, non-lumened devices and device with 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 conditioning phase is initiated during which the chamber is evacuated to less than 0.4 Torr (or 0.05 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 0.4 Torr (or 0.05 kPa) in preparation for injection of the VHP. The sterilizer automatically vaporizes the correct amount of liquid hydrogen peroxide from the multiple-cycle VAPROX HC Sterilant cup. After a six-minute hold segment, filtered air enters the sterilization chamber, increasing the chamber pressure to 500 Torr (or 66.7 kPa). After an additional 2minute hold segment, the chamber pressure is again reduced to 0.4 Torr (or 0.05 kPa) in preparation for the next injection of VHP. VHP is injected four times during each sterilization cycle. Each injection is called a sterilization pulse. After completion of the last VHP injection hold segment, 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 VPRO maX 2 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 4.

Figure 4. Lumen Cycle Pressure Graph



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. VAPROX HC Sterilant for the V-PRO maX 2 Sterilizer uses RFID technology to monitor cup information and sterilant level. No cup code or information needs to be entered by the operator as the RFID is read by the control automatically when a new sterilant cup is inserted. The control also uses this RFID to track and optimize sterilant usage. 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.

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

Sterility Assurance and Sterile Packaging

The Celerity™ and VERIFY® biological and chemical indicator products and Vis-U-All Low Temperature Sterilization Pouches have been designed and validated for use with the V-PRO maX 2 Low Temperature Sterilization processes. Each product is designed to meet applicable International Standards. Only use products that have been validated for the V-PRO maX 2 Low Temperature Sterilization System. Failure to do so may result in a non-sterile device.

Equipment Control

Celerity™ and 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 Celerity™ 20 HP Biological Indicator (with a 20 minute incubation time) offer a fast means of daily microbial monitoring while test packs such as the Celerity™ 20 HP Challenge Pack provide assurance following installation, relocation or major repair.

Load Control

The V-PRO maX 2 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 Celerity™ 20 HP Biological Indicator may also be used to monitor and release loads.

Pack Control

The VERIFY® VH2O2 Indicator Tape secures wrapped items and is used (whether on a wrapped package or pouch) to distinguish between processed and unprocessed items. Chemical Indicator strips such as the VERIFY® 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 maX 2 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 VPRO maX 2 Low Temperature Sterilization System's four sterilization cycles. The following summarizes the test data demonstrating that the VPRO maX 2 Sterilizer cycles and VAPROX HC Sterilant are effective.

Sterility Assurance Level (SAL) Testing

An SAL of 10^{-6} was established for the V-PRO maX 2 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. Microbial Resistance to VHP*

Test Organism	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 maX 2 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 Non Lumen Cycle testing was composed of two sterilization trays containing medical instruments and simulated medical instruments and the entire weight of the validation load was ≥ 50 lbs (22.7 kg).
  - The load for the Fast Non Lumen Cycle testing was composed of one sterilization tray containing medical instruments, simulated medical instruments, and a pouched medical device (inside the tray). The entire load weight was ≥11 lbs (5.0 kg).
  - Two validation loads types were used for the Flexible Cycle testing; the flexible endoscope load and the mixed device load. The flexible endoscope load was composed of two trays, each containing a flexible endoscope and light cord (if not integral to the flexible endoscope) with no addition instruments. The mixed device load was composed of two trays, one containing a flexible endoscope and the other non-lumened instruments and one Tyvek pouch for a total load weight ≥ 24.0 lbs (10.9 kg).
  - The load for the Lumen Cycle was composed of two sterilization trays containing medical instruments and two Tyvek pouches. The entire weight of the validation load was ≥ 19.65 lbs (8.9 kg).

- V-PRO maX 2 Sterilization System ½ Cycle

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

- Test Articles

  Medical instrument material coupons (Tables 3-6), mated configuration medical instrument coupons (Table 7), Teflon lumens (Tables 6 and 8) or stainless steel lumens (Table 9) were challenged with 10^6 Geobacillus stearothermophilus spores and dried. The test articles were placed within the validation load and exposed to a V-PRO maX 2 Sterilizer Non Lumen ½ Cycle, Fast Non Lumen ½ Cycle, Flexible ½ Cycle, or 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 VPRO maX 2 Sterilizer ½ Cycles (Tables 3-9).

