Technical Data Monograph

Reliance™ EPS Endoscope Processing System

STERIS®

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INTRODUCTION

This Technical Data Monograph illustrates the principles of operation and demonstrates the microbiocidal efficacy, materials compatibility, and performance of the Reliance™ EPS Endoscope Processing System (Reliance EPS). The summary test data for microbial efficacy, material compatibility, toxicity/residuals, and self decontamination testing performed on the Reliance EPS are included.

The Reliance EPS is intended for washing and high level disinfection of up to two manually pre-cleaned, immersible, reusable, heat-sensitive, semi-critical devices such as GI flexible endoscopes, bronchoscopes, and their accessories. Some specific examples are: colonoscopes, gastroscopes, sigmoidoscopes, cystoscopes, endoscope valves, cleaning brushes, and irrigation tubing.

The principal elements of the Reliance EPS include:

- Automated, easy-to-use control panel with standardized processing cycles
- Optional washing phases with a pH neutral-based detergent with protease activity
- High level disinfection using low temperature, liquid immersion
- Proprietary, single use, dry chemical formulation of germicide sealed in its own delivery system
- Two rinses with 0.2 µm filtered water following high level disinfection
- Process monitoring and load documentation
- Self-decontamination cycles
- Technology to accommodate a broad spectrum of flexible endoscopes and their accessories
- System features and functions designed for the safety of patients, healthcare workers, medical devices, and the environment
- System designed for ease of use and maintenance

The Reliance EPS **(Figure A)** consists of several components. These components include:

- Reliance™ EPS Processor (including the Endoscope Processing Support)
- Reliance Dry Chemistry
- STERIS Chemical Indicator Validated for Use with Reliance EPS
- Klenzyme® Enzymatic Presoak and Cleaner
- CIP 200® Acid-Based Process and Research Cleaner

