

# **Technical Data Monograph**

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## **Vision® 1300 Series Cart and Utensil Washer/Disinfectors**

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# 1 Introducing: the Vision® 1300 Series Cart and Utensil Washer/Disinfectors

The ultimate goal of infection control practices is to prevent infection from occurring in the first place. Successful infection prevention requires that all surgical instrument case carts, patient care utensils and reusable non-invasive instruments are thoroughly cleaned and disinfected to eliminate the risk of cross-contamination. Since this cleaning and disinfection step is so crucial, the capabilities and quality of a facility's cart and utensil washer-disinfector become critical factors for effective reprocessing and infection control.

This new generation of STERIS cart washer/disinfectors incorporates best-in-class design to achieve superior cleaning of case carts and non-invasive medical devices. The Vision 1300 Series Cart Washer/Disinfectors are able to maximize the area of coverage inside the chamber with innovative spray nozzles. These washers are also designed to be durable and efficient.

Two different configurations are available to meet Customers' needs:

- **Vision® 1321 Cart and Utensil Washer/Disinfector**
- **Vision® 1327 Cart and Utensil Washer/Disinfector**

## 2 Environmentally Conscious Design

Vision 1300 Series Cart and Utensil Washer/Disinfectors are designed to conserve resources and run very efficiently. Using these systems in a sterile processing department can support or help improve environmental management practices in healthcare facilities.

### Optimized cleaning cycles and water consumption

When Prolystica® Ultra Concentrate Chemistries are used in the Vision Washing Systems, cycle times are optimized. The unique Vision cycles are designed to save time on draining and filling functions, and to reduce both water and energy consumption during each cycle.

### Water recycling

These washer/disinfectors consume less water per cycle than other comparable systems. In addition to their cycle efficiencies, a water recycling option is available in Vision Cart 1300 Series and Utensil Washer/Disinfectors for even lower water consumption. As a result, Vision 1300 Series Cart Washers consume fewer resources overall than any previous STERIS cart washer/disinfector models. For example, the new Vision washing systems use 10% less water than the already energy efficient Reliance 130 Cart and Utensil Washer/Disinfectors.

The Vision 1300 Series Systems recycle water by means of reservoirs. This option allows water used for cleaning and disinfection to be reused. After each phase, water is sent back to its dedicated reservoir and 70% of the water is reused. Then, fresh water is added while the chemistry concentration is adjusted for each cycle. The water reuse number can be adjusted to a maximum of 20 times for each reservoir.

Multiple reservoirs in each washer/disinfector provide greater cycle flexibility, allowing a second detergent solution to be used for specific cycles and held in its own dedicated reservoir.

# 3

## Cycle Options

The Vision 1300 Series Cart and Utensil Washer/Disinfectors are pre-programmed with many dedicated cycles designed for specific types of loads. Cycle parameters have been optimized to achieve better cleaning results in a shorter time.

Simple and intuitive, the Vision PC-based control system offers automated cycles with default pre-programmed parameters to maximize the cleaning and disinfection performance of the systems. However, cycle parameters can also be modified easily to meet the individual requirements of a facility's protocols and procedures.

### Cart Low Eco Cycle

The new Cart Low Eco Cycle offers a shorter cycle time. This cycle, intended for case carts shorter than 44 inches, is designed with an innovative feature: the lateral spray arms in the chamber create a half-stroke spray pattern. The washing action is focused at cart height, resulting in the same cleaning performance as the Cart Standard Cycle.

### Cart Standard Cycle

When soiled carts are more than 44 inches high, the lateral spray arms travel for the full stroke to assure thorough cleaning. The washing parameters of this Cart Standard Cycle are programmed to achieve performance equivalent to the Cart Low Eco Cycle.

### Container Cycle

In healthcare facilities today, there is a heightened awareness of the potential for cross-contamination between human waste containers and other items processed in a washer/disinfector. To address this concern, STERIS has designed the Vision Cart Washer Container Rack and programmed a special Container Cycle for the Vision systems, to process containers even more effectively.

The Vision Cart Washer Container Rack can accommodate a wide variety of container sizes and dimensions. The Container Cycle, when used with neutral detergent, is safe for aluminum containers.

