

Technical Data Monograph

AMSCO® 3052 Single-Chamber Washer/Disinfector

AMSCO® 5052 Single-Chamber Washer/Disinfector

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1 The AMSCO® 3052 Single-Chamber Washer/Disinfector and the AMSCO® 5052 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, special attention is needed to prevent patient cross-contamination when instruments are processed for reuse. Furthermore, all surgical instrument patient care utensils and reusable non-invasive instruments 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.

This latest generation of STERIS washer/disinfectors incorporates a design that fits your requirements. The AMSCO 3052 Single-Chamber Washer/Disinfector and the AMSCO 5052 Single-Chamber Washer/Disinfector'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, cool touch handles, and ease of loading from any side.

The independent monitoring system of the AMSCO 3052 Single-Chamber Washer/Disinfector and the AMSCO 5052 Single-Chamber Washer/Disinfector is designed to monitor the critical parameters needed for reliable, effective cleaning and disinfection. The control of the AMSCO 3052 Single-Chamber Washer/Disinfector and the AMSCO 5052 Single-Chamber Washer/Disinfector verifies vital phases of the cycle, the volume of detergent injected and the attainment of intermediate disinfection levels. The data captured by the control are processed and an alarm is emitted if parameters do not meet cycle specifications.

To optimize the cycle times with The AMSCO 5052 Single-Chamber Washer/Disinfector use with Prolystica® Ultra Concentrate chemicals.

2 Prolystica® Ultra Concentrate System

Prolystica Ultra Concentrate Chemicals are formulated with biodegradable ingredients to help protect the environment. Prolystica Ultra Concentrate Chemicals provide superior cleaning and protection of surgical instruments, while providing optimal safety and ease-of-use for staff. The system consists of several formulations; an enzymatic cleaner, a neutral or alkaline detergent, and an optional lubricant.

The ability to enhance productivity with shorter cycle times without sacrificing cleaning performance is the result of a dual-product cleaning cycle using Prolystica Ultra Concentrate Enzymatic Cleaner and Neutral or Alkaline Detergent.

The Prolystica Ultra Concentrate Chemicals are precisely injected at specified intervals and temperatures, allowing them to act under their individual optimal conditions together within the wash cycle for the appropriate and most beneficial cycle times.

Prolystica® Ultra Concentrate Enzymatic Cleaner

Prolystica Ultra Concentrate Enzymatic Cleaner achieves exceptional cleaning performance against blood, mucous and the most challenging fatty soils. This dual enzyme system works exceptionally well within a wide range of water qualities and types.

Prolystica® Ultra Concentrate Neutral Detergent

Prolystica Ultra Concentrate Neutral Detergent cleans blood, mucous and a wide range of challenging fatty soils. Built-in corrosion inhibitors protect instruments and prolong washer life, while chelating and sequestering agents enhance cleaning performance regardless of water quality.

Prolystica® Ultra Concentrate Alkaline Detergent

Prolystica Ultra Concentrate Alkaline Detergent provides exceptional and safe cleaning without a second neutral rinse. Built-in corrosion inhibitors protect instruments and prolong washer life, while chelating and sequestering agents enhance cleaning performance regardless of water quality.

Prolystica® Ultra Concentrate Lubricant

Prolystica Ultra Concentrate Lubricant is a non-silicone product; it 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.

3 Cycle Options

The AMSCO 3052 Single-Chamber Washer/Disinfector and the AMSCO 5052 Single-Chamber Washer/Disinfector are pre-programmed with 8 dedicated cycles designed for specific types of loads and also 8 customizable cycles.

Orthopedic Cycle

Surgical instruments for orthopedic procedures can be very complex. The design of many orthopedic devices, such as drills, reamers and other items, presents a significant cleaning challenge because of crevices, joints and other structural design elements.

Orthopedic soils, such as trapped bone chips, marrow and other debris, are more challenging to remove than other soils.

The AMSCO 3052 Single-Chamber Washer/Disinfector and the AMSCO 5052 Single-Chamber Washer/Disinfector provide a specialized cycle for orthopedic instruments; that cycle is programmed to inject precise doses of Prolystica Ultra Concentrate Enzymatic Cleaner and either Neutral or Alkaline detergent.

54 different orthopedic instruments and 250 hemostats were tested and validated in the AMSCO 3052 Single-Chamber Washer/Disinfector and the AMSCO 5052 Single-Chamber Washer/Disinfector. Devices for hip, knee, shoulder and general orthopedic surgeries were selected to assure a representative sampling of this instrument category.

