Technical Data Monograph

Revital-Ox™ RESERT®
High Level Disinfectant

STERIS®

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1 Introduction

This Technical Data Monograph demonstrates the performance of Revital-Ox RESERT High Level Disinfectant, including the microbiocidal efficacy, materials compatibility, and toxicity testing.

2 High Level Disinfectant Overview

Revital-Ox RESERT High Level Disinfectant

Features: The Revital-Ox RESERT HLD solution is an odorless, ready to use liquid chemical high level disinfectant formulated for the reprocessing of heat sensitive, semi-critical medical devices, such as flexible endoscopes, and their accessories. The solution can be used in manual soak applications or automated endoscope reprocessing systems designed for use with legally cleared, high level disinfectant solutions such as those containing hydrogen peroxide.

Ingredients: The principal components in the Revital-Ox RESERT HLD formulation include:

- 2% hydrogen peroxide (active germicide)
- Buffers
- Metal ion and hardness water chelating agents
- Corrosion inhibitor

Performance Benefits: The Revital-Ox RESERT HLD solution has been formulated to be a safe and easy-to-use liquid high level disinfectant that is environmentally friendly. It has an 18-month shelf life and needs no special venting during use or storage. Revital-Ox RESERT HLD solution may be disposed directly into sanitary sewers.

Use Conditions: After opening, the solution may be stored for use up to 90 days (provided the 90 days does not extend past the expiration date on the container). When poured into a secondary container (i.e. basin), Revital-Ox RESERT HLD solution can be re-used for up to 21 days, or until its concentration falls below the minimum recommended concentration (MRC) of 1.5% hydrogen peroxide. The MRC must be monitored before each use using the Revital-Ox™ RESERT® R60 Solution Test Strip.

Revital-Ox RESERT R60 Solution Test Strip

The Revital-Ox RESERT R60 Solution Test Strip is an easy-to-use dip and read reagent strip for the pass or fail determination of the MRC in Revital-Ox RESERT HLD solution. Because Revital-Ox RESERT HLD solution is reusable, a new test strip is necessary to verify the concentration of hydrogen peroxide in the solution before each processing cycle.

3 Performance Testing

21 Day Stress Testing

Purpose: The stressing procedure is designed to simulate a worst case circumstance of organic loading that might occur when disinfectant solutions are repeatedly reused.

Scope: Revital-Ox RESERT HLD solution at MRC was stressed repeatedly, according to the EPA Use Reuse Method, by adding the following medical equipment and carriers comprised of porcelain penicylinders and glass beads (6 mm).

Medical Equipment - for each 2.5 gallons of solution

- Two sections of corrugated rubber tubing (3-4 ft each)
- One 2-3 liter rebreathing bag
- Face Mask
- Endotrachial Tube
- Y connector

Microorganisms

- *Staphylococcus aureus* ATCC 6538 (non-spore forming)
- *Pseudomonas aeruginosa* ATCC 15442 (non-spore forming)
- *Salmonella enterica* ATCC 10708 (non-spore forming)
- *Bacillus subtilis* ATCC 19659 (spore forming)
- *Clostridium sporogenes* ATCC 3584 (spore forming)

Three lots of Revital-Ox RESERT HLD were challenged each day for up to 21 days at 20±2°C by adding contaminated carriers with microorganisms dried on them. Glass bead carriers contaminated with vegetative non-spore forming bacteria were added to the containers with the disinfection solution and allowed to soak for 10-60 minutes daily. Porcelain carriers contaminated with viable spores were added each day, and permitted to soak over night. Hydrogen peroxide was measured at 1, 7, 14, and 21 days. Test organisms were quantified and resistance measured (spore forming organisms only). The results of the test are reported in **Table 1**.

Table 1: Hydrogen Peroxide for Three Lots of Revital-Ox RESERT HLD Solution After 21 Days Stressing.

