Technical Data Monograph

Reliance® Vision® Single Chamber Washer/Disinfector

STERIS

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1 The Reliance® Vision® Single Chamber Washer/Disinfector

The ultimate goal of infection control practices is to prevent infection from occurring in the first place. In the operating room, a significant portion of the infection prevention focus is on the department's reusable surgical instruments. Special attention is needed to prevent patient cross-contamination when these instruments are processed for reuse. Furthermore, reusable surgical tools must be thoroughly cleaned and decontaminated before they can be successfully sterilized. Since this cleaning and disinfection step is so crucial, the capabilities and quality of a facility's washer-disinfector become critical factors for effective reprocessing and infection prevention.

The Reliance Vision Single Chamber Washer/Disinfector is the latest generation of washer-disinfectors for healthcare providers. The Vision washer's total coverage cleaning system is designed to provide maximum surface area spray coverage inside the chamber, and includes features such as innovative spray nozzles and a self-cleaning centrifugal filter.

The internal monitoring system of the Vision Single Chamber Washer is designed to monitor the critical parameters needed for reliable, effective cleaning and disinfection. The PC control for the Vision washer verifies vital phases of the cycle, the volume of detergent injected, and the attainment of proper thermal disinfection levels. The data captured by the control are processed, and an alarm is emitted if parameters do not meet cycle specifications.

2 Environmentally Conscious Design

The Vision washer is designed to conserve resources. Using this system in a department can support or help improve environmental management practices in hospitals.

Optimized cleaning cycles and water consumption

The Vision washer consumes less water per cycle than other comparable systems, like the Reliance® Genfore™ Washer/Disinfector. The Genfore washer uses 57 gallons of water per cycle, whereas the Vision washer uses 28 gallons. As a result, less time is spent on draining and filling. Plus, when used in combination with Prolystica® Ultra Concentrate Chemistries, cycle times are optimized, thus reducing energy consumption.

Biodegradable chemistries

When using the 10-times concentrated Prolystica® Ultra Concentrate Chemistries, the Vision washer requires a smaller amount of each formulation per gallon of water than traditional chemistries (1/10 oz per gallon of water). In addition, these cleaning chemistries are formulated with built-in corrosion inhibitors that protect instrument surfaces and the washer chamber.

Lower energy and utility costs

The Vision Single Chamber Washer saves more than 100,000 gallons of water annually, compared to washers like Genfore, by using an efficient seven-gallon sump pump rather than a larger unit. The smaller pump also uses less electricity and utilities, and less chemistry per cycle.

3 Prolystica® Ultra Concentrate System

Prolystica Ultra Concentrate Chemistries, which are formulated with biodegradable ingredients, provide superior cleaning and protection for surgical instruments. These precisely formulated products are contained in recyclable, compact, ergonomic packaging that's designed to be easier to use and to reduce the risk of staff injury. The system consists of several formulations; an enzymatic cleaner, a neutral or alkaline detergent, and an optional lubricant. When used in the Vision Single Chamber Washer, these ultra concentrates help optimize the cleaning efficacy of each washing cycle.

The Vision Single Chamber Washer/Disinfector offers enhanced productivity through short cycle times, without sacrificing cleaning performance. This is accomplished with a dual-product cleaning cycle that combines Prolystica Ultra Concentrate Enzymatic Cleaner with the ultra-concentrated neutral or alkaline detergent. The Prolystica Ultra Concentrate Chemistries are precisely injected at specified intervals and temperatures, allowing them to act under their individual optimal conditions, and to work together within the wash cycle.

Prolystica Ultra Concentrate Enzymatic Cleaner

This formulation is very effective at breaking down and dissolving blood, mucous and the most challenging fatty soils. The dual enzyme system works exceptionally well in a wide range of water qualities and types. It prepares instrument surfaces by removing the majority of bioburden before Prolystica detergents thoroughly clean them.

Prolystica Ultra Concentrate Neutral Detergent

This product also cleans blood, mucous and a wide range of challenging fatty soils effectively. It is also formulated with corrosion inhibitors to protect instruments and washer chamber surfaces, and with chelating and sequestering agents to enhance cleaning performance regardless of water quality and type.