Anesthesia Cycle

The AMSCO 3052 Single-Chamber Washer/Disinfector and the AMSCO 5052 Single-Chamber Washer/Disinfector offer a programmed Anesthesia Cycle and a specialized anesthesia rack accessory to clean and disinfect reusable semi-critical components of anesthesia and respiratory equipments. The Anesthesia Rack is designed to hold different types of tubing, bags, masks and respiratory goods.

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 chemicals 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; 15 minutes at 172.9°F (78.3°C) for heat-sensitive devices and 1 minute at 194°F (90°C) 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 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.

- **Instrument Cycle:** The Instrument Cycle is designed to clean, thermally disinfect and dry surgical instruments.
- **Utensil Cycle:** The Utensil Cycle is designed to clean, thermally disinfect and dry utensils such as trays, basins and bowls.
- **Gentle Cycle:** The Gentle Cycle is designed to clean, thermally disinfect and dry delicate surgical instruments.
- **Decontamination Cycle:** The Decontamination Cycle is used on a weekly basis to descale the chamber and rack.

4 Validation Test Program

STERIS designed a test program to separately assess the cleaning, disinfecting and rinsing efficacy of the AMSCO 3052 Single-Chamber Washer/Disinfector and the AMSCO 5052 Single-Chamber Washer/Disinfector in accordance with U.S. Food and Drug Administration ("FDA") Guidance Document¹, standards EN ISO 15883, AAMI 15883 and CSA Z15883.^{2,3,4,5,6,7}

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.

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

Cleaning Standards

To challenge the washing process and to demonstrate compliance with the FDA guideline, CSA Z15883, EN ISO 15883 and AAMI 15883 standards, all cleaning tests were conducted with a coagulated blood and serum based soil. This soil represents a challenge simulating actual in-use conditions and was also used to demonstrate the ability to remove representative organic contamination from reusable medical devices.

To assess the efficacy of the AMSCO 3052 Single-Chamber Washer/Disinfector and the AMSCO 5052 Single-Chamber Washer/Disinfector to reduce protein soil on surgical instruments to an acceptable level as recommended, a Ninhydrin Protein Detection Test Kit (produced by Albert Browne, Ltd., a subsidiary of STERIS Corporation) (less than 9µg/cm²) or a fluorescence detection method (less than 5µg/cm²) were performed to quantify the level of residual proteins after the washing phases.

Testing with Blood and Serum-Based Soil was performed using the following accessories and load configuration (see **Table 1** and **2**).

Instrument Cycle

Instrument Cycle is designed to process surgical instruments. This cycle was tested with the 5-Level Vision Manifold Rack loaded with 500 hemostats and equipped with eight flexible hoses for cannulated instruments. Hemostats forceps were selected because such instruments are used in surgery procedures and present a cleaning challenge due to their configurations and joints mated surfaces.

Orthopedic Cycle

Orthopedic Cycle is designed to process orthopedic instruments. Hips, knees, shoulders and general orthopedic instruments are considered critical as they are introduced directly into the human body. Orthopedic instruments present difficulties when cleaning. 54 orthopedic instruments and 250 hemostats were tested in the 5-Level Vision Manifold Rack equipped with eight flexible hoses for canulated instruments.

Gentle Cycle

Gentle Cycle is performed at low speed to protect delicate instruments and use the General Purpose rack to offer cleaning and disinfection with a lower impact. **Ophthalmic Micro-instruments** were selected to test the Gentle cycle.

Utensil Cycle

Utensil Cycle is designed to process bedpans, trays, basins and bowls. This cycle was validated with bedpans in a General Purpose rack and Multi-functions rack for large items. Bedpans present a cleaning challenge due to their configurations compared to plastic, stainless-steel bowls and kidney dishes.

Table 1. Cleaning Results with Blood and Serum-Based Soil

Cycle	Prolystica® 2x Concentrate Chemistries	Rack	Load	Visual Determination
Instrument	Enzymatic/Neutral	5-Level Vision Manifold Rack + 8 flexible hoses	500 hemostats (10 trays of 50 hemostats) and 8 suction tips	Clean
Orthopedic	Enzymatic/Neutral	5-Level Vision Manifold Rack + 8 flexible hoses	250 Hemostats + orthopedic items + 8 suction tips	Clean
Utensil	Neutral	General Purpose Vision Rack with Multi-functions rack for large items	Bedpans	Clean
Gentle	Neutral	General Purpose Vision Rack	Micro-instruments	Clean
Anesthesia	Neutral	Anesthesia/Respiratory Rack	Anesthesia tubing and respiratory goods	Clean
MIS	Enzymatic/Neutral	Rigid MIS Instrument Rack	Various MIS instruments	Clean

