Technical Data Monograph

Reliance® Vision™ Multi-Chamber Washer/Disinfector

STERIS®

Abstract

This Technical Data Monograph illustrates the principles of operation and demonstrates the cleaning efficacy and the disinfection performance of the Reliance® Vision™ Multi-Chamber Washer/Disinfector. STERIS designed a test program to separately assess the cleaning and the intermediate-level disinfection efficacy of the Reliance Vision Washer/Disinfector in accordance with the Food and Drug Administration standards. The summary test data for cleaning, intermediate-level disinfection, and thermometric testing are included. In addition, the Performance Evaluation section presents a comparative study that demonstrates the cleaning efficacy of the Reliance Vision Washer/Disinfector without the need of a sonic phase.

The Reliance Vision Washer/Disinfector is STERIS's new multi-chamber washer/disinfector designed for improved outcomes, addressing customer requirements for increased productivity and efficiency. Key features of the compact three-chamber Reliance Vision Washer/Disinfector is a high-performance cleaning phase, and a intermediate-level disinfection cycle. The Reliance Vision Washer/Disinfector is intended for use in the cleaning, and intermediate-level disinfection of soiled reusable medical devices such as surgical instruments, utensils, bedpans and anesthesia equipment. The Vision allows the automation of the many steps involved in the manual process, substantially reducing the amount of handling, and increasing the processing capability.

Principles of Operation

STERIS believes that cleaning is the critical first step in reprocessing any device after it has been used on a patient, and the failure to do so can interfere with the effectiveness of subsequent disinfection and/or sterilization processes. The Reliance Vision Washer/Disinfector offers a washing process that merges a mild alkaline detergent, Liqui-Jet™ 2, with an enzymatic cleaner, EnzyCARE® 2, which together offer high cleaning performance. The Reliance Vision Washer/Disinfector also offers the choice of a second wash and a rinse in the rinse chamber to enable a double wash. The first wash is performed in the wash chamber followed by a rinse. The second wash is performed in the rinse chamber followed by a standard rinse and a thermal rinse.

The chambers of the Reliance Vision Washer/Disinfector have been designed as three independent chambers and are built for maximum self draining. The wash chamber executes a pre-wash, an optional pulsed enzyme wash, a standard wash and a rinse. The rinse chamber is dedicated to intermediate-level disinfection, and the drying chamber executes the drying phase.

The Reliance Vision Washer/Disinfector features an Allen-Bradley SoftLogix™ PC-based control system. This control system monitors and controls all phases of each cycle program and displays the status of each chamber, including current chamber temperature and time remaining for each phase. It also offers an ergonomic operator interface display that is easily accessible and viewable by the operator on both ends of the unit.

The Reliance Vision Washer/Disinfector's doors feature a new interlock safety mechanism that prevents clean-side doors from opening at the same time as soiled-side doors. This helps to avoid the risk of cross-contamination. When a cycle is in process, this safety mechanism prevents either door from being opened and aborting the cycle. Double full-glass doors allow the operators to view the chamber interior while a cycle is in progress.

A peristaltic pump dispenses a determined amount of liquid chemical into the chamber during the treatment. Seven pumps are included in a standard unit, four in the wash chamber and three in the rinse chamber. A low-level alarm sounds if the liquid chemical has run low in the container.

The Reliance Vision Washer/Disinfector is equipped with an optional Process Data Validation System (PDVS). This new feature verifies every vital component of the cycle, independent of the control center, using different probes and sensors for redundant assurance of pump outlet pressure, volume of detergent injected, pure water supply conductivity and more. The data captured by the PDVS is interpreted by the control, and an alarm signal is emitted if parameters do not meet cycle specifications.

Performance Evaluation

Cleaning

STERIS has conducted several studies to demonstrate the efficacy of the cleaning phase of the Reliance Vision Washer/Disinfector. To challenge the washing process and to demonstrate compliance with FDA standards, a Blood Base Test Soil was used. In addition, a Nynhydrin Protein Detection Test Kit (produced by Albert Browne, Ltd., a subsidiary of STERIS Corporation) was used to assess residual proteins on the processed items.