Prolystica Ultra Concentrate Alkaline Detergent

This alkaline formulation provides exceptional and safe cleaning without the need for a second neutral rinse. It also includes corrosion inhibitors and chelating and sequestering agents to protect instruments and enhance cleaning performance regardless of water quality.

Prolystica Ultra Concentrate Lubricant

This non-silicone product protects the condition and functionality of surgical instruments and devices but does not compromise steam or ethylene oxide sterilization processes. Since it's a concentrated formulation, a low volume of chemistry is needed in each cycle to maintain the integrity and performance of the devices.

4 Cycle Options

The Vision Single Chamber Washer/Disinfector is pre-programmed with a number of dedicated cycles designed for specific types of loads.

Orthopedic Cycle

Surgical instruments for orthopedic procedures are very complex. The design of many orthopedic devices such as drills, reamers and other items represents a significant cleaning challenge because of crevices, joints and other structural design elements. Also, orthopedic soils such as trapped bone chips, marrow and other debris are more challenging to remove than other soils.

To address these cleaning challenges, the Vision washer provides a specialized cycle for orthopedic instruments. The cycle is programmed to inject precise doses of Prolystica Ultra Concentrate Enzymatic Cleaner and either Neutral or Alkaline detergent, and is designed for use with the washer's orthopedic instrument processing accessories.

More than 80 different orthopedic instruments were tested and validated in the Vision system. Devices for hip, knee, shoulder and general orthopedic surgeries were selected to assure a representative sampling of this instrument category.

Anesthesia Cycle

The Vision Single Chamber Washer system offers a programmed Anesthesia Cycle and a specialized anesthesia rack accessory to clean and disinfect reusable semi-critical components of anesthesia and respiratory equipment. The Vision Washer's Anesthesia Rack accommodates a variety of items such as anesthesia tubing, bags, masks and respiratory goods. The rack is designed to work with the Vision Single Chamber Washer's total coverage cleaning system, to provide a continuous flow of cleaning solution and water through corrugated tubing, hollow articles and other challenging items.

The Anesthesia Cycle includes a thorough cleaning stage followed by a thermal disinfection phase that is comparable to pasteurization and compliant to the CSA Standard Z314.8-08 Decontamination of reusable medical devices. The cycle begins with a pre-wash performed below 45ºC (113ºF) to avoid coagulation of proteins. Next, two separate washing phases are performed using the Prolystica® Ultra Concentrate system for optimum cleaning performance. Enzymatic, neutral or alkaline chemistries can be used during these cleaning phases.

After the wash and rinse phases, the heat-sensitive anesthesia devices are exposed to a thermal disinfection phase. The temperature is lower and longer than other cycles, to protect these items. Disinfection is achieved with a thermal rinse configurations of 172.9°F (78.3°C) for 15 minutes for heat-sensitive devices and 194°F (90°C) for one minute for non heat-sensitive devices. Both configurations result in an A_0 of 600 and offer the same level of disinfection. The thermal phase can also reach an A_0 of 3000, if needed. (A_0 will be discussed later in this monograph.)

Rigid MIS Cycle

Rigid endoscopic and minimally invasive surgical (MIS) instrumentation must be carefully cleaned and dried before sterilization. The Rigid MIS Cycle provides the proper automated sequence of phases to remove both microorganisms and organic soils.

Immediately after the pre-wash phase, a washing phase with a neutral pH enzymatic cleaner begins breaking down blood, fat, and protein from instrument surfaces. Next, a neutral detergent that is safe for a range of metals and plastic compounds is used for the second wash, to thoroughly clean all scopes inside and out.

The MIS Rack is equipped with 12 quick-connect ports for luer locks, and more than 40 adapter fittings for scopes with working channels. Delicate and disassembled parts are held securely in a tray with a cover. In addition to the MIS Rack, four small instrument trays can be loaded to process surgical instruments or to keep sets intact during processing.

5 Validation Test Program

STERIS designed a test program to separately assess the efficacy of the cleaning, rinsing and intermediate-level disinfection phase of a cycle of the Vision Single Chamber Washer/Disinfector, in accordance with the U.S. Food and Drug Administration and ISO 15883 Standards.

STERIS conducted this validation program in a specialized validation laboratory using documented protocols and standard operating procedures. To ensure statistical significance, all tests were conducted in triplicate.