Table 2. Quantitative Cleaning Evaluation with Blood and Serum-Based Soil

Test Conditions				Test Results
Cycle	Rack	Prolystica® 2x Concentrate Chemistries	Load	Non-Visual Quantitative Cleaning Evaluation
Instrument	5-Level Vision Manifold Rack	Enzymatic/Neutral	500 hemostats (10 trays of 50 hemostats) and 8 suction tips	Pass (< 0.87 µg/cm²)*
Orthopedic	5-Level Vision Manifold Rack + 8 flexible hoses	Enzymatic/Neutral	250 Hemostats + orthopedic items + 8 suction tips	Pass (< 9µg/cm²)**
Utensil	General Purpose Vision SC Rack with Multi-functions rack for large items	Neutral	Bedpans	Pass (< 9µg/cm²)**
Gentle	General Purpose Vision SC Rack	Neutral	Micro-instruments	Pass (< 9µg/cm²)**
Anesthesia	Anesthesia/Respiratory Rack	Neutral	Anesthesia tubing and respiratory goods	Pass (< 9µg/cm²)**
MIS	Rigid MIS Instrument Rack	Enzymatic/Neutral	Various MIS instruments	Pass (< 9µg/cm²)**

* fluorescence detection method

** No visible purple discoloration of the swab using Ninhydrin Protein Detection Test Kit.

Rinsing Efficacy

Rinsing efficacy was evaluated with the Instrument and Gentle Cycles by comparing the amount of residue per load item compared to calculated toxicological limits.^{8,9} The evaluation of rinsing efficacy should show that the rinse phase of the Instrument and Gentle cycles 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.

Instruments cycle

The rinsing efficacy of the **Instruments Cycle**, using a 5-Level Vision Manifold Rack loaded with **hemostats**, was assessed using a combination of Prolystica Ultra Concentrate Enzymatic Cleaner and Prolystica Ultra Concentrate Alkaline Cleaner.

For this evaluation, the Total Organic Carbon (TOC) method was used to determine the level of organic residues. By this method, the level of organic carbon is measured 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 the patient.

Furthermore, the Conductivity method was used to evaluate the 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 (see **Table 3**).

Gentle Cycle

The rinsing efficacy of the **Gentle cycle**, using a General Purpose Rack loaded with **micro-instruments**, was assessed using Prolystica Ultra Concentrate Neutral Detergent.

For this evaluation, the Total Organic Carbon (TOC) method was used to determine the level of organic residues. By this method, the level of organic carbon present in the Neutral Detergent is measured.

Table 3 presents the test configurations and results for the rinsing efficacy.

Table 3. Rinsing Efficacy Results

Test Conditions			Test Results					
Cycle	Rack	Prolystica® Ultra Concentrate 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	5-Level Vision Manifold Rack	Enzymatic and Alkaline	3.77	Pass (0.009)	5.80	Pass (<0.006)	1.06	Pass (0.0086)
Gentle	General Purpose Rack	Neutral	2.67	Pass (0.009)	-			

7 Thermal Profile Evaluation

STERIS performed thermal profile testing to verify that the 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 for the disinfection study.

Table 4. Thermal Profile Results

Cycle	Speed	Configuration	Rack	Load	Results
Orthopedic (Instruments)	High	1 minute at 180°F/82.2°C	5-Level Vision Manifold Rack + 8 flexible hoses	250 Hemostats + orthopedic items + 8 suction tips	Pass
Utensil	Low	1 minute at 180°F/82.2°C	General Purpose Vision SC Rack with Multi-functions rack for large items	Bedpans	Pass
Gentle	Low	1 minute at 180°F/82.2°C	General Purpose Vision SC rack	Micro-instruments	Pass
Anesthesia	High	1 minute at 180°F/82.2°C	Anesthesia/Respiratory Rack	Anesthesia tubing and respiratory goods	Pass
MIS	High	1 minute at 180°F/82.2°C	Rigid MIS Instrument Rack	MIS and Rigidscopes	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 EN ISO 15883, AAMI 15883 and CSA Z15883 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 and Utensil Cycles. The results demonstrated that there was temperature uniformity throughout the load, the load carrier and the chamber; that the temperature setpoint 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. For all the tests, the disinfection temperature was 90°C (194°F).