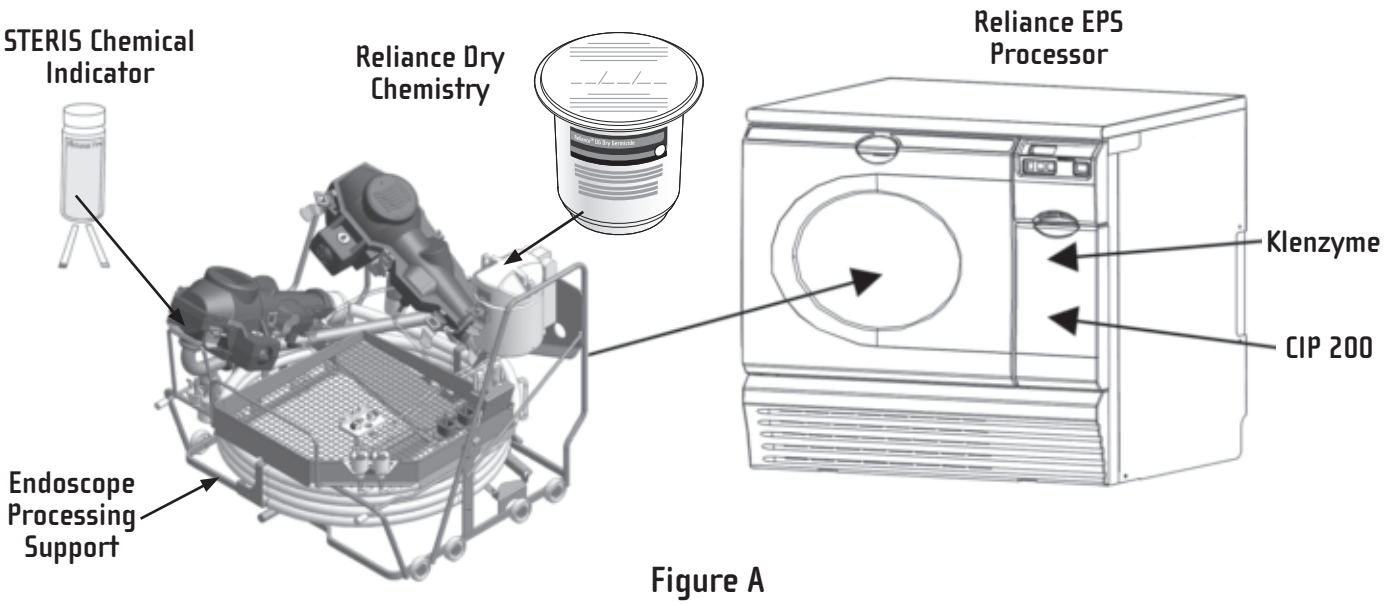


Figure A

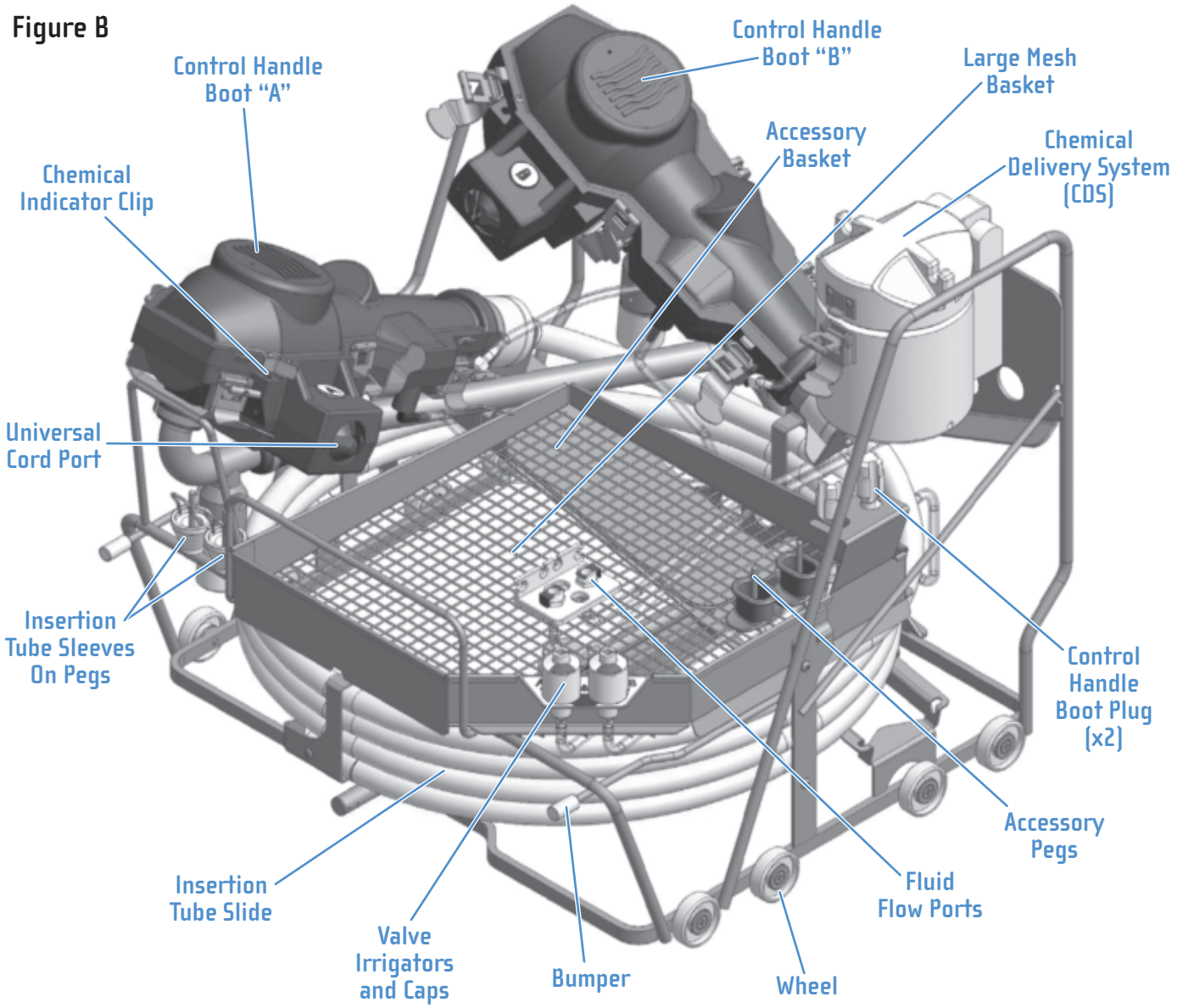
RELIANCE EPS ENDOSCOPE PROCESSING SYSTEM: PRINCIPLES OF OPERATION

The Reliance EPS Processor and its integrated endoscope processing support **(Figure B)** provide for delivery of solutions and fluids to endoscopes and their accessories. Klenzyme and Reliance dry chemistry are introduced into the Reliance EPS Processor to provide washing and high level disinfection. The STERIS chemical indicator, validated for use with the Reliance EPS, indicates the appropiate dose of peracetic acid (PAA), the active ingredient in the high level disinfection solution, during each processing cycle. Decontamination cycles (D-LONG with CIP 200, D-SHORT) are used to help prevent biofilm formation in the Reliance EPS Processor and ensure effective processing following periods of processor inactivity.

The Reliance EPS delivers washing or high level disinfecting solutions and rinse water by several methods:

- The upper and lower spray arms deliver fluids to items placed in the large mesh basket and accessory basket.
- Valve irrigators, located on the endoscope processing support, supply fluid directly to the suction valves.
- The control handle boots ("A" and "B") on the endoscope processing support use a pressure differential to direct fluid flow down the internal channel of flexible endoscopes (see detailed discussion of the control handle boots).
- Fluid flow ports located within the central basket allow Reliance EPS Flow Units to provide direct flow to accessories with channels (irrigation tubes) and to those endoscope channels without ports on the control handle.

Figure B

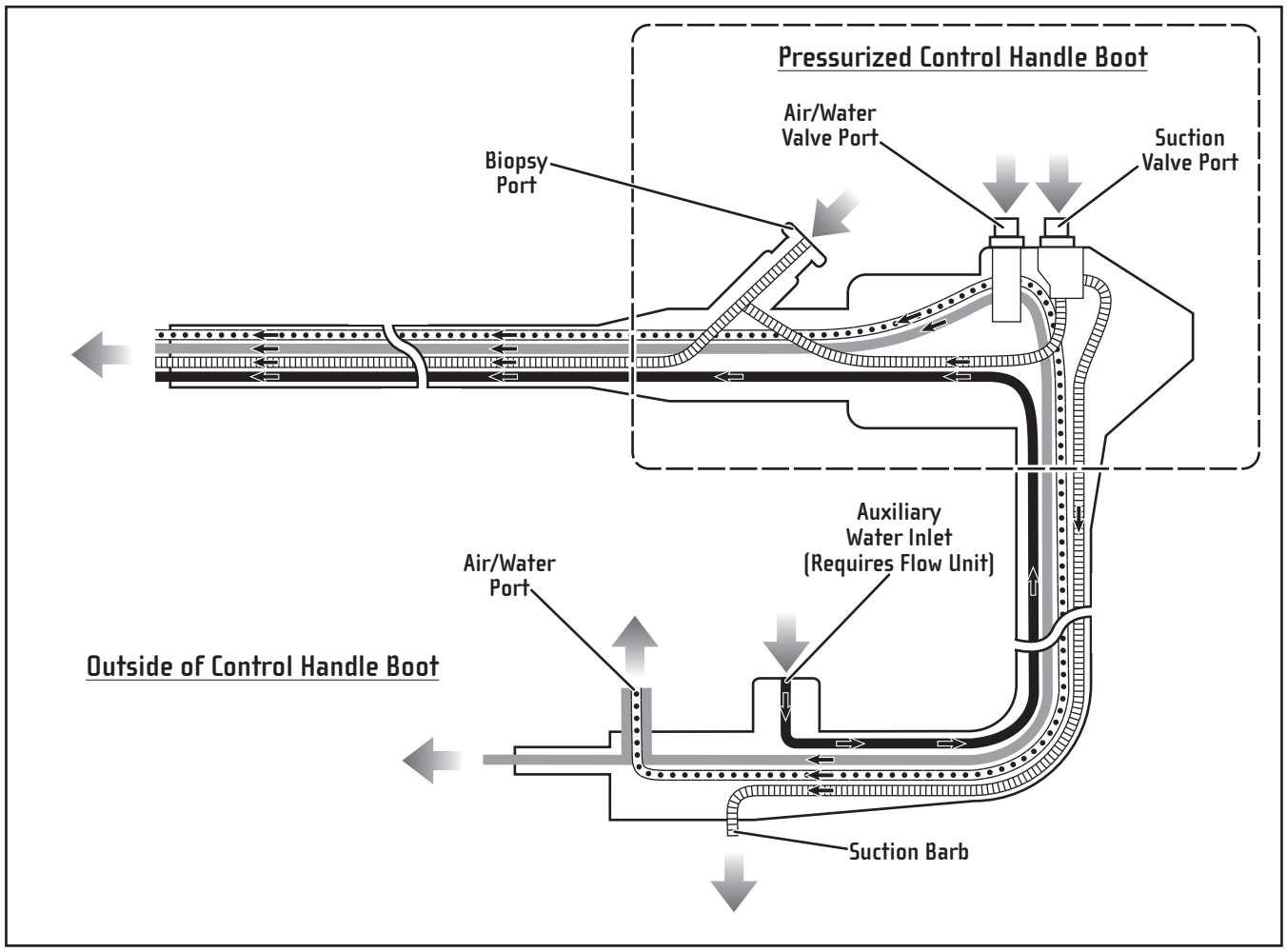


Control Handle Boots

The unique design of the Reliance EPS Processor control handle boots limits the need for connectors for processing flexible endoscopes (no special connectors are needed for ~ 86% of endoscopes, indicated in the Endoscope Quick Reference Guide*). A pressure differential is produced when solutions are directed into the control handle boot **(Figure C)**. Solutions are flowed through all channels simultaneously since the channels are all interconnected (suction/biopsy via the biopsy port and suction valve port, air/water channel via the air/water valve port); the channels are thus fully irrigated. Any additional independent or connected channels with an opening on the control handle are also irrigated in this manner. Klenzyme, Reliance dry chemistry high level disinfection solution, and rinse water are all effectively delivered to internal endoscope channels using this technology.

***Note:** A Flow Unit may be required for an endoscope with an auxiliary water channel or for an endoscope with a non-removable mechanically activated valve located on the control handle.

Figure C: Control Handle Boot



CONSUMABLES

Reliance Dry Chemistry

Reliance dry chemistry is a proprietary, two-part dry powder formulation that is delivered to the Reliance EPS Processor from a pre-measured, single-use container. Two precursor agents in the dry formulation combine with water during the automated process to generate peracetic acid. The first precursor, acetylsalicylic acid, is contained within the top compartment of the container. The second precursor, sodium perborate, is located in the bottom compartment of the container. These precursors, mixed with water in the processor, will generate peracetic acid for the high level disinfection process.