### Utensil Cycle

This cycle is designed to process a large variety of utensils using the improved Vision Cart Washer Utensil Rack. To avoid cross-contamination with any other items processed in the Vision 1300 Series Cart and Utensil Washer/Disinfector, water is not recycled at the end of the wash and thermal phases of the Utensil Cycle.

### Quick Cycle

This fast cycle cleans case carts shorter than 44 inches. The Quick Cycle is designed to rapidly process items that do not need to be thermally disinfected before their use. The Quick Cycle has no disinfection guarantee.

### Instrument Cycle

Vision 1300 Series Cart and Utensil Washer/Disinfectors are extremely versatile. In addition to the cycles discussed so far, a special Instrument Cycle is also programmed into the system to allow surgical instrument processing using the Vision Cart Washer Instrument Washing Manifold Rack. This two-level rack with manifolds has a capacity of up to 18 instrument trays.

This cycle option can be extremely useful for departments that have high peak demand for reprocessed surgical instruments but do not have the capacity or resources to add another washer to the department.

Instrument Cycle cleaning and disinfection is achieved by the combined action of the alternating movement of rotary spray arms on the instrument washing manifold rack accessory, and the lateral traveller spray arms of the washer/disinfector. The resulting action and spray coverage help assure superior cleaning of the surgical instruments and the washer chamber.

During the Instrument Cycle, the Vision 1300 Series Cart and Utensil Washer/Disinfector's internal monitoring system confirms the volume of detergent delivery, cleaning parameters, attainment of thermal disinfection level and cycle status. All the critical

disinfection parameters are monitored by the Vision PC control system. The data captured by the control is processed and an alarm signal is emitted if parameters do not meet cycle specifications.

### Other Specialized Cycles

Other cycles are programmed into these systems for special purposes. For example, some utensils are made of aluminum, which can be damaged by alkaline detergents. The Alumsafe Cycle is programmed for use with a pH neutral detergent to allow effective washing and disinfection of aluminum items without damage.

Another special cycle, the Bed Cycle, was created specifically to process patient beds.

## 4 Validation Test Program

STERIS designed a test program to separately assess the cleaning, disinfecting and rinsing efficacy of the Vision 1300 Series Cart and Utensil Washer/Disinfector in accordance with the Food and Drug Administration, ISO 15883 and AAMI 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.

For each validated cycle, a load was selected to represent worst-case conditions. Cart Low Eco Cycle was tested using case carts. The Container Cycle, used with the Vision Cart Washer Container Rack, was evaluated using a broad range of containers of various lengths, widths and depths, to simulate actual health facility conditions. The Instrument Cycle was tested using 900 hemostats loaded in the instrument tray rack. Hemostat forceps were selected because they are commonly used in surgical procedures and present a cleaning challenge due to their configurations and joints.

## 5 Cleaning Efficacy Testing

Cleaning efficacy was evaluated using visual and non-visual inspection to assess soil removal. Items were processed through only the washing phase of the appropriate cycle and were evaluated immediately after the washing process without exposure to the thermal rinse and drying phases for each respective cycle.

Depending on the particular validated cycle being tested, one of two different test soils was used; an artificial test soil or a blood and serum-based soil.

### European Cleaning Standards

To challenge the washing process and to demonstrate compliance with the ISO 15883 and AAMI 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**

Cycles	Prolystica® Ultra Concentrate Cleaning Chemistries	Rack	Load	Visual Determination*/Ninhydrin test**
Container	Neutral	Vision cart washer container rack	Various containers of various sizes	Clean/Pass
Instrument	Enzymatic/Neutral	Instrument washing manifold rack	360 hemostats ( <u>18 trays</u> of 20 hemostats)	Clean/Pass

\* According to Recommended Practices for Washing and Disinfection.

\*\* No visible purple discoloration of the swab.

### North American Cleaning Standards

Because FDA and AAMI recommend that simulated-use testing includes a representative challenge simulating 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.