Cleaning efficacy was evaluated by inspection, and rinsing efficacy was evaluated by comparing the amount of residue per load item with estimated toxicological limits. Intermediate-level disinfection efficacy was evaluated by calculating the reduction of a known concentration of microorganisms in ampules located in the critical areas of the washer chamber, as established by thermal profiling.

6 Cleaning Efficacy Testing

Cleaning efficacy was evaluated by visual and non-visual inspection to assess soil removal. The items were processed through only the washing phases of the appropriate cycles, and were evaluated immediately after the cleaning process without exposure to the thermal rinsing and drying phases of their respective cycles.

All cleaning tests were conducted with two different test soils; an artificial test soil and a blood and serum based soil.

European Cleaning Standards

To challenge the washing process and to demonstrate compliance with the ISO 15883 standards, the Browne Washer Disinfector Test Soil was used. Shown to be equivalent to the UK test soil described in ISO 15883-5, the Browne Test Soil is also easy to use for equipment commissioning and performance qualification at initial installation.

In addition, a Ninhydrin Protein Detection Test Kit (produced by STERIS Corporation) was used to assess residual proteins on the processed items. Testing with Browne Test Soil was performed using the accessories and load configuration presented in **Table 1.**

Table 1: Cleaning results with Browne Test Soil Ninhydrin Test

Cycle	Prolystica® Cleaning Chemistries	Rack	Load	Visual Determination*/ Ninhydrin test**
Instrument Cycle	Enzymatic and Neutral	5-level rack	200 hemostats	Clean/Pass
Instrument Cycle	Enzymatic and Alkaline	5-level rack	200 hemostats	Clean/Pass
Orthopedic Cycle	Enzymatic and Neutral	3-level rack	Orthopedic and cannulated	Clean/Pass
Orthopedic Cycle	Enzymatic and Alkaline	3-level rack	Orthopedic and cannulated	Clean/Pass
Gentle Cycle	Neutral	3-level rack	Micro instruments	Clean/Pass
Gentle Cycle	Neutral	General purpose Rack	Various utensils	Clean/Pass
Utensil Cycle	Enzymatic and Alkaline	2-level rack	Bedpans and bowls	Clean/Pass
Utensil Cycle	Enzymatic and Neutral	2-level rack	OR shoes	Clean/Pass
Rigid MIS	Neutral	MIS Rack	MIS and rigid scopes	Clean/Pass
Anesthesia Cycle	Enzymatic and Alkaline	Anesthesia Rack	Anesthesia tubing and respiratory goods	Clean/Pass

North American Cleaning Standards

Because FDA and AAMI recommend that simulated-use testing includes a representative challenge that imitates actual in-use conditions, the tests presented in **Table 2** were also conducted. A blood and serum-based soil was used to demonstrate the ability to remove representative organic contamination from reusable medical devices.

Cleaning cycles tested with simulated-use instrument loads

For each validated cycle, a load was selected to represent worst-case conditions.

The **Instrument Cycle** was tested using a five-level rack loaded with hemostats. Hemostat forceps were selected because they are commonly used in surgical procedures and present a cleaning challenge due to the serrations in the jaws.

The **Orthopedic Cycle** was tested with orthopedic instruments for hip, knee, shoulder and general procedures. These types of surgical tools are classified as critical devices since they are introduced directly into the human body. They also have design features that represent a significant challenge to the cleaning process. Approximately 80 orthopedic instruments were used in a three-level rack equipped with flexible hoses for cannulated instruments.

The **Gentle Cycle** operates at low speed to protect delicate instruments and offer cleaning and disinfection with a lower impact. Ophthalmic micro-instruments were selected to test the Gentle Cycle.

The General Purpose Rack was also tested using the Gentle Cycle. This accessory, designed to process non-critical medical devices, was loaded with various kinds of utensils (bowls, surgical lamp handles, kidney dishes and bowls) and processed in the Gentle Cycle.

Intended to process bedpans, trays, basins and bowls, the Utensil Cycle was tested with bedpans and various types of bowls in a two-level rack. In addition, this cycle was tested for its ability to thoroughly clean medical shoes (clogs) that are commonly worn in the OR. Since the two-level rack is now designed to accommodate such items, this testing was done to assure that the design of the rack accessory is adequate to process clogs.