Cleaning efficacy was evaluated by visual and non-visual inspection of soil removal. The hemostats and hollowwares were soiled using a blood-base test soil composed of citrated sheep's blood, bovine calf serum and saline. The hemostats were placed in trays in the open position, the hollowwares were placed in the Multi Purpose Basin rack and both were allowed to dry for 30 minutes. The hemostats and hollowwares were then processed through the cleaning phase of the appropriate cycles and were subsequently evaluated for visual residual soil and for non-visual residual proteins (Ninhydrin Protein Detection Test Kit) remaining on the test items.

The cleaning efficacy was evaluated for the cleaning process only, which includes a pre-wash, a wash and two rinse phases. The items were evaluated immediately after the cleaning process without being exposed to the thermal rinsing and drying phases of their respective cycles. To ensure statistical significance, all tests were conducted in triplicate and the results shown are averages. Testing was performed using the following accessories and load configurations (see Table 1).

TABLE 1: ACCESSORIES, LOAD CONFIGURATIONS AND RESULTS - CLEANING

Accessory	Test items	Type	Quantity	Detergent	Cycle processed	Visual Determination*/ Ninhydrin test**
5-Level Manifold Instrument Rack FDV24-500	Surgical instruments	Hemostat forceps	10 Trays of 50 hemostats	Liqui-Jet™ 2	INSTRUMENTS	Clean /Pass
Multi Purpose Basin Rack FD02-000	Hollowwares	Stainless steel round bowls	4	Liqui-Jet™ 2	UTENSILS	Clean /Pass
		kidney dish stainless steel	11			
		plastic bowls	9			
		rectangular pans stainless steel	2			

* According to Recommended Practices for Washing and Disinfection.
** No visible purple discoloration of the swab.

The visual and non-visual evaluation of the items following the cleaning phase showed that the Reliance Vision Washer/ Disinfector provides cleaning efficacy when used with Liqui-Jet™ 2 detergent, and designated accessories, fully loaded, under representative worst-case conditions.

Self Decontamination

A major design consideration of the Reliance Vision Washer/Disinfector was minimizing the possibilities of microbial adhesion and retention. For this reason the Vision was designed to tilt all the piping, to use materials unfavorable to microbial adhesion, to increase and stabilize the temperature inside the chamber, and to allow maximum self-draining inside the system.

The Reliance Vision Washer/Disinfector also offers a decontamination cycle for the wash and thermal chambers. Results of STERIS's studies have demonstrated that a decontamination cycle is an effective means of decontaminating instruments and utensils and helps to prevent biofilm formation when performed every seven days using a liquid descaler as chemical agent.

Disinfection with biological indicators

Thermal disinfection efficacy was determined by microbial charge reduction and expressed in terms of percent and logarithmic reduction values. A thermal profile test was first performed to determine worst-case accessories and the test items' coldest spots (see thermometric tests below). *Escherichia coli, Pseudomonas aeruginosa, Staphylococcus aureus,* and *Enterococcus faecalis* (vegetative forms of bacteria) and *Mycobacterium hassiacum* (mycobacterium specie) were used to evaluate the intermediate-level disinfection efficacy. Acceptable performance is met for intermediate-level disinfection if a minimum of a 6-log reduction in population of vegetative microorganisms and a minimum of 3-log reduction of thermophilic representative mycobacterium specie are achieved after being processed through the thermal phase only.

Sterile soybean casein digest broth was inoculated with the vegetative microorganisms to constitute a mixed suspension of vegetative bacteria. Sterile 7H9 broth medium was inoculated with *Mycobacterium hassiacum* as a pure suspension culture. High-density culture (10^8 CFU/mL of the mixed suspension and 10^5 CFU/mL of *Mycobacterium hassiacum*) in stationary-growth phase were used for the validation tests. Aliquots of the mixed suspension and the mycobacteria suspension were separately sealed into glass ampules, placed randomly throughout the load in known cold spots, and processed through the thermal phase. A positive control was performed by dilution and standard plate counts to determine the initial titers of the test organisms.

The percent and logarithmic reduction figures were calculated from the difference between recovered bacterial counts on control (initial population: not processed through the thermal disinfection) and test ampule bacterial counts (processed through the thermal disinfection). To ensure statistical significance, all tests were conducted in triplicate and the results shown are averages. The table below (see Table 2) shows the effectiveness of the disinfection with test organisms. We obtained more than a 6-log reduction in population of vegetative microorganisms and more than a 3-log reduction of thermophilic representative mycobacterium specie for each accessory tested.