Reliance dry chemistry **(Figure D)** has been engineered to provide a safe and easy-to-use formulation for healthcare workers. Reliance dry chemistry has an 18-month shelf life from date of manufacture while factory sealed inside the over package. Once the container has been removed from the factory packaging, it has a two-week shelf life. The formulation of the Reliance dry chemistry needs no special venting for storage, is safe for disposal without special treatment, and has no airfreight restrictions.

Figure D

Klenzyme Enzymatic Presoak and Cleaner

Klenzyme is a neutral-based detergent with protease activity. It is provided in Bag-in-a-Box packaging for easy delivery of the detergent to the Reliance EPS Processor. Klenzyme has been successfully used for over 10 years in manual and automated processes to clean medical devices.

STERIS Chemical Indicator

The STERIS chemical indicator validated for use with the Reliance EPS Endoscope Processing System verifies the generation of an effective dose of PAA during the high level disinfection cycle. A new chemical indicator strip is used for each Reliance EPS Cycle.

CIP 200 Acid-Based Process and Research Cleaner

CIP 200 is circulated throughout the Reliance EPS during the D-LONG cycle. In validation testing, after a high level challenge with *Pseudomonas aeruginosa* followed by a five day inactive period, the D-LONG cycle has been shown to effectively disinfect the processor.

THE RELIANCE EPS ENDOSCOPE PROCESSING CYCLE

The Reliance EPS Cycle is a fully automated and validated cycle consisting of a washing phase (optional), a high level disinfection phase, two filtered water rinse phases, and a final air purge phase. All additives are pre-measured by the processor and used only once **(Table 1)**.

The optional washing phase uses Klenzyme. The user may select one or two washing phases, each of which can be adjusted to be between 5 to 10 minutes. Each washing phase is followed by a filtered water rinse phase.

For each new cycle, a new container of Reliance dry chemistry is placed within the Chemical Delivery System (CDS) prior to the start of the cycle. Water enters the CDS at 50°C (122°F) to dissolve and mix the Reliance dry chemistry components. The components are mixed within the Reliance EPS for the next four minutes, generating peracetic acid, the active ingredient in the Reliance dry chemistry high level disinfection solution.

The high level disinfection phase includes a 6-minute exposure segment during which the high level disinfection solution is continuously circulated throughout the processor (including over every surface and through the channels of the endoscopes) at a controlled temperature of 50-57°C (122-134.6°F).

Following the high level disinfection phase, two rinse phases occur using water filtered through two prefilters and a 0.2 µm bacterial retentive filter. After rinsing, an air purge phase follows in which HEPA filtered air is circulated through the endoscope channels to help remove excess water.

Table 1: Reliance EPS Endoscope Processing System: EPS Cycle

	Optional Phases							
	With Washing		Repeat Washing					
Phase	**Wash**	**Rinse**	**Wash**	**Rinse**	**High Level Disinfection**	**Rinse 1**	**Rinse 2**	**Air Purge**
Water Type	HTW	HTW	HTW	HTW	HTW	HTW	HTW	
Set point temperature °C (°F)	Heated to 48.0°C (118.4°F)		Heated to 48.0°C (118.4°F)		Heated to 50.0°C (122.0°F)			
Time (min:sec)	05:00 Adjustable (05:00-10:00)	00:40	05:00 Adjustable (05:00-10:00)	00:40	10:00 Generation: 04:00* Disinfection: 06:00 *Generation starts when water temperature reaches 50.0°C (122.0°F)	00:40	00:40	04:00 Adjustable: (04:00-30:00) Time is extended to 60:00 if cycle is not ended manually after set time.
Chemical	Klenzyme		Klenzyme		Reliance dry chemistry			
Concentration mL/L (oz/gal)	2 (1/4)		2 (1/4)					

HTW = 0.2 µm filtered hot tap water

SELF DECONTAMINATION CYCLES – BIOFILM PREVENTION

The Reliance EPS Endoscope Processing System contains two self-decontamination cycles, D-SHORT and D-LONG, both of which are intended to prevent the formation of biofilm. These cycles are designed to provide redundant decontamination processes as a preventative maintenance measure in the processor. The two cycles are to be used without endoscopes, flow units, and accessories present in the processor. The processor is software controlled to automatically require the running of the D-SHORT cycle every 54 hours. If a D-SHORT cycle is not completed within this time interval, the processor is locked out from use until a D-LONG cycle is performed.

Biofilm

Biofilm is an organic polymer matrix that is synthesized by microorganisms under certain environmental conditions that include standing water, a nutritional source, and the presence of a biofilm-forming organism. The presence of water is the key condition as the organisms that form the biofilm matrix are ubiquitous in aqueous environments.

D-SHORT

The D-SHORT decontamination cycle is intended to help prevent those microorganisms commonly associated with the formation of biofilm from establishing a foothold within any area of the Reliance EPS Processor. The cycle is to be completed within 54 hours of a previous decontamination cycle and consists of 13 minutes at 82.2°C (180°F) with a 20-minute air purge at 115.6°C (240°F). While no single temperature is officially recognized for sanitization and self-decontamination, these temperatures have been shown to kill bacteria and exceed temperatures routinely used for other thermal decontamination processes.

D-LONG

The D-LONG decontamination cycle consists of adding CIP 200, along with hot water. The decontamination solution is then circulated through the processor for 20 minutes; this is followed by three rinses to remove the solution from the processor and a 10-minute hot air purge. D-LONG is to be used on those occasions when the D-SHORT cycle has not been completed within the past 54 hours. The D-LONG cycle is intended to help prevent formation of biofilm that may have developed within the unit during periods of inactivity greater than 54 hours. This cycle is not only at an elevated temperature, but also provides for the chemical prevention of biofilm through the use of CIP 200.

Summary

The two self-decontamination cycles were shown to be effective as follows:

- D-SHORT cycle can kill bacteria that have potential to form a biofilm.
- D-LONG cycle can disinfect the Reliance EPS Processor after a high level challenge with *P. aeruginosa* followed by a five day inactive period

Table 2: Reliance EPS Endoscope Processing System : System Decontamination Cycles

D-SHORT (Decontamination cycle only, do not run with endoscopes, accessories, or Flow Units.)

Phase	Wash	Air Purge
Water Type	HTW	
Set point temperature °C (°F)	Heated to 82.2°C (180°F)	Heated to 115.6°C (240.0°F)
Time (min:sec)	13:00	20:00 (Venting 10:00, Cooling 10:00)

D-LONG (Decontamination cycle only, do not run with endoscopes, accessories, or Flow Units.)

Phase	Wash	Rinse 1	Rinse 2	Rinse 3	Air Purge
Water Type	HTW	HTW	HTW	HTW	
Set point temperature °C (°F)	Heated to 82.2°C (180°F)				Heated to 115.6°C (240.0°F)
Time (min:sec)	20:00 Chemical is injected 10 minutes after temperature is reached	00:30	00:30	00:30	14:00 (Venting 10:00, Cooling 04:00)
Chemical additive	CIP 200				
Concentration mL/L (oz/gal)	16 (2)				

HTW = 0.2 µm filtered hot tap water

PERFORMANCE EVALUATIONS

Washing Studies

STERIS Corporation conducted studies to assess the performance of the washing phase of the Reliance EPS Endoscope Processing System. Published washing studies show that a prevalent component of the soil found on devices following a clinical procedure is protein[1]. Protein burden was thus used by STERIS as an indicator of the level of soil remaining on a device following processing in the Reliance EPS. These studies documented the level of protein on devices after a patient procedure and prior to manual pre-cleaning as 1.8 – 115.5 µg/cm^2 [1].