Day	Lot 1	Lot 2	Lot 3
	H_2O_2%	H_2O_2%	H_2O_2%
Pre-Day 1	1.56	1.56	1.56
Post-Day 7	1.55	1.55	1.55
Post-Day 14	1.50	1.50	1.51
Post-Day 21	1.50	1.50	1.51

Conclusion: Over the 21 day stress period, no significant changes were observed for three lots of Revital-Ox RESERT HLD in hydrogen peroxide concentration (1.56 – 1.50%). The solutions were shown to be stable after 21 days of worst case stressing, and suitable for further tests to evaluate potency under in-vitro, Simulated Use, and In Use conditions.

4 Microbial Efficacy Testing

In-vitro Potency

Purpose: To demonstrate that Revital-Ox RESERT HLD solution is sporicidal, tuberculocidal, virucidal, bactericidal, and fungicidal.

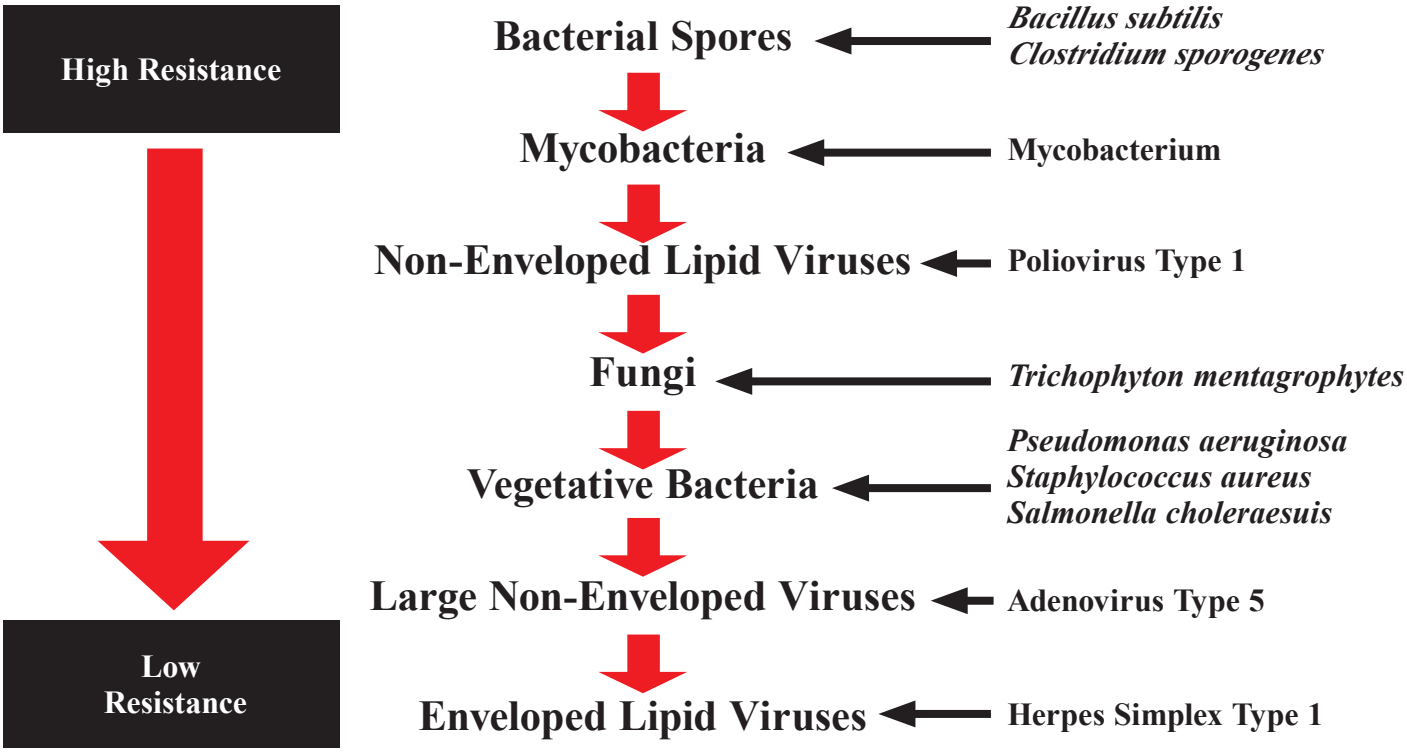
Scope: Microbial efficacy testing was conducted under worst-case stressing and bioburden loads, according to the following methods outlined in **Table 2:**

