

Technical Data Monograph

Resert™ HLD

High Level Disinfectant-Chemosterilant

STERIS®



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Introduction

This Technical Data Monograph demonstrates the performance of Resert™ HLD High Level Disinfectant-Chemosterilant, including the microbiocidal efficacy, materials compatibility, and toxicity/ residuals on medical devices.

Consumables

Resert HLD High Level Disinfectant-Chemosterilant

The Resert HLD solution is an odorless, ready to use liquid chemical germicide formulated for the reprocessing of heat sensitive medical devices, such as rigid and flexible endoscopes, and their accessories. The solution can be used in manual soak applications or automated endoscope reprocessing systems designed to be compatible with oxidizing germicides, such as hydrogen peroxide.

The principal components in the Resert HLD formulation include:

- 2% hydrogen peroxide (active germicide)
- pH stabilizers
- Metal ion and hardness water chelating agents
- Corrosion inhibitors



The Resert HLD solution has been formulated as a safe and easy-to-use liquid germicide for healthcare workers and the environment. It has a 12-month shelf life and needs no special venting during use or storage. Resert HLD solution is safe for direct disposal into sanitary sewers, and has no air-shipping restrictions.

Once opened and/or placed into a secondary container (i.e. basin), Resert HLD solution can be re-used for up to 14 days, or unless its minimum effective concentration (MEC) falls below 1.8% hydrogen peroxide. The MEC must be monitored before each use using the 2% AHP test strips.

2% AHP Test Strip Chemical Indicator

The 2% AHP Test Strip Chemical Indicators (Part No. AHP2) are easy-to-use dip and read reagent strips for a pass or fail determination of MEC in the Resert HLD solution. A new 2% AHP test strip is used before each processing cycle.