Due to the similarities between the Non Lumen and the Flexible Cycles, device materials evaluations conducted in the Non Lumen Cycle support the microbicidal efficacy of the Flexible Cycle. Examples of material efficacy testing are shown in Table 3, and additional testing has been conducted to establish efficacy for all materials identified as compatible with the V-PRO Sterilization process. All materials have been evaluated for efficacy, and from this testing the most resistant material for surface sterilization was identified. This worst case material was used in cycle evaluations (see Tables 4, 5 and 7) to establish microbicidal efficacy for all materials.

Table 3. ½ Cycle Microbicidal Efficacy Evaluation – Medical Instrument Materials

Medical Instrument Material	# Sterile/# Tested	
	Non Lumen Cycle*/ Flexible 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
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 (PTFE)	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 Flexible Cycle

** Tests conducted in the Non Lumen Cycle qualify sterilization in the Lumen Cycle

Table 4. Non Lumen ½ Cycle Microbicidal Efficacy Evaluation

Test Article	# Sterile/# Tested
Worst Case Material Coupons	18/18

Table 5. Fast Non Lumen ½ Cycle Microbicidal Efficacy Evaluation

Test Article	# Sterile/# Tested
Worst Case Material Coupons	9/9

Table 6. Flexible ½ Cycle Microbicidal Efficacy Evaluation with Flexible Endoscope Load

Lumen Size (ID x Length mm)	# Lumens Sterile/# Tested
1 x 1050	30/30

Table 7. Flexible ½ Cycle Microbicidal Efficacy Evaluation with Mixed Load

Test Article	# Sterile/# Tested
1 mm ID x 1050 mm Length Lumens	15/15
Worst Case Material Coupons	9/9

Table 8. Lumen ½ Cycle Microbicidal Efficacy Evaluation with Stainless Steel Lumens

Channel Configuration	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

* crescent shaped lumen

Table 9. ½ Cycle Microbicidal Efficacy Evaluation - Mated Instrument Materials

Material	Coupon Pairs Sterile/Pairs Tested		
	Non Lumen Cycle	Fast Non Lumen Cycle	Flexible Cycle**
Stainless Steel	6/6	9/9	6/6
Titanium	6/6	9/9	N/A***
Delrin	N/A*	N/A*	6/6
Ultem			6/6
Radel			6/6
Noryl			6/6

* N/A = Not Applicable. The Non Lumen Cycle and Fast Non Lumen Cycle are only intended to sterilize stainless steel and titanium mated surfaces.
** Tests conducted in the Flexible Cycle qualifies sterilization in the Lumen Cycle
*** Tests conducted in the Non Lumen Cycle qualifies sterilization in the Flexible Cycle and Lumen Cycle

Conclusion:

All of the device materials, mated device materials and lumens challenged with 10^6 Geobacillus stearothermophilus spores were sterile after exposure to either a VPRO maX 2 Sterilizer Non Lumen ½ Cycle, Fast Non Lumen ½ Cycle, Flexible ½ Cycle, or Lumen ½ Cycle as applicable, thereby establishing a SAL of 10^{-6} for the VPRO maX 2 Low Temperature Sterilization System.

Modified Total End Point Kill (VHP Dose Evaluation)

Testing was performed to demonstrate half cycle efficacy and a modified total kill endpoint for the VPRO maX 2 Sterilizer cycles under worst case sterilization conditions. The test is termed modified total kill endpoint because the parameter varied is the concentration of vaporized hydrogen peroxide (amount of sterilant injected) rather than the traditional method of varying exposure time. The standard VAPROX HC Sterilant injection weight and reduced injection weights of sterilant were evaluated.

The Non Lumen Cycle was evaluated using the worst case challenge material in a series of reduced hydrogen peroxide concentration experiments. The inoculated and dried worst case challenge material coupon test articles were placed within the validation load for the cycle. 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 10).

Table 10. Non Lumen Cycle VHP Dose Evaluation

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

A similar experiment was conducted in the V-PRO maX 2 Sterilizer Fast Non Lumen Cycle. The inoculated and dried worst case challenge material coupon test articles were individually pouched and placed within the validation load. Various amounts of hydrogen peroxide were introduced into the chamber under V-PRO maX 2 Sterilizer Fast 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 4.1 mg/L VHP (Table 11).