Table 2: Microbial Potency of Revital-Ox RESERT HLD Solution

Test	Test Method	Organism	Result	Result
Bactericidal (8 minutes)	AOAC 955.14 *Salmonella cholerasuis*	*Salmonella enterica* ATCC 10708	0/60 Positive Carriers	Passed
	AOAC 955.15 *Staphylococcus aureus*	*Staphyloccocus aureus* ATCC 6538	0/60 Positive Carriers	Passed
	AOAC 964.02 *Pseudomonas aeruginosa*	*Pseudomonas aeruginosa* ATCC 15442	0/60 Positive Carriers	Passed
Fungicidal (8 minutes)	AOAC 955.17 Fungicidal	*Trichophyton mentagrophytes* ATCC 9533	0/2 Positive Tubes	Passed
Virucidal (8 minutes)	US EPA DIS/TSS-7 (November 1981) "Efficacy Data Requirements: Virucides"	Poliovirus Type 1 Chat Strain (ATCC VR-1562)	≥ 3.42 log10 Reduction No survivors	Passed
		Herpes Simplex Type 1 ATCC VR-260	≥ 3.10 log10 Reduction No survivors	Passed
		Adenovirus Type 5 (ATCC VR-5)	≥ 3.22 log10 Reduction No survivors	Passed
Tuberculocidal (8 minutes)	Asenzi Quantitative Suspension Test	*Mycobacterium terrae* ATCC 15755	6.08 log10 Reduction	Passed
	prEN 14563 Carrier Test		6.63 log10 Reduction	Passed
Sporicidal (6 hours)	AOAC 966.04 Sporicidal Activity of Disinfectants	*Bacillus subtilis* ATCC 6633	0/360 Positive Carriers	Passed
		Clostridium sporogenes ATCC 3584	0/360 Positive Carriers	Passed
	AOAC Confirmatory Sporicidal	*Bacillus subtilis* ATCC 6633	0/120 Positive Carriers	Passed
		Clostridium sporogenes ATCC 3584	0/120 Positive Carriers	Passed
	EN 14347	*Bacillus subtilis* ATCC 6633	6.66 log10 Reduction 45 minute D-value	Passed
		Clostridium sporogenes ATCC 3584	6.51 log10 Reduction 27 minute D-Value	Passed

Conclusion: A wide variety of test organisms, from those having low resistance to most germicides (vegetative bacteria) to organisms known to be highly resistant (bacterial spores), were employed to demonstrate the effectiveness of Revital-Ox RESERT HLD solution, as shown in Figure A.

Figure A. Correlation of Microbial Resistance to Organisms Tested in Revital-Ox RESERT HLD Solution



Simulated Use (Instrument) Testing

Purpose: To demonstrate the effectiveness of stressed Revital-Ox RESERT HLD solution to high level disinfect medical instruments under worst-case, laboratory conditions.

Scope: The Simulated Use Test was performed with stressed, out of specification Revital-Ox RESERT HLD (1.54% hydrogen peroxide). Five clinical endoscope sets comprised of flexible endoscopes, procedural endoscope accessories (i.e. valves), and cleaning accessories were challenged, in triplicate, with *Mycobacterium terrae* ATCC 15755 under worst-case temperatures (18-19°C), and organic (5% serum, final v/v), and inorganic (400 ppm AOAC hard water) soil conditions. The devices were prepared for full immersion according to the device manufacturers' instructions (minimal channel flush/fill of 90 mL), and statically soaked for 8 minutes. Afterwards, the devices were immediately removed from the disinfectant solution and drained without rinsing. Select external surfaces and all internal surfaces (channels) were neutralized using an elution fluid containing 0.1% catalase. The neutralized fluid was collected, filter plated onto prepared Middlebrook 7H11 agar enriched with Middlebrook OADC, and incubated for ≥14 days at 37±2°C. Test samples were enumerated and the decimal log reductions calculated by comparing to positive control bioburden counts from inoculated clinical endoscopes sets not exposed to the disinfectant solution.