**Table 2: Cleaning Results with Blood and Serum-based Soil**

Cycles	Prolystica® Ultra Concentrate Cleaning Chemistries	Rack	Load	Visual Determination
Cart Low eco	Alkaline		Case carts	Clean
Container	Neutral	Vision cart washer container rack	Various containers	Clean
Instrument	Enzymatic/Neutral	Instrument washing manifold rack	900 hemostats ( <u>18 trays</u> of 50 hemostats)	Clean

In addition to visual inspection and in accordance with FDA recommendations, a non-visual quantitative evaluation of cleaning efficacy was performed for the Instrument Cycle tests. To assess the efficacy of the Vision 1327 Washing System to reduce protein soil on surgical instruments to an acceptable level (less than 5µg/cm<sup>2</sup>) as recommended, a fluorescence method was performed to quantify the level of residual proteins after the washing phases. Results are presented in **Table 3**.

**Table 3: Quantitative Cleaning Evaluation with Blood and Serum-based Soil**

Test Conditions				Test Results		
Cycles	Prolystica® Ultra Concentrate Cleaning Chemistries	Rack	Load	Replicate # 1	Replicate # 2	Replicate # 3
Instrument	Instrument Washing Manifold Rack	Enzymatic/Neutral	900 hemostats ( <u>18 trays</u> of 50 hemostats)	Clean Pass < 1.0 µg/cm <sup>2</sup>	Pass < 0.87 µg/cm <sup>2</sup>	Pass < 0.87 µg/cm <sup>2</sup>



Rinsing efficacy was evaluated by comparing the amount of residue per load item compared to calculated toxicological limits. The evaluation of rinsing efficacy should show that the rinse phase of the Instrument Cycle removes the residues coming from cleaning chemicals to levels that are not hazardous to patients or end-users, and that do not interfere with a terminal process such as sterilization.

The rinsing efficacy of the Instrument Cycle was assessed for loads on the Instrument Washing Manifold Rack and cycles run with Prolystica Ultra Concentrate Enzymatic Cleaner and Prolystica Ultra Concentrate Alkaline Cleaner.

Up to three different methods were used 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.

Table 4: Test Configurations and Rinsing Efficacy Results

Test Conditions			Test Results					
Cycles	Rack	Prolystica® Ultra Concentrate Cleaning Chemistries	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	Instrument washing manifold rack	Enzymatic and Alkaline	3.77	0.021	5.80	<0.01	1.06	Pass 0.0095

# 7 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 coolest spots in the chamber.

Table 5: Thermal Profile Results

Cycle	Configuration	Rack	Load	Results
Cart Low eco	1-minute at 176°F (80°C)		Case carts	Pass
Container	1-minute at 176°F (80°C)	Vision cart washer container rack	Various containers	Pass
Instrument	3-minutes 10 seconds at 185°F (85°C)	Instrument washing manifold rack	900 hemostats (18 trays of 50 hemostats)	Pass

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, on the load carrier and on the chamber walls to monitor the appropriate phase as per specifications in ISO 15883 and AAMI 15883 standards. Temperature was recorded at one-second intervals throughout the appropriate validated cycle phase.

The thermometric profile was assessed for the washing and thermal phases of the Instrument Cycle, and for the thermal phase of the Container Cycle. 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 the phases analyzed; and that the temperature profiles were repeatable in subsequent cycles. The thermometric conditions of the load, the load carrier and the chamber for these cycles were verified.

**Table 6: Thermometric Test Results**

Cycle	Configuration	Rack	Load	Results
Container	10-minutes at 176°F (80°C)	Vision cart washer container rack	Various containers	Pass
Instrument	15-minutes 50 seconds at 185°F (85°C)	Instrument washing manifold rack	360 hemostats (18 trays of 20 hemostats)	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 the  $A_0$ , 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.

In the Vision Cart 1300 Series Washer/Disinfectors, three different  $A_0$  settings are available:  $A_0$  60, 600, and 3000. Different guidelines are suggested for each  $A_0$  cycle, depending on how patient-critical the load items are. For example,  $A_0$  60 setting is recommended for items that can only be in contact with intact skin, while  $A_0$  600 is recommended for surgical instruments. The guidelines follow ISO 15883 recommendations, but healthcare providers can select the setting that works best under their own established procedures and protocols.

After selecting the  $A_0$  setting on the PC control, the user will be asked to select a temperature. If a higher temperature is selected, the disinfection time will be reduced to achieve the same  $A_0$  disinfection level. The reduction will be made automatically by the washer-disinfector PC control.