Table 11. Fast Non Lumen Cycle VHP Dose Evaluation

VHP Concentration* (mg/L)	# Sterile Coupons /# Tested
1.2	0/9
2.5	6/9
4.1	9/9
8.6	9/9

* Calculated Chamber Concentration

The two load configurations for the V-PRO maX 2 Sterilizer Flexible Cycle, 2 flexible endoscopes (Flexible endoscope load) and 1 flexible endoscope with non-lumened load (≥ 24.0 lbs, Mixed Device Load), were exposed to varying concentrations of VHP and the number of sterile test articles versus number tested was determined. All lumens and 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 (Tables 12 and 13)

Table 12. Flexible Cycle VHP Dose Evaluation with Flexible Endoscope Load

VHP Concentration* (mg/L)	# Sterile Coupons /# Tested
0.5	0/30
2.5	2/30
5.0	29/30
6.0	30/30
8.6	30/30

* Calculated Chamber Concentration

Table 13. Flexible Cycle VHP Dose Evaluation with Mixed Device Load

VHP Concentration* (mg/L)	# Sterile Lumens /# Tested	# Sterile Coupons /# Tested
0.5	0/15	0/9
2.5	0/15	7/9
5.0	10/15	9/9
6.0	15/15	9/9
8.6	15/15	9/9

* Calculated Chamber Concentration

Tests established that the worst case challenge to the V-PRO maX 2 Sterilizer Lumen Cycle was the longest and narrowest stainless steel lumen test article. Using the inoculated stainless steel lumen test article placed within the validation load, various amounts of hydrogen peroxide were introduced into the chamber under V-PRO maX 2 Sterilizer Lumen ½ Cycle conditions and the number of sterile test articles versus number tested were 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 14).

Table 14. Lumen Cycle VHP Dose Evaluation

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

Conclusion:
The V-PRO maX 2 Sterilizer Non Lumen, Fast Non Lumen, Flexible, and 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 maX 2 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, AOAC Official Method 966.04, "Sporicidal Activity of Disinfectants." It is required that a combination of at least 720 carriers are tested and all to demonstrate the absence of growth following exposure and incubation. All 720 carriers were confirmed to be sterile following exposure to the V-PRO maX 2 Sterilizer Fast Non Lumen using three separate lots of VAPROX HC Sterilant (Table 15 and data not shown). Sporicidal testing conducted in the V-PRO maX 2 Sterilizer Fast Non Lumen Cycle verifies efficacy in the VPRO maX 2 Sterilizer Non Lumen, Flexible, and Lumen Cycles.

Table 15. Fast Non Lumen Cycle 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**

* Tests conducted in the Fast Non Lumen Cycle also qualify the Non Lumen, Flexible, and Lumen Cycles

Conclusion:
The VPRO maX 2 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 maX 2 Low Temperature Sterilization Systems' ability to sterilize medical instruments. The following summarizes the test data demonstrating that the VPRO maX 2 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 processed through V-PRO maX 2 Sterilizer Non Lumen, Fast Non Lumen, Flexible, or Lumen Cycles. After exposure, the medical instrument sites were sampled and evaluated for growth of the test organism. The number of sterile devices versus the number of devices tested was determined (Tables 16-20). All devices were sterile under worst case simulated use conditions.

Table 16. Non Lumen Cycle Simulated Use Evaluation

Medical Instrument	Inoculation Site	# Sterile / # Tested
Cavity Clip	Surface	3/3
Tourniquet	Surface	3/3
Scissors (stainless steel)	Hinge (Mated Surface)	3/3
Scissors (titanium)	Hinge (Mated Surface)	3/3

Table 17. Fast Non Lumen Cycle Simulated Use Evaluation

Medical Instrument	Inoculation Site	# Sterile / # Tested
Cavity Clip	Surface	3/3
Tourniquet	Surface	3/3
Flexible Nasopharyngoscope	Surface	3/3
Scissors	Hinge (Mated Surface)	3/3