Conclusion: Revital-Ox RESERT HLD passed the Simulated Use Test by effectively reducing the decimal log population of test organism in all five clinical endoscope sets by an overall mean value of 7.42 (6.86-8.55 log10 reduction), as shown in **Table 3**. The test demonstrated that stressed Revital-Ox RESERT HLD is effective in simulated use conditions.

Table 3: Simulated Use Efficacy of Revital-Ox RESERT HLD Solution.

Manufacturer/ Model Number	Clinical Set/Accessory	External Surface Site	Internal Surface (Channel)	Log Reduction
Olympus	Bronchoscope	CH, BR	SB	7.67
	Duodenoscope	CH, BR	SB, AW, EGW	7.09
	Biopsy Valve	Entire Surface		
	Suction Valve	Entire Surface		
	Air/water Valve	Entire Surface		
Pentax	Dual Biopsy Colonoscope	CH, BR	SB (2), AW, WJ	8.55
	Biopsy Valve	Entire Surface		
	Suction Valve	Entire Surface		
	Air/water Valve	Entire Surface		
	Channel Selector	Entire Surface		
	Channel Cleaning Brush	Coil	N/A	
Fujinon	Duodenoscope	CH, BR	SB, AW	6.86
	FOV-DV7 Biopsy Valve	Entire Surface		
	SB 500/G Suction Valve	Entire Surface		
	AW 500/G Air/water Valve	Entire Surface		
	Fujinon MPC-ST Bite Block	Entire Surface		
Karl Storz	Flexible Cystoscope	CH, BR	SB	6.92

CH = Control Handle; BR = Bending Rubber on Distal Tip of Insertion Tube; SB = Suction/Biopsy; AW = Air/water EGW = Elevator Guide Wire; WJ = Water Jet

In Use (Instrument) Testing

Purpose: The purpose of this test is to demonstrate the efficacy of Revital-Ox RESERT HLD under clinical use conditions.

Scope: In Use testing was performed using manually cleaned, patient soiled flexible endoscopes (clinical endoscope sets) intended for use in any one of four patient access points, as follows

- Nasopharyngeal
- Gastro-intestinal
- Colon/Small Bowel
- Urogenital

The manual soak procedure was performed by hospital personnel, according to the Revital-Ox RESERT HLD instructions for use and the instrument manufacturer's reprocessing instructions, and consisted of:

- Pre-cleaning the devices
- Reprocessing the devices for 8 minutes at ≥ 20°C in a manual soak basin containing Revital-Ox RESERT HLD
- Performing a one minute rinse of the devices in 10 liters of water with 90 mL purged through each device channel.

Following the procedure, the instruments were sampled to validate the efficacy of Revital-Ox RESERT HLD solution under In Use, clinical test conditions.

Conclusion: Pre-cleaned, representative patient soiled endoscopes were manually reprocessed in Revital-Ox RESERT HLD for 8 minutes at ≥ 20°C, and shown to be effectively high level disinfected under In Use test conditions, as demonstrated in **Table 4**.

Table 4: In Use Efficacy of Revital-Ox RESERT HLD Solution.

Total Colony Forming Units (CFU) for Devices Based Upon Exposure Route of Entry Into a Patient				
Test Trial	**Nasopharyngeal Route Olympus Bronchoscope**	**Colon/Small Bowel Route Olympus Colonoscope**	**Gastro-Intestinal Route Olympus Duodenoscope & Gastroscope**	**Urogenital Route ACMI Ureteropyeloscope**
Pre-Clean Control	204	1.33×10^7	1.78×10^6	3
Post- Clean Control	1.16×10^4	7.40×10^3	1.87×10^3	41
High Level Disinfection	0	0	0	0
	0	0	0	0
	0	0	0	0

5 Materials Compatibility

Compatibility: Substrate

Purpose: To demonstrate the compatibility of Revital-Ox RESERT HLD solution with various materials used in the construction of semi-critical medical devices.