TABLE 2: ACCESSORIES, LOAD CONFIGURATIONS AND RESULTS - DISINFECTION WITH BIOLOGICAL INDICATORS

Test Conditions			Test Results	
Accessory	**Test Organism**	**Initial Population (CFU/mL)**	**Log Reduction (log_{10})**	**Percent Reduction (%)**
5 Level Rack	Mixed suspension vegetative organisms	$9.2x10^{10}$	>10.6	>99.99
	Mycobacterium hassiacum	$3.7x10^8$	>8.6	>99.99
Multi-Purpose Basin Rack	Mixed suspension vegetative organisms	$3.4x10^{11}$	>10.7	>99.99
	Mycobacterium hassiacum	$3.7x10^8$	>8.1	>99.99
Anesthesia Rack	Mixed suspension vegetative organisms	$2.4x10^9$	>9.4	>99.99
	Mycobacterium hassiacum	$3.9x10^8$	>8.5	>99.99

Thermometric tests

STERIS performed thermometric tests to meet specified conditions throughout the chamber, the load, and the load carrier during the operating cycle. The thermometric profile was assessed for the wash and thermal rinse phases of an Instruments cycle, using a five-level rack loaded with hemostats, and a Utensils cycle, using a multi purpose basin (MPB) rack loaded with stainless steel bowls and pans.

Thermocouples were placed on the load, the load carrier and on the chamber walls, to monitor wash phase and thermal phase temperatures. The temperatures were recorded at 2-second intervals throughout the wash and thermal rinse phases. For all the tests, the disinfection temperature was 90°C for a holding period of 10 minutes.

A thermometric profile of the load, the load carrier and the chamber was achieved with success: there was temperature uniformity throughout the load, the load carrier and the chamber; the temperature set point was maintained during the holding period for both wash and thermal phases; and temperature profiles were repeatable in subsequent cycles.

Comparative study between Reliance 777 and Reliance Vision Washer/Disinfectors

STERIS has performed complementary testing to establish the similarity of cleaning efficacy between the new Reliance Vision three-chamber washer/disinfector and the Reliance 777 five-chamber washer/disinfector with sonic option. The comparative study was performed under similar conditions except for the extra sonic phase on the Reliance 777 Washer/Disinfector. See Table 3 for the parameters used for the study:

TABLE 3: COMPARATIVE PARAMETERS FOR STUDY

	Reliance Vision Washer/Disinfector	Reliance 777 Washer/Disinfector
Accessory	4-Level Manifold Instrument Rack	2-Level Manifold Instrument Rack
Load	400 Hemostats forceps	200 Hemostats forceps
Cycle	Instruments	Instruments
Cycle Phase	Pre-wash	Pre-wash
	Wash at 150°F	Wash at 150°F
		Sonic Wash (4 min. phase)
	Rinse	Rinse
Test Soil	Blood-base test soil	Blood-base test soil
Detergent	Liqui-Jet 2	Liqui-Jet 2

The results show that the cleaning performance of the Reliance Vision Washer/Disinfector was improved by 37% as compared to the Reliance 777 Washer/Disinfector equipped with an ultrasonic chamber. Increased productivity was also achieved since twice the hemostats where cleaned in the Reliance Vision Washer/Disinfector.

Conclusion

In conclusion, the Reliance Vision three-chamber washer/disinfector achieved better and faster cleaning, providing increased productivity in a smaller footprint.

References

1. Food and Drug Administration. Good Laboratory Practice for Non-clinical Laboratory Studies. United States Federal Register, Revised April 1, 2003 (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, February 7, 2002.
3. Food and Drug Administration/Office of Device Evaluation. Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance, FDA, Washington DC, USA, 1996.
4. CSA International. Decontamination of Reusable Medical Devices. CSA Standard Z314.8-00. Section 11.7.2. p. 17. March 2000.
5. NHS Estates, Washer-disinfectors Validation and Verification, Health Technical Memorandum 2030, p. 124-125; 131, London, UK, 1997.

Footnotes

1. SoftLogix™ is a trademark of Allen-Bradley, a Rockwell Automation Company.

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