Table 18. Flexible Cycle Simulated Use Evaluation with Flexible Endoscope Load

Medical Instrument	Inoculation Site	# Sterile / # Tested
Flexible Epiduroscope	1 mm ID x 1075 mm length lumen	3/3
Flexible Dual Channel Bronchoscope	1.5 mm ID x 700 mm length and 2 mm ID x 730 mm length lumens	3/3 3/3

Table 19. Flexible Cycle Simulated Use Evaluation with Mixed Device Load

Medical Instrument	Inoculation Site	# Sterile / # Tested
Flexible Epiduroscope	1 mm ID x 1075 mm length lumen	3/3
Flexible Dual Channel Ureterorenoscope	1 mm ID x 998 mm length and 1 mm ID x 850 mm length lumens	3/3 3/3
Cavity Clip	Surface	3/3
Colorectal Intestinal Dilator	Surface	3/3
Flexible Nasopharyngoscope	Surface	3/3
Scissors	Hinge (Mated Surface)	3/3

Table 20. Lumen Cycle Simulated Use Evaluation

Medical Instrument	Selected 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 x 527 mm lumen	3/3
	1.17 x 500 mm lumen	3/3
Hysteroscope (triple channel)	1.2 x 275 mm lumen	3/3
Sheath (triple channel)	2.8 x 317 mm lumen	3/3

* crescent shaped lumen
** ID= Internal Diameter

Conclusion:
The VPRO maX 2 Low Temperature Sterilization Systems utilizing VAPROX HC Sterilant reproducibly sterilized challenging medical instruments inoculated with high levels of the most resistant organism, G. stearothermophilus spores, in the presence of an inorganic and organic challenge.

- Clinical Use Evaluation
  The VPRO maX 2 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 V-PRO maX 2 Sterilizer Non Lumen, Fast Non Lumen, Flexible or Lumen Cycle. 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 21- 25).

Table 21. 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 22. Fast Non Lumen Cycle Clinical Use Evaluation

Medical Instrument	Selected Site	# Sterile / # Tested
Tourniquet	Surface	3/3
Surgical Hemostats	Hinge	3/3
Syringe Plunger	Tip	3/3
Flexible Endoscope	Insertion Tube Surface	3/3

Table 23. Flexible Cycle Clinical Use Evaluation with Flexible Endoscope Load

Medical Instrument	Selected Site	# Sterile / # Tested
Flexible Laryngoscope	1.5 mm ID x 768 mm length lumen	3/3
Flexible Dual Channel Bronchoscope	1.5 mm ID x 700 mm length and 2.0 mm ID x 730 mm length lumen	3/3 3/3

Table 24. Flexible Cycle Clinical Use Evaluation with Flexible Endoscope Load

Medical Instrument	Selected Site	# Sterile / # Tested
Flexible Endoscopes	1.5 mm ID x 768 mm length lumen or 1.0 mm ID x 825 mm length lumen	3/3
	Insertion Tube Surface	3/3
Colorectal Intestinal Dilator	Surface	3/3
Surgical Scissors	Hinge	3/3
Syringe Plunger	Tip	3/3
Flexible Dual Channel Ureterorenoscope	1 mm ID x 998 mm length lumen, 1 mm ID x 850 mm length lumen	3/3 3/3

Table 25. 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	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 mm ID x 510 mm length lumen, 1.17 mm ID x 500 mm length lumen or 0.85 mm ID x 520 mm length lumen, 1.4 mm ID x 520 mm length lumen	6/6
Hysteroscope (triple channel) or Sheath (triple channel)	1.2 mm ID x 275 mm length lumen, 1.2 mm ID x 275 mm length lumen, 1.8 mm ID x 310 mm lumen or 2.8 mm ID x 317 mm length lumen 1.8 mm ID x 300 mm length lumen (2x1.5)* mm ID x 285 mm length lumen	9/9

* crescent shaped lumen

Conclusion:
The VPRO maX 2 Sterilizer Non Lumen, Fast Non Lumen, Flexible, and Lumen 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 maX 2 Low Temperature Sterilization System:

- An SAL of 10^{-6} has been established through ½ cycle testing and 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 maX 2 Sterilizer utilizing VAPROX HC Sterilant.