Twelve flexible endoscopes and six accessories were each tested in triplicate to evaluate the washing performance of the Reliance EPS. Studies were conducted using a simulated test soil (Edinburgh Quebec soil containing egg yolk, whole citrated sheep blood, gastric hog mucin, 0.85% saline, and bovine calf serum). The test soil was suctioned from the distal tip to the light guide end for each endoscope. Selected surface sites on the endoscopes and accessories were also inoculated. After inoculation, the devices were air dried for 30 minutes prior to processing.

Washing performance testing was conducted under worst case conditions for the following variables:

- Temperature
- Water quality
- Washing time

Positive control results for inoculated endoscopes showed that on average approximately 264 µg/cm^2 of protein were present on the soiled endoscopes; this is roughly double the highest amount of protein found on patient-soiled devices prior to manual pre-cleaning. Approximately 697 µg/cm^2 of protein were present on soiled accessories, which is six times that observed on clinically-used devices prior to manual pre-cleaning[1](Table 3).

Following a single washing phase lasting five minutes, average protein (soil) levels for each type of endoscope/ accessory were significantly reduced to < 5 µg/cm^2 for all endoscopes and accessories tested (Table 3).

Table 3: Protein Levels After One Washing Phase in the Reliance EPS

Clinically Relevant Endoscope or Accessory	Remaining Protein
Positive Control - Endoscope (Unprocessed)	264 µg/cm^2
Pentax Duodenoscope	< 5 µg/cm^2
Pentax Gastroscope	*< 5 µg/cm^2
Pentax Enteroscope (2 tested)	< 5 µg/cm^2
Pentax Colonoscope (2 tested)	< 5 µg/cm^2
Pentax Intubation Scope	< 5 µg/cm^2
Olympus Dual Biopsy Channel Gastroscope	< 5 µg/cm^2
Olympus Colonoscope (2 tested)	< 5 µg/cm^2
Olympus Bronchoscope	< 5 µg/cm^2
Fujinon Colonoscope	< 5 µg/cm^2
Positive Control - Accessory (Unprocessed)	697 µg/cm^2
Cleaning Brush	< 5 µg/cm^2
Bite Block	< 5 µg/cm^2
Air/Water Valve	< 5 µg/cm^2
Suction Valve (2 tested)	< 5 µg/cm^2
Irrigation Tube	< 5 µg/cm^2

*Limit of detection for protein assay.

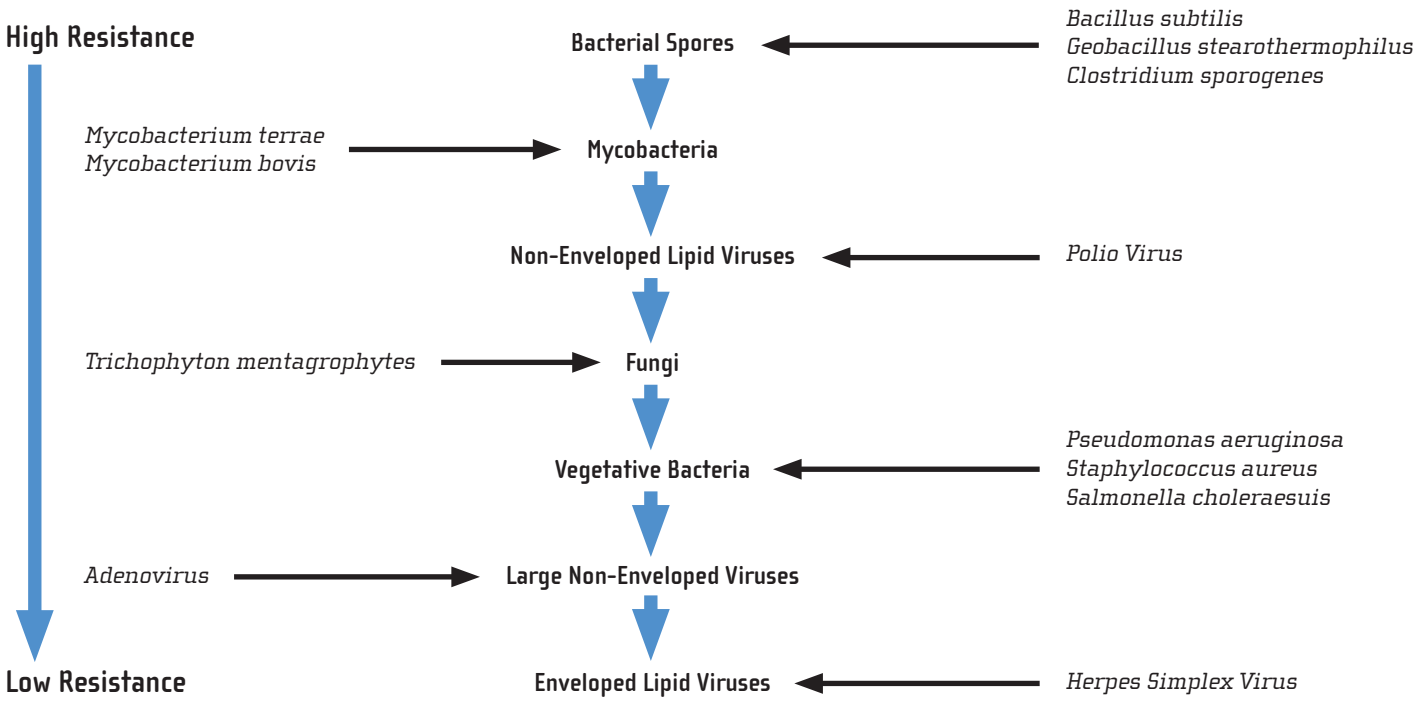
Conclusion of the Washing Studies

In summary, the testing showed that the Reliance EPS significantly reduced protein burdens on the listed instruments under specified worst case conditions. **The Reliance EPS washing phase does NOT replace manual pre-cleaning and is only intended to supplement manual pre-cleaning.**

Microbial Efficacy Testing

Microbial efficacy testing was conducted using a variety of methods and different organisms to confirm the efficacy (*in vitro*, *in situ*, simulated use and in use) of Reliance dry chemistry high level disinfection solution under a variety of conditions. As depicted in **(Figure E)**, an assortment of organisms, from those with low resistance to most germicides (vegetative bacteria), to those with the highest known resistance (bacterial spores), were tested after exposure to Reliance dry chemistry high level disinfection solution.

Figure E: Classes of Microorganism Ranked from Least to Most Susceptible to Chemical Disinfectants (S. Block, 4th Edition, 1991[2])



Potency Testing

BACTERIAL ENDOSPORES

In Situ AOAC Carrier Testing

STERIS Corporation used a modification of the AOAC carrier test (AOAC Test Method #966.04) to determine sporicidal activity of the Reliance dry chemistry high level disinfection solution. Testing was conducted in a simulated processor under worst case conditions for the following variables:

- Water quality
- Temperature
- PAA concentration
- Fluid circulation

STERIS conducted a modified AOAC carrier test to demonstrate the effectiveness of the Reliance EPS. Spore loaded polyester loops and porcelain penicylinders were exposed to Reliance dry chemistry high level disinfection solution in a simulated processor which replicated the minimum operating conditions of the Reliance EPS processor. Testing was performed with three lots of Reliance dry chemistry. A total of 720 carriers, each loaded with $\geq \geq 1 \times 10^4$ colony forming units (CFU)/carrier, were tested (360 porcelain penicylinders and 360 polyester suture loops). Each batch of carriers was confirmed to be appropriate for testing by exhibiting a resistance of $\geq \geq 2$ minutes when exposed to 2.5N HCl. Acceptable performance (Pass) was determined for the Reliance dry chemistry high level disinfection solution if no carriers exhibited growth following completion of the worst case test cycle.