Performance Evaluations

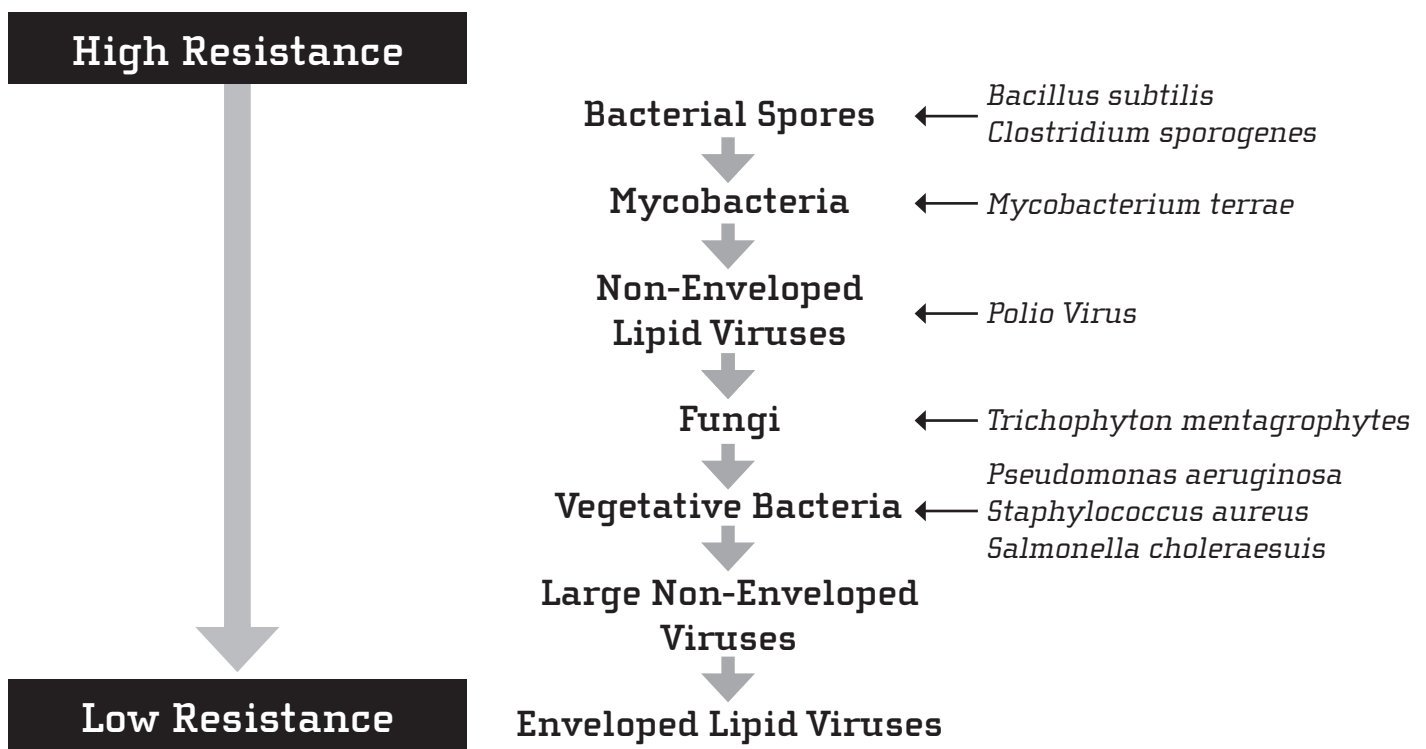
Microbial Efficacy Testing

The Resert HLD solution has been validated to be sporicidal, tuberculocidal, virucidal, bactericidal and fungicidal. Microbial efficacy testing was conducted using the following procedures with different organisms to demonstrate the broad applications for use and validate the efficacy of the Resert HLD solution.

- Quantitative Carrier Test (QCT-1) *in-vitro* method to determine the potency of Resert HLD solution. The QCT-1 test was developed and conducted by Dr. Syed Sattar at the Centre for Research in Environmental Microbiology (CREM), University of Ottawa (Ottawa, Canada).
- Manual Re-use Protocol to simulate worst case challenge to devices exposed to the Resert HLD solution. The protocol was based on the Manual Re-use Stress method created by the U.S. EPA (1984).

As depicted in Figure A, a wide variety of test organisms, from those with low resistance to most germicides (vegetative bacteria), to organisms with the highest known resistance (bacterial spores), were tested after exposure to the Resert HLD solution.

Figure A:



QCT-1

QCT-1 testing of the Resert HLD solution was conducted under *in-vitro* worst case conditions as indicated below:

- High organic challenge (2% fetal bovine serum)
- Time and temperature
 - 6 hour exposure for sporocidal at 20°C
 - 5 minute exposure for tuberculocidal, fungicidal and bactericidal at 20± 2°C
 - 5 minute exposure for virucidal at 23± 1°C
- Hydrogen peroxide concentration (1.73%)

Testing was performed with three lots of Resert HLD solution. A total of 30 glass vial carriers per organism type, each loaded with $\geq 1 \times 10^6$ colony forming unit (cfu)/carrier, were tested. Acceptable performance (Pass) was determined for the Resert HLD solution lots when no carriers exhibited growth following completion of the worst case test exposure. In addition, the testing met the acceptance criteria for positive controls, negative controls, neutralization and growth promotion.

Table 1: Microbial Efficacy Testing with Resert HLD High Level Disinfectant-Chemosterilant

Test	Organism	Result
Sporicidal	<i>Bacillus subtilis</i>	Pass
	<i>Clostridium sporogenes</i>	Pass
Tuberculocidal	<i>Mycobacterium terrae</i>	Pass
Virucidal	<i>Polio Virus, Sabin ATCC VR-192</i>	Pass
Fungicidal	<i>Trichophyton mentagrophytes</i>	Pass
Bactericidal	<i>Pseudomonas aeruginosa</i>	Pass
	<i>Staphylococcus aureus</i>	Pass
	<i>Salmonella choleraesuis</i>	Pass

Manual Re-use Stress

Twenty liters of each of three lots of Resert HLD solution were stressed each day over a 14 day period by challenge the solutions with two types of test carriers, Pyrex® glass beads and stainless steel penicylinders, contaminated and dried with *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Salmonella choleraesuis*, *Bacillus subtilis* and *Clostridium sporogenes*. A cumulative bioburden count of at least 10⁴ cfu/mL/day was achieved. Additionally, one complete set of inhalation equipment was added to each batch of test solution three times daily to further challenge the solution.