5 Materials Compatibility

The VPRO maX 2 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 VPRO maX 2 Low Temperature Sterilization System is safe for medical instruments. Representative medical instruments composed of a variety of materials were subjected to fifty VPRO maX 2 Lumen Cycles (worst case, longest sterilant exposure) with functional evaluations performed before and after the tests. Table 26 lists representative materials and types of instruments evaluated for material compatibility.

Table 26. Material Compatibility*

Materials	Instrument Evaluated	Cosmetic Change	Functionality
PLASTICS			
Delrin	Defibrillator	None	Pass
EVA	Slide for Cannula Tubing	Slight yellowing	Pass
Kraton	Pediatric Tuohy Borst Adapter	None	Pass
Neoprene	Neoprene Rubber Tubing	None	Pass
Noryl	STERIS V PRO Sterilization Tray	None	Pass
Nylon	Resectoscope Sheath ID ring	Fading	Pass
PMMA	Contact	None	Pass
Polycarbonate	Reusable Nebulizer	None	Pass
PEEK	Endoscope	None	Pass
Polyethylene	Piston Syringe with Thumb Control Ring	None	Pass
Polypropylene	STERIS V-PRO Sterilization Tray	None	Pass
Polystyrene	Non-vented Luer Dispenser Tip Cap	None	Pass
Polyurethane	Flexible Endoscope	None	Pass
PVC	Reusable Nebulizer	None	Pass
Radel	Adapter for STERIS SYSTEM 1	None	Pass
Santoprene	Mouthpiece	None	Pass
Silicone	High Frequency Cord	None	Pass
Teflon (PTFE)	Resectoscope Working Element	None	Pass
Ultem	Instrument Tray	None	Pass
METALS			
Aluminum	Wide Field Vitrectomy Lens	Loss of black color	Pass
Brass	Bridge Adapter	None	Pass
Cobalt Chromium	Rod	None	Pass
Copper	Tongue Scraper	Color change	Pass
Gold	Forceps	None	Pass
Nitinol	Vascular Dilator	None	Pass
Platinum	Kimura Spatula	None	Pass
Silver	Garrett Vascular Dilator	None	Pass
Stainless Steel	Telescope	None	Pass
	Forceps		
Titanium	Knife	Fading	Pass
CERAMICS AND OTHERS			
Alumina	Surgical Knife Blade	None	Pass
Diamond	Knife	None	Pass
Glass	Telescope	None	Pass
Sapphire/Ruby	Knife	None	Pass
Silicon Nitride	Surgical Blade	None	Pass
Zirconium Nitride	Forceps	None	Pass
Zirconium Oxide with Yttrium Oxide	Surgical Knife Blade	None	Pass

Table 26. Material Compatibility*

Materials	Instrument Evaluated	Cosmetic Change	Functionality
COATINGS			
Aluminum Titanium Nitride	Forceps	None	Pass
Aluminum Titanium Nitride/ Chromium Nitride	Forceps	None	Pass
Diamond Like Carbon	Forceps	None	Pass
Titanium Nitride	Forceps	None	Pass
Titanium Nitride/Titanium Carbonitride	Forceps	None	Pass
Tungsten Carbide	Forceps	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.

Device temperature post-processing will be from a few degrees higher (e.g. ~3-5°C) than its starting room temperature up to 20°C higher (e.g. ~25-40°C) depending on the device material, sterilization cycle and total load weight.

Conclusion:
Exposure to numerous cycles in the V-PRO maX 2 Sterilizer does not significantly affect the appearance or functionality of most medical instruments.

6 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).

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

These by-products do not present toxicity concerns to the user. There are three conditions under which the V-PRO maX 2 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 liquid hydrogen peroxide used for gaseous hydrogen peroxide sterilization is packaged within a sealed cup to minimize interaction of the user with the sterilant liquid. 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 Vapors

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 commonly used medical device materials after sterilization in V-PRO maX 2 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 VPRO maX 2 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 maX 2 Sterilization System 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 the primary source document for this assessment. The VPRO maX 2 Sterilization System is shown to reduce the levels of residues on representative medical devices (12 medical devices including: flexible endoscopes, resectoscopes, 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 maX 2 Sterilizer effectively eliminates toxic process residuals.

Conclusion:
The sterilization process of the VPRO maX 2 Sterilizer is safe for the environment, safe for the patient and safe for the user.

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