Table 2: Cleaning results with blood and serum-based soil

Cycle	Prolystica® Cleaning Chemistries	Rack	Load	Visual Determination
Instrument Cycle	Enzymatic and Neutral	5-level rack	500 hemostats	Clean
Instrument Cycle	Enzymatic and Alkaline	5-level rack	500 hemostats	Clean
Orthopedic Cycle	Enzymatic and Neutral	3-level rack	Orthopedic and cannulated	Clean
Orthopedic Cycle	Enzymatic and Alkaline	3-level rack	Orthopedic and cannulated	Clean
Gentle Cycle	Neutral	3-level rack	Micro instruments	Clean
Gentle Cycle	Neutral	General Purpose Rack	Various utensils	Clean
Utensil Cycle	Enzymatic and Alkaline	2-level rack	Bedpans and bowls	Clean
Utensil Cycle	Enzymatic and Neutral	2-level rack	OR shoes	Clean
Rigid MIS	Enzymatic and Neutral	MIS Rack	MIS and rigid scopes	Clean
Anesthesia Cycle	Neutral and Neutral	Anesthesia Rack	Anesthesia tubing and respiratory goods	Clean

7 Rinsing Efficacy

The evaluation of rinsing efficacy should show that the rinse phase of the cleaning cycle removes the residues from cleaning chemicals. Residues need to be reduced to levels that are not hazardous to patients or end-users, and that do not interfere with a terminal process such as sterilization.

Rinsing efficacy tested in different cycles

The rinsing efficacy of the Instrument Cycle was evaluated using a five-level rack loaded with hemostats, and tested for residuals from two different cleaning chemistry pairings: a combination of Prolystica Ultra Concentrate Enzymatic Cleaner with Prolystica Ultra Concentrate Alkaline Detergent; and a combination of Prolystica Ultra Concentrate Enzymatic Cleaner with Prolystica Ultra Concentrate Neutral Detergent.

For this evaluation, the total organic carbon (TOC) method was used to determine the level of residual detergent. This method measures the level of organic carbon from all sources, including protein carbons such as enzymes found in enzymatic detergents. The colorimetric method was also used to determine the level of enzymes retained in the detergents, since the presence of an enzymatic residual is critical for patients.

In addition, the conductivity increase method was used to evaluate ionic residue, since some substances in the alkaline cleaner are not detectable either by the TOC method or by the colorimetric method.

For each method, calibration curves depicting residue concentration as a function of carbon, enzyme or conductivity were created using known concentrations of each chemical.

The measurements were made after processing the test items in the washer/disinfector using the appropriate combination of detergents, and calibration curves were used to determine the concentration of active substances and the average residue level per item.

The rinsing efficacy of the Gentle Cycle was evaluated using a three-level rack loaded with ophthalmic micro-instruments, and tested for residuals of Prolystica Ultra Concentrate Neutral Detergent.

The total organic carbon (TOC) method was again used to determine the level of organic carbon present in the neutral detergent. These results were then compared to toxicological limit values as established by a published scientific method (6) that describes the calculation of the acceptable daily intake per patient based on the most toxic ingredients of the detergent. **Table 3** presents the test configurations and results for rinsing efficacy.

Table 3: Test configurations and rinsing efficacy results

Test conditions			Test Results					
Cycle	Rack	Prolystica® Cleaning Chemistry	Total Detergent Criteria (mg/item)	Total Detergent Results (mg/item)	Enzyme Fraction Criteria (mg/item)	Enzyme Fraction Results (mg/item)	Ionic Fraction Criteria (mg/item)	Ionic Fraction Results (mg/item)
Instrument Cycle	5-level rack	Enzymatic and Neutral	2.67	0.007	5.80	0.008	-	-
Instrument Cycle	5-level rack	Enzymatic and Alkaline	1.06	0.013	5.80	0.03	1.06	0.008
Gentle Cycle	2-level rack	Neutral	2.67	0.011	-	-	-	-