Table 2: Manual Re-use Stress

TEST	ORGANISM	RESULT
Sporicidal	<i>Bacillus subtilis</i>	Pass
	<i>Clostridium sporogenes</i>	Pass
Tuberculocidal	<i>Mycobacterium terrae</i>	Pass
Virucidal	<i>Polio Virus, Sabin ATCC VR-192</i>	Pass
Fungicidal	<i>Trichophyton mentagrophytes</i>	Pass
Bactericidal	<i>Pseudomonas aeruginosa</i>	Pass
	<i>Staphylococcus aureus</i>	Pass
	<i>Salmonella choleraesuis</i>	Pass

Conclusion of Microbial Efficacy Testing

Resert HLD High Level Disinfectant-Chemosterilant has been shown to be sporicidal, tuberculocidal, virucidal, fungicidal, and bactericidal.

Materials Compatibility

STERIS evaluated the compatibility of Resert HLD solution on materials of construction used in the manufacturing of medical devices, such as flexible and rigid endoscopes, including endoscope accessories and cleaning adapters, and representative manual (i.e. soak basins) and automated endoscope reprocessing (AER) system components. The original equipment manufacturer's (OEM) devices and components were examined after multiple treatment cycles for evidence of:

- Cosmetic changes (i.e. corrosion, surface pitting, oxidation, discoloration) using visual analysis
- Functional changes using flow and leakage testing
 - Degradation in channel flow dynamics
 - Leakage testing
 - Degradation in device performance
 - Changes in mechanical resistance
 - Defects in lens adhesive
 - Loss of tubing and o-ring flexibility using weight analysis

The OEM 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, polyethylene, polytetrafluoroethylene, and stainless steel. In addition, these scopes contained the critical endoscope functional features and systems; angulation system, light guide fibers, suction control, and an air/water delivery system.

The OEM components selected had critical design features found in the disinfectant circulation route of all manual and automated endoscope reprocessing systems, where applicable: device soak basin, and liquid chemical germicide (LCG) reservoir, drain valve assembly, disinfectant valve assembly, water regulator, water filter, and pump. Each of these design components are manufactured with the same basic materials: stainless steel, polyurethane, polyethylene, polysulfone, and polycarbonate.

Trained STERIS employees and a third party repair facility determined through independent evaluation that the cosmetic integrity and functional performance of the original equipment manufacturers instruments were acceptable at the end of the evaluation.

Representative Endoscopes and Endoscope Accessories

A total of seven representative flexible Original Equipment Manufacturer (OEM) endoscopes along with the endoscope accessories and cleaning adapters were immersed in soaking basins containing Resert HLD solution and processed for up to 1000 cycles.

At the completion of the exposure, the OEM devices were removed from the basins and evaluated for evidence of changes in functional and cosmetic appearances, as listed above. The cosmetic and mechanical performance of the valves and accessories were also evaluated. A "Pass" result was determined when device functionality was not affected by exposure in the Resert HLD solution. No significant cosmetic changes, (i.e. corrosion and excessive wear) occurred with the devices, nor was functionality of any of the test devices affected.

Table 3: Representative Endoscopes

Manufacturer	Device	Equivalent Number of Cycles	Results
Fujinon	Flexible Colonoscope Bite Block	> 1000	Pass
Karl Storz	Flexible Cystoscope	> 300	Pass
	Mycobacterium terrae		
Olympus®	Flexible Duodenoscope Suction Control Valve Air Water Feeding Valve Irrigation Tube	> 1000	Pass
	Rigid Resectoscope Camera Head Fiberoptic Cord	> 300	Pass
Pentax®	Flexible Colonoscope Suction Control Valve Air/Water Feeding Valve Water Jet Connector Cap Biopsy Valve Cap Channel Cleaning Brush	> 1000	Pass
Stryker®	Camera Head	> 300	Pass

OEM Cleaning Adapters

Additionally, select OEM flexible endoscope cleaning adapters were tested for material compatibility for no less than 400 cycles.