Table 4: STERIS Spore Testing with Reliance Dry Chemistry High Level Disinfection Solution

Organism	Result
Bacillus subtilis	Pass
Clostridium sporogenes	Pass

Corroborative testing was performed by an independent test laboratory, using identically prepared inoculated carriers (120 porcelain penicylinders and 120 polyester suture loops) with the following results.

Table 5: Spore Testing with Reliance Dry Chemistry High Level Disinfection Solution

Organism	Result
Bacillus subtilis	Pass
Clostridium sporogenes	Pass

In Vitro D-Value Testing

STERIS Corporation further performed *in vitro* D-value testing with Reliance dry chemistry high level disinfection solution using *Geobacillus stearothermophilus*, the organism previously identified as the most resistant organism to peracetic acid[3]. A D-value is defined as the time required to reduce the population one logarithm. Testing was performed by suspending *G. stearothermophilus* spores in solutions of Reliance dry chemistry, which employed worst case conditions for the following variables:

- Water quality
- Temperature
- PAA concentration

D-value testing in two independent studies with *G. stearothermophilus* in Reliance dry chemistry high level disinfection solution at 50°C resulted in values ranging from 36 seconds to 41 seconds.

Conclusion of Bacterial Endospore Testing

The Reliance dry chemistry high level disinfection solution effectively destroys bacterial endospores when evaluated by both the modified AOAC carrier method and by D-value testing.

MYCOBACTERIA

In Situ AOAC Carrier Testing

An independent laboratory used the AOAC carrier test in a simulated processor (AOAC Test Method# 965.12) to determine activity of the Reliance dry chemistry high level disinfection solution against mycobateria. Inoculated carriers (30 stainless steel penicylinders with ≥ ≥ 5.3 x 10^6 CFU/carrier) were processed under worst case conditions for the following variables:

- Water quality
- Temperature
- PAA concentration
- Fluid circulation

Testing was performed with three lots of Reliance dry chemistry. Acceptable performance (Pass) was determined if no carriers exhibited growth following testing.

Table 6: Mycobacteria Testing with Reliance Dry Chemistry High Level Disinfection Solution

Organism	Result
Mycobacterium bovis	Pass

In Vitro D-value Testing (Ascenzi suspension method)

STERIS Corporation performed testing using the Ascenzi suspension method to quantify the kill rate of *Mycobacterium terrae* ATCC 15755 when exposed to Reliance dry chemistry high level disinfection solution. Four trials were performed with each of three lots of Reliance dry chemistry for 12 trials total. Testing employed worst case conditions for the following variables:

- Water quality
- Temperature
- PAA concentration

The average D-value for all trials was 6.3 ± 2.1 seconds.

Conclusion of Mycobacteria Testing

Reliance dry chemistry high level disinfection solution effectively destroys mycobacteria. In addition, the contact time of 10 minutes (4-minute generation segment followed by a 6-minute exposure segment) is sufficient to reduce the mycobacteria population by 6 logs (calculation based on D-value).

VIRUS

An independent laboratory performed virus testing for STERIS. Three viruses were selected for testing. Virus testing exposed each of the viruses to the process parameters of the Reliance EPS. Acceptable performance (Pass) was determined if ≥ ≥4 log reduction in population was achieved for each of the viruses tested.

Table 7: Virus Testing with Reliance Dry Chemistry High Level Disinfection Solution

Organism	Result
Poliovirus Type 1 – non-enveloped lipid virus	Pass
Adenovirus Type 5 - large non-enveloped virus	Pass
Herpes simplex virus Type I – enveloped lipid viruses	Pass

All controls met minimum acceptable criteria for media sterility, viability, quantitative viability, cytotoxicity, and neutralization.

Conclusion of Virus Testing
Virus testing demonstrates that the system will effect a ≥ 4 log reduction in population of the indicator viruses.

VEGETATIVE BACTERIA

In Situ AOAC Carrier Testing
An independent laboratory performed the AOAC carrier tests (AOAC Test Method# 955.14, 955.15 & 962.02) with Reliance dry chemistry high level disinfection solution in a simulated processor. Inoculated carriers (540 stainless steel penicylinders with ≥ 2 x 10^6 CFU/carrier) were processed under worst case conditions for the following variables:

- Water quality
- Temperature
- PAA concentration
- Fluid circulation

Testing was performed with three lots of Reliance dry chemistry. Acceptable performance (Pass) was determined if no carriers exhibited growth following testing.

Table 8: Vegetative Bacteria Testing with Reliance Dry Chemistry High Level Disinfection Solution

Organism	Result
Salmonella choleraesuis ATCC 10708	Pass
Staphylococcus aureus ATCC 6538	Pass
Pseudomonas aeruginosa ATCC 15442	Pass

In Vitro AOAC Carrier Testing
STERIS Corporation performed confirmatory bacteria testing (180 stainless steel penicylinders with ≥ 5.5 x 10^6 CFU/carrier) per the AOAC methodologies. All testing was essentially as detailed above, except it was performed in a test tube with a non-circulating solution of Reliance dry chemistry high level disinfection solution. One lot of Reliance dry chemistry was used for testing.

Table 9: STERIS Vegetative Bacteria Testing with Reliance Dry Chemistry High Level Disinfection Solution

Organism	Result
Salmonella choleraesuis ATCC 10708	Pass
Staphylococcus aureus ATCC 6538	Pass
Pseudomonas aeruginosa ATCC 15442	Pass

Conclusion of Vegetative Bacteria Testing
Reliance dry chemistry high level disinfection solution effectively destroys vegetative bacteria.

FUNGUS

In Situ AOAC Carrier Testing
An independent laboratory performed the AOAC carrier testing (AOAC Test Method# 955.17) with Reliance dry chemistry high level disinfection solution in a simulated processor with carriers (30 porcelain penicylinders) inoculated with *Trichophyton mentagrophytes* ATCC 9533 conidia suspended in a 5% serum solution. Carriers were inoculated with 6.6×10^6 conidia/carrier, exceeding the minimum requirement of 5×10^6 conidia/carrier. Fungus carriers were processed under worst case conditions for the following variables:

- Water quality
- Temperature
- PAA concentration
- Fluid circulation

Testing was performed with three lots of Reliance dry chemistry. Acceptable performance (Pass) was determined if no carriers exhibited growth following testing.

Table 10: Fungus Testing with Reliance Dry Chemistry High Level Disinfection Solution

ORGANISM	RESULT
Trichophyton mentagrophytes ATCC 9533	Pass

In Vitro AOAC Suspension Testing
Suspension testing was performed in accordance with AOAC methodology. The test included a 6-minute exposure of *T. mentagrophytes* in suspension at 48±2°C with worst case PAA concentration using three lots of Reliance dry chemistry. Acceptable performance (Pass) was determined if no growth was detected following testing.

Table 11: AOAC Fungus Testing with Reliance Dry Chemistry High Level Disinfection Solution

ORGANISM	RESULT
Trichophyton mentagrophytes ATCC 9533	Pass

Conclusion of Fungus Testing
Reliance dry chemistry high level disinfection solution effectively destroys fungal conidia.

Medical Device Testing

SIMULATED-USE

To demonstrate the effectiveness of the Reliance EPS for high level disinfection of medical devices, STERIS conducted simulated-use testing of representative or worst case medical devices with respect to size and features that are difficult to disinfect.

Twelve flexible endoscopes and nine endoscope accessories were used to verify that high level disinfection was reproducibly achieved in the Reliance EPS.