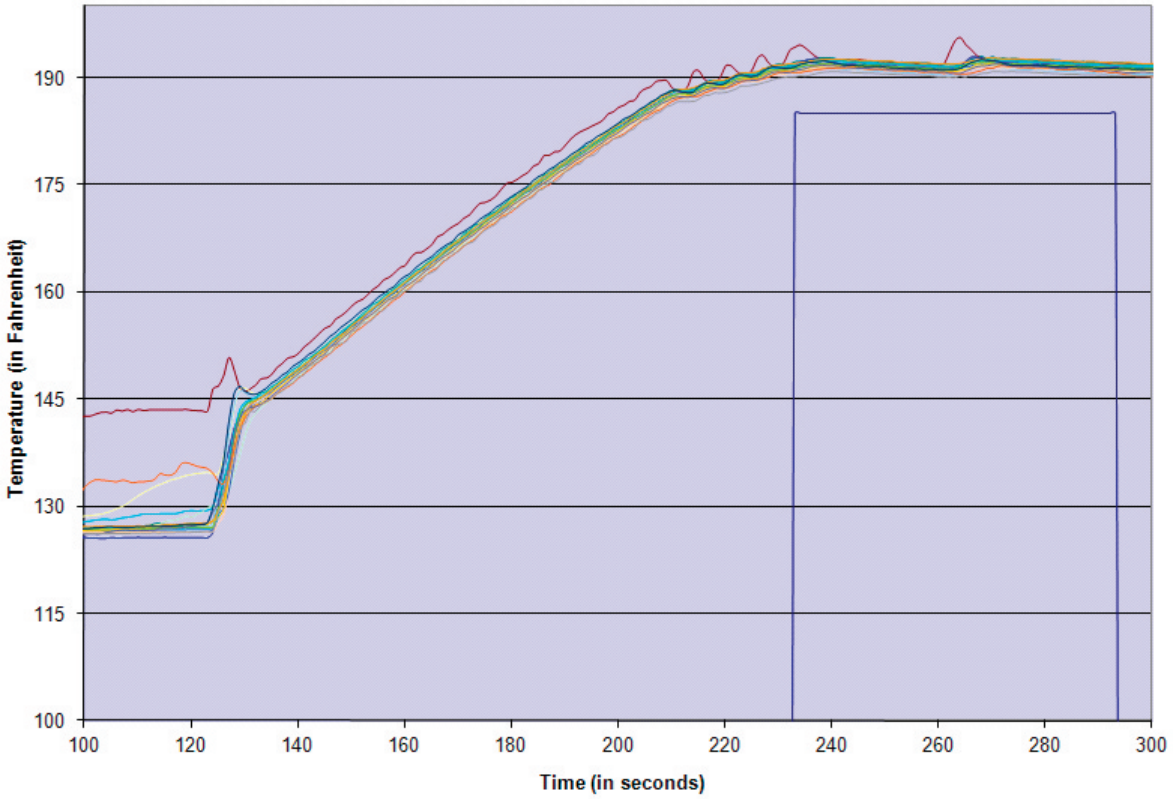
8 Thermal Profile Evaluation

STERIS performed thermal profile testing to verify that the rack accessory and the load reached and maintained the desired preset disinfection temperature for the pre-programmed period of time. This thermal profile also helped identify the worst-case accessories and the coolest spots in the chamber. These 'risk sites' were tested in the disinfection test.

Table 4: Thermal profile results

Cycle	Speed mode	Configuration	Rack	Load	Results
Instrument Cycle	High	1 minute at 185˚F	5-level rack	500 hemostats	Pass
Gentle Cycle	Low	1 minute at 185˚F	3-level rack	Micro instruments	Pass
Gentle Cycle	Low	1 minute at 185˚F	General purpose rack	Various utensils	Pass
Utensil Cycle	High	1 minute at 185˚F	2-level rack	Bedpans and bowls	Pass
Rigid MIS	Low	1 minute at 185˚F	MIS rack	MIS and rigid scopes	Pass
Anesthesia Cycle (heat-sensitive)	Low	15 minutes at 170.6˚F	Anesthesia rack	Anesthesia tubing and respiratory goods	Pass
Anesthesia Cycle	Low	1 minute at 185˚F	Anesthesia rack	Anesthesia tubing and respiratory goods	Pass

Thermal profile of the instrument cycle with 5-level manifold rack



9 Thermometry

STERIS performed thermometric tests to verify that the specified conditions are achieved throughout the chamber, the load and the load carrier during the operating cycle. Thermocouples were placed on the load, the load carrier and on the chamber walls, to monitor wash phase and thermal phase temperatures as per specifications in ISO 15883-1:2006. The temperatures were recorded at one-second intervals throughout the wash and thermal rinse phases. For all the tests, the disinfection temperature was 90°C (194°F) for a holding period of 20 minutes.