Scope: The cosmetic and functional compatibility of materials used in the construction of semi-critical medical devices, such as flexible endoscopes and automated endoscope reprocessing (AER) systems, were evaluated in Revital-Ox RESERT HLD solution. The solution was prepared to be at or above the maximum manufacturing specification for hydrogen peroxide, and tested under static continuous immersion at 25±2ºC to simulate worst case conditions for product use. The following materials were evaluated by trained STERIS employees and found to be **compatible** with Revital-Ox RESERT HLD solution:

Plastics:

- Acrylic, Acrylonitrile-butandiene-styrene (ABS), High Density Polyethylene (HDPE), Nylon, Lexan® polycarbonate, Polyester, Polypropylene, Radel® polyphenylsulfone, Polystyrene, Udel® polysulfone, Polyvinyl Chloride (PVC), and Teflon® polytetrafluoroethylene polymer

Elastomers:

- Ethylene Propylene Diene Monomer rubber (EPDM)42, Neoprene® chloroprene synthetic rubber, Polyurethane, Red Natural Rubber, Silicone Rubber, and Viton®-A fluoroelastomer

Metals:

- Aluminum 1100, Aluminum 6061AN (anodized aluminum), Chrome Plated Steel, Gold Plated Steel, C1010 Mild Steel, Solder 30 Sn/70 Pb, and Stainless Steel (302, 316, and 410)

Revital-Ox RESERT HLD is not compatible with the following materials under any conditions of use:

- Brass, Chrome Plated Brass, Copper, Monel S, Nickel Plated Steel, Silver, and Tungsten Carbide

Revital-Ox RESERT HLD is **compatible** with **secondary storage containers** made from the following materials:

- Acrylonitrile-butandiene-styrene (ABS)
- High Density Polyethylene (HDPE)
- Polycarbonate
- Polyethylene
- Polypropylene
- 316 Stainless Steel

Conclusions: Testing demonstrated that Revital-Ox RESERT HLD solution prepared above the maximum manufacturing specification for hydrogen peroxide was compatible with the most common materials of construction used in semi-critical medical devices such as flexible endoscopes. A summary of materials tested is shown in **Table 5**.

Table 5: Material Compatibility Comparison Matrix for Revital-Ox RESERT HLD.

Materials	Compatibility with Revital-Ox RESERT HLD
Plastics:	
Acrylic	YES
Acrylonitrile-butadiene-styrene (ABS)	YES
High Density Polyethylene (HDPE)	YES
Nylon	YES
Polycarbonate	YES
Polyester	YES
Polypropylene	YES
Polyphenylsulfone	YES
Polyvinyl Chloride (PVC)	YES
Fluorocarbon (PTFE)/Teflon®	YES
Elastomer:	
Ethylene Propylene Diene Terpolymer (EPDM)	YES
Neoprene	YES
Polyurethane	YES
Red Natural Rubber	YES
Silicone	YES
Viton A	YES
Metals:	
Aluminum	YES
Anodized Aluminum (6061)*	YES
Chrome Plated Steel	YES
Gold Plated Steel	YES
Mild Steel	YES
Solder 70/30	YES
Stainless Steel (302,316,410)	YES
Brass**	NO
Chrome Plated Brass**	NO
Copper**	NO
Monel S**	NO
Nickel Plated Steel**	NO
Silver**	NO
Tungsten Carbide**	NO

* cosmetic change in color can occur in anodized aluminum due to wide variety of anodization process.

** not compatible under any use condition

Compatibility: Devices and Automated Endoscope Reprocessing Systems

Purpose: To demonstrate the compatibility of Revital-Ox RESERT HLD with OEM medical devices.