A working suspension of *Mycobacterium terrae* ATCC 15755 was prepared and inoculated into all internal channels. Selected external sites and accessories were also inoculated. Devices were air dried for > 30 minutes prior to processing. Three replicate test trials were performed for each endoscope and accessory. A standard 10-minute total contact time (4-minute generation segment followed by a 6-minute exposure segment) without a washing phase was performed for each device load. Testing was performed using worst case conditions for the following variables:

- Water quality
- PAA concentration
- Control handle boot pressure

All internal channels, selected external surface sites and accessories were harvested following processing. Acceptable performance was determined if each trial resulted in a >≥ 6 log reduction of *M. terrae*.

Table 12: Simulated-Use Testing with Reliance Dry Chemistry High Level Disinfection Solution

Clinically Relevant Endoscope with Associated Accessory	Average Log Reduction
Pentax Duodenoscope with Cleaning Brush	> 7 log
Pentax Enteroscope with Air/Water Valve	> 7 log
Pentax Dual Channel Colonoscope with Suction Valve	> 7 log
Pentax Gastroscope	> 7 log
Pentax Enteroscope with Suction Valve	> 7 log
Pentax Colonoscope	> 7 log
Pentax Intubation Scope	> 7 log
Olympus Colonoscope with Irrigation Tube	> 7 log
Olympus Dual Biopsy Channel Gastroscope with Irrigation Tube	> 7 log
Olympus Colonoscope with Suction Valve	> 7 log
Olympus Bronchoscope with Suction Valve	> 7 log
Fujinon Colonoscope with Bite Block	> 7 log

Conclusion for Simulated-Use Testing

The Reliance EPS with Reliance dry chemistry high level disinfection solution reproducibly disinfects medical devices challenged with high levels of *Mycobacterium terrae*.

IN-USE

The Reliance EPS was evaluated in a clinical setting with clinically used endoscopes and patient soil. Devices were selected to represent the range of endoscope designs likely to be encountered in the clinical setting:

- Bronchoscope (pulmonary, bronchial)
- Duodenoscope (upper GI, esophageal)
- Colonoscope (lower GI, bowel)

After patient use, clinical personnel manually pre-cleaned each device per the endoscope manufacturer's instructions and the clinical site's standard procedures, placed the device in the Reliance EPS Processor, initiated the processing cycle, and confirmed successful completion of the cycle.

Three trials were performed for each endoscope. One of the three trials incorporated a five-minute washing phase with exposure to Klenzyme to confirm that this phase did not negatively impact high level disinfection efficacy.

Positive control recovery sampling was performed before and after manual pre-cleaning, showing reduction (but not elimination) of clinical microbiological loads by manual pre-cleaning, as expected.

After the processing cycle, each endoscope's internal channels, selected external surfaces and selected accessories were harvested using the same method as was used for the simulated-use tests.

No remaining clinical isolates were recovered from any of the endoscopes after any trial in the clinical setting as shown in **(Table 13)**. The manual pre-cleaning step reduced the microbial load on the devices but did not eliminate bioburden. This testing confirmed the effectiveness observed in simulated-use testing by demonstrating that no organisms were recovered from endoscope surfaces or channels following a standard Reliance EPS Cycle with Reliance dry chemistry high level disinfection solution, with or without a washing phase.

Table 13: In-Use Testing with Reliance Dry Chemistry High Level Disinfection Solution

Test Site		Post Processing Recovery (CFU)								
		Bronchoscope			Duodenoscope			Colonoscope		
		Trial 1	Trial 2	Trial 3	Trial 1	Trial 2	Trial 3	Trial 1	Trial 2	Trial 3
External (2 per Scope)		0	0	0	0	0	0	0	0	0
Internal	Biopsy/Suction	0	0	0	0	0	0	0	0	0
	Air/Water									
	Elevator Guide Wire									
Accessory	Suction Valve				0	0	0	0	0	0
	Air/Water Valve				0	0	0	0	0	0
	Biopsy Valve				0	0	0	0	0	0

Conclusion for In-Use Testing
In a clinical setting using a representative range of patient-used flexible endoscopes, high level disinfection efficacy was achieved using Reliance dry chemistry high level disinfection solution in the Reliance EPS Processor. No organisms were recovered from endoscopes after the processing cycle.

Materials Compatibility

STERIS Corporation performed device materials compatibility evaluations to ensure that the Reliance dry chemistry high level disinfection solution is safe for representative medical devices, accessories, and components. Devices, and accessories, and components were examined, after multiple treatment cycles, for evidence of:

- Corrosion
- Degradation in light transmission of optics
- Degradation in device performance
- Changes in mechanical resistance
- Cosmetic changes (i.e. surface pitting, oxidation, discoloration)
- Loss of tubing and o-ring flexibility
- Defects in lens adhesive

Five representative flexible endoscopes **(Table 14)** and 28 accessories/components **(Tables 15 and 16)** were processed in Reliance EPS for 300 complete endoscope processing cycles with Reliance dry chemistry high level disinfection solution at 50 ± 2°C (122 ±3.6°F). The complete cycle consisted of a 10-minute high level disinfection phase (4-minute generation segment and a 6-minute exposure segment), two 40-second rinse phases, and an air purge phase. The devices were removed from the processor after each cycle to simulate normal handling methods. Due to the expected increased durability, the endoscope accessories **(Table 15)** and component parts **(Table 16)** were processed through an additional 150 cycles for a total of 450 cycles, or 4500 minutes of exposure to the Reliance dry chemistry high level disinfection solution.

At intervals of 100 cycles, the devices were evaluated for evidence of changes in functionality or cosmetic appearance, as listed above. A change in device performance could act as an indicator of material incompatibility. An acceptable result (Pass) was determined when device functionality was not affected by exposure in the Reliance EPS. Some cosmetic changes, (i.e. color changes and normal wear) occurred with the devices, but these changes did not affect the functionality of the device.

Table 14: Materials Compatibility Testing with Reliance Dry Chemistry High Level Disinfection Solution

Device	Number of Cycles Processed	Result
Pentax Video Enteroscope	300	Pass
Pentax Video Duodenoscope	300	Pass
Pentax Video Sigmoidoscope	300	Pass
Olympus Gastrointestinal Fiberscope	300	Pass
Fujinon Video Upper Gastroscope	300	Pass

The five devices selected had critical design features found in all flexible endoscopes: insertion tube, bending section or bending rubber, control body, control knobs, umbilical cable, light guide end, soaking cap, and metal ports or connectors. Each of these design features are manufactured with the same basic materials: polyurethane, rubber, glass, anodized aluminum, polytetrafluoroethylene, polyethylene, and stainless steel. In addition, these scopes contained critical endoscope features and systems needed for functionality: angulation system, light guide fibers, suction control, and an air/water delivery system.

The accessories used with the endoscopes listed in **(Table 14)** perform the same critical functions (for example suction and air/water feeding) and are comprised of the same basic materials used in many other device accessories. Additionally, Reliance EPS Flow Units and components of Flow Units were also tested for material compatibility.