Table 5. Thermometric Test Results

Cycle	Speed	Rack	Load	Results
Orthopedic (Instruments)	High	5-Level Vision Manifold Rack + 8 flexible hoses	250 Hemostats + orthopedic items + 8 suction tips	Pass
Utensil	Low	General Purpose Vision SC Rack with Multi-functions rack for large items	Bedpans	Pass
Gentle	Low	General Purpose Vision SC rack	Micro-instruments	Pass
Anesthesia	High	Anesthesia/Respiratory Rack	Anesthesia tubing and respiratory goods	Pass
MIS	High	Rigid MIS Instrument Rack	MIS and Rigidscopes	Pass

Thermal disinfection with the A₀ option

According to EN ISO 15883 series standards, the use of A₀ 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 A₀, 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 AMSCO 3052 Single-Chamber Washer/Disinfector and the AMSCO 5052 Single-Chamber Washer/Disinfector, four different A₀ settings are available: A₀ 60, 600, 3000 and 12,000. Different guidelines are suggested for each A₀ cycle, depending on how patient-critical the load items are. For example, A₀ 60 setting is recommended for items that can only be in contact with intact skin, while A₀ 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 A₀ setting on the PC control, the control will calculate the thermal phase time depending of the maximum temperature that can be reached inside the washer/disinfector. This temperature is related to the altitude where the washer/disinfector is installed; 185.9°F [85.5°C] if washer/disinfector is configured at an altitude higher than 1640 ft [500 m] and 194°F [90°C] if washer/disinfector is configured at a lower altitude (unit Hardware Option).

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 an intermediate-level thermal disinfection is to achieve at least a 6-log reduction of a mixed suspension of vegetative organisms and a 3-log reduction of a thermophilic mycobacterium species.¹

The test method consisted of positioning ampoules containing a mixed suspension culture of vegetative organisms and ampoules containing mycobacteria suspension 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 ampoules 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 ampoule 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 ampoules processed in the disinfection cycle. Test results are shown in **Table 6**.

Table 6. Disinfection Efficacy Testing

Test Conditions			Test Results		
Cycle	Rack	Test Organisms	Positive Controls (cfu/ml)	Recovered Counts (cfu/mL)	Log Reduction
Orthopedic (Instrument)	5-Level Vision Manifold Rack	Mixed suspension vegetative organisms ¹	1.46 x10 ⁹	< 1	Pass > 9.16
		<i>Mycobacterium hassiacum</i> broth	9.0 x10 ⁶	< 1	Pass > 6.96
Utensil	General Purpose Vision SC Rack with Multi-functions rack for large items	Mixed suspension vegetative organisms ¹	1.3 x10 ⁹	< 1	Pass > 9.13
		<i>Mycobacterium hassiacum</i> broth	9.16 x10 ⁶	< 1	Pass > 6.96
Gentle	General Purpose Vision SC Rack	Mixed suspension vegetative organisms ¹	9.4x10 ⁸	< 1	Pass > 8.97
		<i>Mycobacterium hassiacum</i> broth	1.16x10 ⁷	< 1	Pass > 7.06
Anesthesia respiratory goods cycle 1 minute at 82.2°C	Anesthesia/Respiratory Rack	Mixed suspension vegetative organisms ¹	1.1x10 ⁹	< 1	Pass > 9.04
		<i>Mycobacterium hassiacum</i> broth	1.13x10 ⁷	< 1	Pass > 7.05
Anesthesia respiratory goods cycle 15 minutes at 78.3°C (172.9°F)	Anesthesia/Respiratory Rack	Mixed suspension vegetative organisms ¹	1.03x10 ⁹	< 1	Pass > 9.01
		<i>Mycobacterium hassiacum</i> broth	1.23x10 ⁷	< 1	Pass > 7.09
Rigid MIS	Rigid MIS Instrument Rack	Mixed suspension vegetative organisms ¹	1.03x10 ⁹	< 1	Pass > 9.01
		<i>Mycobacterium hassiacum</i> broth	1.3x10 ⁷	< 1	Pass > 7.11

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

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Self-Decontamination

Washing systems carry the inherent risk of microbial adhesion and retention. The AMSCO 3052 Single-Chamber Washer/Disinfector and the AMSCO 5052 Single-Chamber Washer/Disinfector 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.

The AMSCO 3052 Single-Chamber Washer/Disinfector and the AMSCO 5052 Single-Chamber Washer/Disinfector also offer a decontamination cycle for the chamber. STERIS studies have demonstrated that a decontamination cycle is a good procedure to use to decontaminate and prevent biofilm formation when performed every seven days using Liquid Descaler as the chemical agent.

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