**Table 6:  $A_0$  Features**

#### $A_0$ 60

Temperature in °C (°F)	Time	Cycles Available
80°C (176°F) Value by default for this $A_0$	60 seconds	<ul style="list-style-type: none"> <li>• Cart Low Eco Cycle</li> <li>• Cart STD</li> <li>• Utensil</li> <li>• Bed</li> </ul>
85°C (185°F)	19 seconds	<ul style="list-style-type: none"> <li>• Alumsafe</li> </ul>



## A<sub>0</sub> 600

Temperature in °C (°F)	Time	Cycles Available
80°C (176°F)	10-minutes	<ul style="list-style-type: none"> <li>• Cart Low Eco Cycle</li> <li>• Cart STD</li> <li>• Utensil</li> <li>• Bed</li> <li>• Alumsafe</li> <li>• Container</li> </ul>
85°C (185°F) <b>Value by default for this A<sub>0</sub></b>	3-minutes 10-seconds	<ul style="list-style-type: none"> <li>• Cart Low Eco Cycle</li> <li>• Cart STD</li> <li>• Utensil</li> <li>• Bed</li> <li>• Alumsafe</li> <li>• Container</li> <li>• Instrument</li> </ul>

## A<sub>0</sub> 3000

Temperature in °C (°F)	Time	Cycles Available
85°C (185°F)	15-minutes 50-seconds	<ul style="list-style-type: none"> <li>• Container</li> <li>• Instrument</li> </ul>

# 9 Disinfection Efficacy

To evaluate the disinfection effectiveness of a washer-disinfector, FDA recommends a specific reduction of microorganisms measured by a log reduction.

The FDA criterion to achieve low-level thermal disinfection is to achieve at least a 6-log reduction of a mixed suspension of vegetative organisms. For the Instrument Cycle, intermediate-level thermal disinfection was the goal. Using the criteria of at least a 6-log reduction of a mixed suspension of vegetative organisms and a 3-log reduction of a thermophilic mycobacterium species, intermediate-level thermal disinfection was achieved.

The test method consisted of positioning ampules containing a mixed suspension culture of vegetative organisms (and ampules containing mycobacteria suspension for the Instrument Cycle only) in predefined 'coldest' spots of the rack accessories and test items (defined in 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 performed and compared 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**.

**Table 7: Disinfection Efficacy Testing**

Test conditions			Test Results			
Cycle	Rack	Test organisms	Disinfection Level	Positive Controls (cfu/ml)	Recovered Counts (cfu/mL)	Log Reduction
Cart Low Eco Cycle		Mixed suspension vegetative organisms <sup>1</sup>	Low	1.5 x 10 <sup>9</sup>	< 1	Pass > 9.16
Container Cycle	Vision cart washer container rack	Mixed suspension vegetative organisms <sup>1</sup>	Low	1.2 x 10 <sup>9</sup>	< 2.5	Pass > 8.98
Instrument Cycle	Instrument washing manifold rack	Mixed suspension vegetative organisms <sup>1</sup>	Low	1.1 x 10 <sup>9</sup>	< 1.7	Pass > 8.95
Instrument Cycle	Instrument washing manifold rack	<i>Mycobacterium hassiacum</i>	Intermediate	1.7 x 10 <sup>8</sup>	< 1.4	Pass > 8.08

1. A mixed suspension of *Staphylococcus aureus*, *Pseudomonas aeruginosa* and *Enterobacter aerogenes*.

# 10

## Self Decontamination

Washing systems carry the inherent risk of microbial adhesion and retention. Vision 1300 Series Cart and Utensil Washer/Disinfectors were designed with features to minimize this risk. 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 systems have a built-in decontamination cycle for the washer chamber. The washer chamber, all the reservoirs and all the piping are cleaned during the Decontamination Cycle. The detergent recommended for this cycle is a phosphate-free descaler, to help remove residues.

The PC control can also prompt users to perform tasks that will help prevent biofilm formation. Depending on factors such as the facility's water quality and the number of loads run daily, it is possible to determine how many cycles can be run before decontamination should to be performed. When the number is reached, the control will tell you that it is time to run a decontamination cycle. These additional reminders are also programmed:

- Inspect and clean chamber filter
- Inspect and clean spray arms and nozzles
- Inspect and clean the spray arms on instrument rack (if this option is selected)

# 11

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