The thermometric profile was assessed for the Wash and the Thermal phases of the Instrument Cycle, the Utensil Cycle and the Gentle Cycle.

The Instrument Cycle was tested using a loaded 5-Level Manifold Rack.

The Utensil Cycle was evaluated using a loaded 2-Level Manifold Rack with a Multi-function Rack for large items on the first level, and a Multi-function Rack for small items on the second level.

The Gentle Cycle was tested using a 3-Level Manifold Rack and a General Purpose Rack.

The results demonstrated that there was temperature uniformity throughout the load, the load carrier and the chamber; that the temperature set point was maintained during the holding period for both wash and thermal phases; and that the temperature profiles were repeatable in subsequent cycles.

Table 5: Thermometric testing results

Cycle	Speed mode	Rack	Load	Results
Instrument Cycle	High	5-level rack	200 hemostats	Pass
Gentle Cycle	Low	3-level rack	Micro instruments	Pass
Gentle Cycle	Low	General purpose rack	Various utensils	Pass
Utensil Cycle	High	2-level rack	Bedpans and bowls	Pass

Thermal disinfection with the A_0 option

According to ISO 15883 series standards, the use of A_0 is recommended to achieve the desired level of disinfection for certain categories of processed items. Energy in a washer-disinfector during thermal disinfection with moist heat can be measured by A_0, a parameter closely related to temperature and time. It is linked to the inactivation of microorganisms; when microorganisms are exposed to a specific temperature over a specified time, the microorganisms are killed.

The ISO 15883-1 standard recommends different A_0 values depending on the load processed. In the Vision Single Chamber Washer/Disinfector, it is possible to reach an A_0 level between 600 and 3000. The time and temperature conditions required for the Vision Single Chamber Washer to obtain these A_0 levels are in **Table 6.**

Table 6: Parameters to reach A_0 in the Vision Single Chamber Washer/Disinfector

A_0	Time	Temperature
600	60 seconds (1 minute)	90^0C (194^0F)
3000	300 seconds (5 minutes)	90^0C (194^0F)

10 Disinfection Efficacy

To evaluate the disinfection effectiveness of a washer/disinfector, FDA recommends a specific reduction of microorganisms measured by a log reduction. The thermal disinfection cycle of the Vision Single Chamber Washer achieves the criteria for intermediate-level thermal disinfection set by FDA, which is to achieve at least a 6-log reduction of a mixed suspension of vegetative organisms, and a minimum of 3-log reduction of *thermophilic mycobacterium* species (2).

The disinfection efficacy of the thermal phase in the Reliance Vision Single Chamber Washer/Disinfector was evaluated using six different accessories, and load items representative of accessories and loads that are typically placed in a medical washer/disinfector.

The test method consisted of locating ampules containing a mixed suspension culture of vegetative organisms and ampules containing mycobacteria suspension in predefined coldest spots of an accessory (defined from the thermal profile study) and processing them in the appropriate disinfection cycle. The ampules were then evaluated by the method of microbial charge reduction and expressed as log-reduction values.

To evaluate the log reduction value after the thermal phase, microbial charge reduction of each process ampule containing microorganisms was evaluated by comparison with a positive control not exposed to thermal disinfection. Positive controls were serially diluted and enumerated by spread plate methods, as were the ampules processed in the disinfection cycle. Test results are shown in **Table 7.**

Safe and rapid intermediate level disinfection is achieved in the Vision Single Chamber Washer with exposure at 194°F (90°C) for just one minute. These parameters are supported with scientific data.