Scope: Testing was performed to confirm the compatibility of Revital-Ox RESERT HLD with the following representative semi-critical devices and device accessories shown in **Table 6**. OEM instruments were placed under static, continuous immersion ranging from 12.4 hours to 134 hours (93 to 1005 cycles).

The OEM devices and accessories shown in **Table 6** represent those tested to confirm compatibility with a wide variety of commonly used semi-critical devices per STERIS's device validation program. Therefore not all compatible devices will be listed. STERIS's device validation program often works directly with device manufacturers to validate devices for materials compatibility. Validation work completed with device manufacturers and incorporation into device Instructions for Use include: **Aloka, BK Medical, ConMed, Cook Medical, EndoChoice, Esaote, Karl Storz, Medovations, PCI Medical, Optim, Philips, Richard Wolf, Sandhill, Siemens, Sonoscape, Toshiba, Unisensor, Verathon, Volk Optical, Zonare.** Testing continues through STERIS's device validation program; contact STERIS or the device manufacturer for updates.

Table 6: Validated Materials Compatibility of Representative Devices and Accessories

Device Manufacturer	Device Name	Model Number
Olympus	Flexible Cystoscope	CYF-4
	Flexible Cystoscope	CYF-5
	Flexible Colonoscope	CF-140L
	Flexible Colonoscope	CF-H180AL
	flexible Colonoscope	CF-HQ190L
	Flexible Duedenoscope	JF-140F
	Flexible Gastroscope	GIF-XP160
	Flexible Ultrasound Endoscope	GF-EU160
	Flexible Ultrasound Endoscope	GF-UM160
	Flexible Ultrasound Endoscope	GF-UC140P
	Olympus Camera Head w/ Fiberoptic Cable	MH-201
	Air/Water Valve	MB-197
	Air/Water Valve	MH-438
	Biopsy Brush	MH-507
	Biopsy Valve	MB-358
	Bite Block	MB-142
	Channel Plug	MH-944
	Irrigation Tube	MAJ-855
	Suction Valve	MH-443
	Injection Tube	MH-946
	Water Bottle	MAJ-901
	Rigid Resectoscope	A2011A
Pentax	Flexible Colonoscope	EC-3831LK
	Flexible Colonoscope	EC-3890TLK
	Video Small Bowel Endoscope	VSB-3440
	Cleaning Brush	CS6015S
	Suction Valve	OB-B76
	Biopsy Valve	OF-B70
	Air/Water Port	OF-G117
	Suction/ Air-water Valve Cap	OF-B115
	Water Jet Adaptor	OF-B72
Fujinon	Flexible Colonoscope	EC-250 HL5

Device Manufacturer	Device Name	Model Number
Gyrus ACMI	Ureteroscope	DUR-8
	Aligator Forceps	8393.0002
BK Medical	Camera Head	5514961
	Camera Head Coupler	5261.32
Boston Scientific	SpyGlass Direct Visualization Probe	M00546030
ConMed	American Dilator 15F	00270
	American Dilator 60F	00291
Ecleris	Sinuscope	SN0430175
	Flexible Video Laryngoscope	EX1
Guard RFID Solutions	TotGuard™ Umbilical Tag	UT-1BLF
GE Healthcare	Transducer	RIC5-9-RS
	Transducer	RIC5-9-D
	Transducer	E8C
	Transducer	6.5 MTZ
	Transducer	IC5-9
	Transducer	RIC5-9
Hitachi	BiPlane Urology Probe	EUP-CC531
Medovations	Bougies	1206-XX
	Bougies	1207-XX
	Bougies	1208-XX
	Bougies	1209-XX
	Bougies	1210-XX
	Bougies	1212-XX
	Dilators	1214-XX
Neoprobe	Quantrix/OR 8 MHz Flex Probe	4216
	Quantrix/OR 4 MHZ Flex Probe	4292
	Detector Probe Cables	2024/2060
	Detector Probe Collimator	1013
Siemens	TEE Probe	Accuson TE-V5Ms
Scholly Fiberoptic	Flexible Naso-pharyngoscope	31.1001s
	Zoom endo-coupler	05.0059/05.0060s/05.0063x/05.0065s/ PV124s/PV126S
Stryker	Camera Head	782