Table 15: Materials Compatibility Testing with Reliance Dry Chemistry High Level Disinfection Solution

Device Accessories	Number of Cycles Processed	Result
Pentax Forward Water Jet Connector and Irrigation Tube	450	Pass
Pentax Water Jet Check Valve Adapter with black rubber check valve	450	Pass
Pentax Water Jet Connector Cap	450	Pass
Pentax Air/Water (A/W) Feeding Valve	450	Pass
Pentax Suction Control Valve	450	Pass
Pentax Bite Block	450	Pass
Pentax Rubber Inlet Seals	450	Pass
Pentax Channel Cleaning Brush	450	Pass
Pentax A/W Suction Valve Cylinder Cleaning Brush	450	Pass
Olympus A/W Valve	450	Pass
Olympus Suction Valve	450	Pass
Olympus Mouth Piece	450	Pass
Olympus Semi-disposable Biopsy Valve	450	Pass
Olympus Channel Cleaning Brush	450	Pass
Olympus Channel-opening Cleaning Brush	450	Pass
Fujinon Biopsy Cap	450	Pass
Fujinon A\W Valve	450	Pass
Fujinon Suction Valve	450	Pass
Fujinon Bite Block	450	Pass

Table 16: Materials Compatibility Testing with Reliance Dry Chemistry High Level Disinfection Solution

Device Components	Number of Cycles Processed	Result
Pentax Diopter Adjustment Ring	450	Pass
Pentax Strain Relief Boot	450	Pass
Pentax Forward Body Cover	450	Pass
Olympus Switch Block Units	450	Pass
Olympus Control Body Handles	450	Pass
Olympus C-Cover	450	Pass
Olympus Bending Rubber	450	Pass
Olympus Angulation Knob Set	450	Pass
Olympus Eyepiece	450	Pass

Conclusion of Materials Compatibility Testing

Testing with Reliance dry chemistry high level disinfection solution showed no functional or performance damage (change) for representative endoscopes after 300 cycles in a Reliance EPS. Endoscope accessories and endoscope components showed no damage (change) after 450 cycles in the Reliance EPS. There were some cosmetic changes, (i.e. color changes and normal wear) that occurred, but these did not affect the functionality of the devices. Flow Units showed no damage (change) after 1900 cycles in the Reliance EPS.

Materials compatibility testing has shown that *in situ* cycling of representative flexible endoscopes, accessories, adapters, and components in the Reliance EPS causes no functional damage in the OEM devices as a result of normal exposure to Reliance dry chemistry high level disinfection solution.

Toxicity and Residuals Testing

Toxicity Analysis

Under normal conditions of use the Reliance EPS operator is not exposed to the contents of the Reliance dry chemistry container, the disinfection solution or processor rinse water. Nevertheless, a variety of toxicological evaluations were performed on these components of the processing system, to determine what, if any, safety risks were associated with inadvertant exposure. The following toxicological evaluations were commissioned or undertaken by STERIS for the components of the Reliance dry chemistry container and/or the disinfection solution and processor rinse water, as appropriate based on their respective potential for exposure:

- Literature review of known toxicological hazards of all raw materials
- Tests for skin irritation, skin sensitization, acute oral toxicity, primary eye irritation, cytotoxicity, and genotoxicity

Conclusion

Results of these evaluations show that:

- The dry powder components in the Reliance dry chemistry container may cause irritation to the eye, skin, and respiratory system, and may be harmful if swallowed.
- The acetylsalicylic acid (aspirin) in the Reliance dry chemistry container is potentially harmful if ingested, may cause acute toxic effects in individuals susceptible to acetylsalicylic acid (aspirin) toxicity, and may cause sensitization (allergic reaction) in some individuals if inhaled or ingested.
- Pregnant women should avoid exposure to the contents of the container.
- The disinfection solution is practically nontoxic if ingested, mildly irritating to the eyes, non-mutagenic, non-sensitizing and would not be expected to cause significant adverse effect if contact or other exposure occurs.
- Processor rinse water and aqueous extracts of processed devices are not cytotoxic.

RESIDUAL TESTING

Representative medical devices were processed through a Reliance EPS Cycle incorporating worst case conditions of exposure to the chemical components of the disinfection solution. The exposed devices were extracted in deionized water at 37°C on both interior and exterior surfaces to remove any residue that might be present. The extracted samples were assayed for the two components of the disinfection solution known to have the potential for toxic effects in humans. Exhaustive extraction of the medical devices showed that the residual levels for these components were well below the established levels for safety. Additionally, an *in vitro* cytotoxicity test was performed on extracts from medical devices similarly processed under worst case conditions as described above. Results showed no evidence of cell lysis or toxicity after 48 hours.

Conclusion

Exhaustive extracts from medical devices were shown to be non-cytotoxic and to have chemical components well below acceptable residual limits. Thus any residue remaining on the processed medical devices is well below toxic levels and poses no known risk to patients.

Specific instructions are incorporated into Reliance dry chemistry labeling to provide guidance to follow in the unusual event of inadvertant exposure.

Self Decontamination Cycles

Effectiveness of Decontamination Cycles

STERIS Corporation conducted testing to demonstrate the effectiveness of the Reliance EPS's D-LONG and D-SHORT decontamination cycles. A baseline evaluation of a Reliance EPS Processor used in a clinical setting for in-use studies was conducted. The processor had been used to high level disinfect clinically used endoscopes and accessories over a period of months and was then left undisturbed at the conclusion of the testing. At the time of the baseline evaluation, the processor had been sitting idle for several weeks. Biofilm was not microbiologically detected at any of the 26 processor sampling sites.

D-LONG Evaluation

A biofilm was intentionally established within the Reliance EPS Processor by inoculating the processor with $>10^9$ colony forming units (CFU) of *Pseudomonas aeruginosa* in diluted growth medium. The microbial contamination was circulated through the processor and the unit was allowed to sit idle for five days under ambient moist conditions. After five days, the processor chamber was rinsed briefly to remove non-attached bacterial contamination. Thirty sites within the processor were then sampled to confirm the presence of a biofilm. Recovered contamination ranged from 5.4×10^5 – 2.0×10^8 CFU/site. A D-LONG cycle was then performed and the sites were re-sampled. No contamination was detected after the D-LONG cycle (due to the sampling method, these results are expressed as <5 CFU/site) **(Table 17)**.

D-SHORT Evaluation

Immediately following the D-LONG cycle evaluation, the processor was re-inoculated with $>3 \times 10^8$ CFU of *Pseudomonas aeruginosa*. The contamination was circulated throughout the processor and the processor was allowed to sit idle for 48 hours. The same 30 sites as evaluated for the D-LONG cycle were evaluated in the D-SHORT tests. An initial contamination level was determined prior to initiating the D-SHORT cycle, with bacterial counts ranging from 1.2×10^2 – 2.1×10^4 CFU, although there were several sites that did not exhibit any contamination (<5 CFU/site). A D-SHORT cycle was performed and the processor re-sampled. No contamination was detected (due to the sampling method, these results are expressed as <5 CFU/site). **(Table 17)**. A second evaluation of the D-SHORT cycle was conducted, using the same methodology as in the first. In this case, fewer sites showed evidence of contamination before the D-SHORT cycle. After the D-SHORT cycle, no contamination was detected.

Table 17: D-LONG and D-SHORT Decontamination Cycles

D-LONG		D-SHORT			
Microbial Load after Five Days of Incubation (CFU/site)	Recovery after D-LONG Cycle (CFU/site)	Microbial Load after Two Days of Incubation (CFU/site)	Recovery after First D-SHORT Cycle (CFU/site)	Microbial Load after Two Days of Incubation (CFU/site)	Recovery after Second D-SHORT Cycle (CFU/site)
5.4×10^5 to 2.0×10^8	None detected (<5 CFU/site)	1.2×10^2 to 2.1×10^4	None detected (<5 CFU/site)	$<5 \times 10^0$ to 1.9×10^3	None detected (<5 CFU/site)

Conclusion

The two decontamination cycles provided by the Reliance EPS, D-LONG and D-SHORT, help to prevent the formation of biofilm within the Reliance EPS Processor.