Table 7: Test configurations and disinfection efficacy testing

Test conditions			Test Results		
Cycle	**Rack**	**Test organism**	**Positive Controls (cfu/ml)**	**Recovered Counts (cfu/mL)**	**Log Reduction**
Instruments Cycle	5-level rack	Mixed suspension vegetative organisms[1] *Mycobacterium hassiacum*	1.7×10^9 6.1×10^6	< 9.1 < 9.4	> 8.30 > 5.84
Gentle Cycle	3-level rack	Mixed suspension vegetative organisms[1] *Mycobacterium hassiacum*	1.7×10^9 4.1×10^6	< 10 < 10	> 8.23 > 5.59
Gentle Cycle	General purpose rack	Mixed suspension vegetative organisms[2] *Mycobacterium hassiacum*	8.9×10^8 1.7 x10	< 1 1.5	> 8.92 >8.05
Utensil Cycle	2-level rack	Mixed suspension vegetative organisms[1] *Mycobacterium hassiacum*	1.9×10^9 3.2×10^6	< 10 < 10	> 8.28 > 5.49
Rigid MIS	MIS rack	Mixed suspension vegetative organisms [3] *Mycobacterium hassiacum*	1.4×10^9 1.5×10^8	26.0 3.5	> 8.81 7.93
Anesthesia Cycle (heat-sensitive)[5]	Anesthesia rack	Mixed suspension vegetative organisms [4] *Mycobacterium hassiacum*	1.4×10^9 1.0×10^8	< 1 < 1.4	> 9.15 > 7.86
Anesthesia Cycle	Anesthesia rack	Mixed suspension vegetative organisms [4] *Mycobacterium hassiacum*	1.4×10^9 5.6×10^7	< 1 < 1.4	> 9.13 > 7.60

1. A mixed suspension of *Staphylococcus aureus, Escherichia coli, Pseudomonas aeruginosa and Enterococcus faecalis*
2. A mixed suspension of *Staphylococcus aureus, Escherichia coli, Pseudomonas aeruginosa*
3. A mixed suspension of *Staphylococcus aureus, Enterobacter aerogenes, Pseudomonas aeruginosa*
4. A mixed suspension of *Staphylococcus aureus, Klebsiella pneumoniae, Pseudomonas aeruginosa*
5. The thermal configuration is 15 minutes at 170.6˚ F

11 Self Decontamination

Washing systems carry the inherent risk of microbial adhesion and retention. Vision Single Chamber Washer/Disinfectors were designed with features to reduce this risk to a minimum. Specific design elements include the tilting of piping, using materials unfavorable to microbial adhesion, increasing and stabilizing chamber heat, and ensuring maximum self-draining.

In addition, the Vision Single Chamber Washer has a built-in decontamination cycle for the washer chamber. STERIS studies have demonstrated that a decontamination cycle performed every seven days can help prevent biofilm build-up. The cleaning agent recommended for this cycle is Prolystica Restore® Descaler & Neutralizing detergent, to help remove residues.

12 References

1. Food and Drug Administration. Good Laboratory Practice for Non-clinical Laboratory Studies. United States Federal Register (21 CFR Part 58).
2. Food and Drug Administration/Office of Device Evaluation. Class II Special Controls Guidance Document: Medical Washers and Medical Washer-Disinfectors; Guidance for the Medical Device Industry and FDA Review Staff, FDA, Rockville, MD, USA
3. International Organization for Standardization. Washer-disinfectors - Part 1: General requirements, terms and definitions and tests (ISO 15883-1:2006).
4. International Organization for Standardization. Washer-disinfectors - Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc. (ISO 15883-2:2006).
5. International Organization for Standardization. Washer-disinfectors - Part 5: Test soils and methods for demonstrating cleaning efficacy (ISO/TS 15883-5:2005).
6. Conine, D.L., Naumann, B.D. and Hecker, L.H. (1992) Setting Health-Based Residue Limits for Contaminants in Pharmaceuticals and Medical Devices, Quality Assurance: Good Practice, Regulation, and Law, 1: 3, pp. 171-180.
7. Agence d'évaluation des technologies et des modes d'intervention en santé. Comparative analysis of pasteurization and thermal disinfection in a washer-disinfector: Anesthesia and respiratory devices, ETMIS 2009;Vol.5: N07
8. CSA. Canadian Standard Association. Decontamination of reusable medical devices. (Z314.8-08).

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