Table 4: OEM Cleaning Adapters

Manufacturer	Device	Equivalent Number of Cycles	Results
Fujinon	Cleaning Adapter Set	> 400	Pass
Olympus	Channel Plug		Pass
	Injection Tube		Pass
Pentax	Dual Suction/Airwater Valve Cap		Pass
	Air water port adapter		Pass

AER System Materials of Construction

New and previously exposed materials from the Medivators™ DSD-91E and DSD-201 Reprocessing Systems were assembled together to simulate the route by which disinfectant is circulated throughout the AER system. The simulated AER test system was exposed to Resert HLD solution for an equivalent of no less than 12,000 cycles. The cosmetic and functional integrity of the materials were evaluated and shown to be retained at the end of the study.

Table 5: AER System Components

COMPONENT	EQUIVALENT NUMBER OF CYCLES	RESULT
Basin	> 12,000	Pass
Water Regulator		Pass
Sporox Compatible Disinfectant Filter		Pass
GA/Sporox Compatible High Sediment 0.2 water filter		Pass
LCG Reservoir		Pass
Disinfectant Pump		Pass
Drain Valve Assembly		Pass
Disinfectant Valve Assembly		Pass
Heater Assembly		Pass

Conclusion of Material Compatibility Testing

Testing with Resert HLD solution showed no functional or performance damage (change) for endoscopes and endoscope accessories after processing for between approximately 300 and 1000 cycles. OEM cleaning components showed no damage (change) after approximately 400 cycles. There were no significant cosmetic changes, (i.e. corrosion and excessive wear) that occurred, nor was the functionality of the devices affected.

Moreover, compatibility testing of the materials used in the construction of the Medivators DSD-91E and DSD-201 Reprocessing Systems has shown that static immersion causes no functional damage to materials as a result of short and long term exposure.

Toxicity and Residue Testing

Toxicity testing of the Resert HLD solution was performed to determine the safety risks, if any, associated with human contact with these materials. Despite the solution being acidic, the use dilution form of the product was shown to have no corrosive effect on the skin at in use concentrations, although some irritation may occur in those users who are sensitive to some of the solution components.

A third party, *in-vitro* biocompatibility test was performed at NAMSA, Inc., Northwood, OH, to determine whether the Resert HLD potentially degraded materials and/or caused the formation of residues on medical devices that could pose a risk to the patient. A representative medical device was processed through four consecutive, five minute high level disinfectant exposure cycles (20 minutes), and three deionized water rinses. At the conclusion of the exposures, the device was submerged in deionized water and placed into an incubator set to 37°C to extract any residues present. In addition to testing the extraction samples for *in-vitro* biocompatibility, they were also assayed to measure the amounts of any residual chemicals.

The final rinse and extract samples showed no evidence of cell lysis or toxicity using the ISO certified iso-elution *in-vitro* biocompatibility method with mouse fibroblast cells. Moreover, the final rinse and extraction samples confirmed that any amount of Resert HLD solution remaining on devices were well below the acceptable daily intake amount.

Guidance Documents and Standards Applicable to the Resert HLD High Level Disinfectant-Chemosterilant

The following standards and guidance documents were used in the development of Resert HLD High Level Disinfectant-Chemosterilant

EN ISO 9001:94

Canadian Therapeutic Product Program Disinfectant Drugs Guidelines (1999)

ASTM International. Standard Test Method for Efficacy of Virucidal Agents Intended for Inanimate Environmental Surfaces Designation E 1053-97. ASTM International; 2002

EN ISO 10993-5 (1992) Biological Evaluation of medical devices Part 5: Tests for cytotoxicity: *in vitro* methods

ASTM International. Standard quantitative carrier test method to evaluate the bactericidal, fungicidal, mycobactericidal and sporicidal potencies of liquid chemical germicides (E 2111-05). Vol. 11.05. Conshohocken, PA: ASTM International; 2005.

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