Summary of Testing Results

The summary test data in this Technical Data Monograph demonstrates the microbial efficacy, material compatibility, toxicity/ residual and self decontamination testing for the Reliance EPS Endoscope Processing System. The material presented in this document shows that the Reliance EPS is capable of high level disinfection of semi-critical medical devices.

REFERENCES

1. Alfa, MJ, Degagne P, Olson N. Worst-case soiling levels for patient-used flexible endoscopes before and after cleaning. AJIC. Oct. 1999, pg. 392-401.
2. S. Block, 4th Edition 1991.
3. Justi, C. Amato V, Antloga K, Harrington S, McDonnell G. Demonstration of a Sterility Assurance Level for a Liquid Chemical Sterilization Process. Aentr Steril 2001; 9(3): pg. 163-176.

GUIDANCE DOCUMENTS AND STANDARDS APPLICABLE TO THE RELIANCE EPS ENDOSCOPE PROCESSING SYSTEM

The following standards and guidance documents were used in the development of the Reliance EPS:

Reliance EPS Processor

Medical Device 93/42/EEC, Class IIa, Annexes I and II

prEN 15883-1	Washer-disinfectors general requirements, definitions and tests, 04/2002.
prEN 15883-4	Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes, 07/2003.
EN 55011	Industrial, Scientific and Medical (ISM) Radio-Frequency Equipment – Radio Disturbance Characteristics – Limits and Methods of Measurement.
EN 61000, Part 4-2, 4-3, 4-4, 4-5, 4-6	Testing and Measurement Techniques
CISPR 22	Limits and Methods of Measurements of Radio Disturbance Characteristics of Information Technology Equipment.
Electro Magnetic Compatibility: CISPR 22	Limits and Methods of Measurements of Radio Disturbance Characteristics of Information Technology Equipment.
EN 50082	Electromagnetic Compatibility – Generic Immunity Standard – Part 1 Residential, Commercial and Light Industry.
EN 61326	Electrical Equipment for Measurement Control and Laboratory Use, EMC Requirements Part : General Requirements Including Amendments A1 :1998; IEC 61326 :1997 + A1 :1998
Electrical: EN/IEC-61010-1	Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use Part 1 : General Requirements (IEC 61010-1 :1990 + A1 :1992, modified +A2 :1995.
IEC-61010-2-045	Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use – Part 2-045 : Particular Requirements for Washer Disinfectors Used in Medical, Pharmaceutical, Veterinary and Laboratory Fields.
UL 3101-1, First edition, 1993	The Standard for Safety of Laboratory Use Electrical Equipment
CAN/CSA C22.2 No. 1010.1-92	Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use
Mechanical: ISO-3746	Acoustics – Determination of sound power levels of noise sources using sound pressure – Survey method using an enveloping measurement surface over a reflecting plane.
FDA Guidance	Content and Format of Premarket Notification (510K) Submissions for Automated Endoscope Washers, Washer/Disinfectors, and Disinfectors Intended for Use in Healthcare Facilities, August 1993.

Reliance Dry Chemistry

EN ISO 9001:2000	Quality Systems – Model for Quality Assurance
ISO 13485:2003/ EN 46001:96	Quality Systems – Medical Devices – Particular requirements for application of EN ISO 9001
ISO 14969:2003	Quality Systems – Medical Devices – Guidance on the application of ISO 13485 and ISO 13488
EN 724:94	Guidance on the application of EN29001 and EN46001 for non-active medical devices
EN ISO 10993-1:97	Biological Evaluation of Medical Devices, Pt 1: Evaluation and testing.
EN ISO 10993-3:92	Biological Evaluation of Medical Devices, Pt 5: Tests for cytotoxicity: in vitro methods
EN ISO 10993-10:95	Biological Evaluation of Medical Devices, Pt 10: Tests for irritation and sensitization
EN ISO 10993-11:93	Biological Evaluation of Medical Devices, Pt 11: Tests for systemic toxicity.
EN 980:96/ISO 15223:2000	Graphical Symbols for Use in Labeling Medical Devices
EN 1041:98	Information Supplied by the Manufacturer with Medical Devices
BS 5283:1986	Terms relating to disinfectants
US EPA DIS/TSS-7	Efficacy Data Requirements: Virucides
ASTM E 1053-97	Standard Test Method for Efficacy of Virucidal Agents Intended for Inanimate Environmental Surfaces.
ASTM E 1482-92	Standard Test Method for Neutralization of Virucidal Agents in Virucidal Efficacy Evaluations.
AOAC 966.04	Sporicidal Activity of Disinfectants
AOAC 965.12	Tuberculocidal Activity of Disinfectants
AOAC 955.17	Fungicidal Activity of Disinfectants

AOAC 955.14	Testing Disinfectants against *Salmonella choleraesuis*
AOAC 955.15	Testing Disinfectants against *Staphylococcus aureus*
AOAC 964.02	Testing Disinfectants against *Pseudomonas aeruginosa*
FDA CFR 21: Part 820	Quality System Regulation
Directive 92/32/EEC amending 67/548/EEC	Council Directive on the approximation of the laws, regulations, and administrative provisions relating to the classification, packaging & labeling of dangerous substances.
Directive 1999/45/EC	Council Directive concerning the approximation of the laws, regulations, and administrative provisions relating to the classification, packaging & labeling of dangerous preparations.
FDA Draft Guidance	Guidance for Industry – Stability Testing of Drug Substances and Drug Products June 1998 Ascenzi JM, Ezzel RJ, Wendt TM. A More Accurate Method for measurement of Tuberculocidal Activity of Disinfectants. Applied and Environmental Microbiology. Sept. 1987, pg. 2189 – 2192. TGA Therapeutics Good Order 54, 54A, Standard for composition, packaging, labeling and performance of disinfectants and sterilants
FDA Guidance	"Content and Format of Premarket Notification [510(k)] Submissions for Liquid Chemical Sterilants/High Level Disinfectants", 2000
Canadian Therapeutic Products Programme	Disinfectant Drugs Guidelines (1999) as per General Standards Board CAN/CGSB-2.161-97 recommendations

STERIS Chemical Indicator

EN ISO 9001:2000	Quality Systems – Model for Quality Assurance.
ISO 13485:2003/ EN 46001:96	Quality Systems – Medical Devices – Particular Requirements for application of EN ISO 9001.
ISO 14969:2003	Quality Systems – Medical Devices – guidance on the application of ISO 13485 and ISO 13488.
EN 724:94	Guidance on the application of EN 29001 and EN 46001 for non-active medical devices.
BS EN 867-2:1997	Non-biological systems for use in sterilizers – Part 2. Process indicators (Class A).
EN 980:96/ISO 15223:2000	Graphical Symbols for Use in Labeling Medical Devices
EN1041:98	Information Supplied by the Manufacturer with Medical Devices
FDA CFR21: Part 820	Quality System Regulation
FDA Guidance	"Content and Format of Premarket Notification [510(k)] Submissions for Liquid Chemical Sterilants/High Level Disinfectants", 2000

Klenzyme Enzymatic Presoak and Cleaner

EN ISO 9001:2000	Quality Systems – Model for Quality Assurance
EN 46001:96	Quality Systems – Medical Devices – Particular Requirements for application of EN ISO 9001
21 CFR Parts 808, 812 and 820	Medical Devices ; Current Good Manufacturing Practice (CGMP) ; Quality System Regulation

CIP 200 Acid-Based Process and Reseach Cleaner

EN ISO 9001:2000	Quality Systems – Model for Quality Assurance
EN 46001:96	Quality Systems – Medical Devices – Particular Requirements for application of EN ISO 9001

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