Revital-Ox RESERT HLD has been shown to be compatible with non-plated, stainless steel rigid devices, such as rigid cystoscopes, when tested on a respective set of rigid scopes with continuous submersion in Revital-Ox RESERT HLD for at least 40hrs (or the equivalent of 480 cycles) at 25C. As such, Revital-Ox RESERT HLD can be used on rigid devices composed of compatible materials in cases where high level disinfection is appropriate.

Note: Many rigid scopes, depending on clinical applications, may require sterilization. Revital-Ox RESERT HLD is not cleared for use as a sterilant and is therefore not appropriate for use on rigid devices that require sterilization. It is necessary to follow the manufacturer's reprocessing instructions for such rigid devices.

Plated or soft metals are rarely used in the construction or repair of rigid devices; however, if present, these materials could be damaged by exposure to Revital-Ox RESERT HLD. Please refer to **Table 5** of this Technical Data Monograph for a list of soft metals this chemistry is not compatible with. If a device's construction is not known when determining compatibility with Revital-Ox RESERT HLD, contact the device manufacturer.

Purpose: To demonstrate the compatibility of Revital-Ox RESERT HLD with materials used in the construction of automated endoscope reprocessing (AER) systems and whole AER units under extended contact times.

Scope: Testing was performed to confirm the compatibility of Revital-Ox RESERT HLD with the materials used in the construction of representative AER systems shown in **Table 7** and whole AER units shown in **Table 8**. Each of these design features are often 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 OEM materials were not damaged at the end of the evaluation.

Table 7: Compatible Materials used in the Construction of Automated Endoscope Reprocessing Systems

Component	Days	Equivalent Number of Cycles
Basin	43	7,740
Water Regulator		
"Sporox Compatible" Disinfectant Filter		
"GA/Sporox Compatible" High Sediment 0.2 Water Filter		
LCG Reservoir		
Disinfectant Pump		
Drain Valve Assembly		
Disinfectant Valve Assembly		
Heater Assembly		

Table 8: Functional Compatibility with Automated Endoscope Reprocessing Systems

Manufacturer	AER system	Number of Cycles performed	Reuse Life expressed as Cycles	Compatibility Results
Medivators	DSD-201 (Life Cycle)	500	52	Pass
	DSD-201 (Preventative Maintenance Parts)	1000		Pass
	MV-2 Table Top	500	47	Pass
Custom Ultrasonics	System 83 Plus (Two consecutive quarterly maintenance periods)	729	60	Pass

The reuse life of Revital-Ox RESERT HLD was also evaluated in AER systems as reported in **Table 8**. This information is expressed in terms of reprocessing cycles and represents the number of effective use cycles of Revital-Ox RESERT HLD in the AER before the solutions test strip showed the active of the chemistry to be below the Minimum Recommended Concentration (MRC). The number of cycles presented was determined experimentally for each AER system and is the average of at least nine replicates of the study.

The use of Revital-Ox RESERT HLD in AER systems must be part of a validated reprocessing procedure. Such procedures must include recommendations for solution reuse. In a clinical setting, many variables can impact the actual number of cycles achieved before the chemistry reaches its MRC. Variables like working condition of the AER, bioburden loads, and the type of devices being reprocessed impact the reuse life of the chemistry. As such, the use of the Revital-Ox RESERT R60 Solution Test Strip at the beginning of each cycle should be incorporated into procedures to ensure the hydrogen peroxide concentration of the Revital-Ox RESERT HLD is maintained above the MRC. Good pre-cleaning practices and preventative maintenance processes on all AER systems can help to maximize the number of effective cycles achieved during the 21 day reuse life.

Conclusion of Material Compatibility Testing:

Testing with Revital-Ox RESERT HLD solution showed no functional damage of the devices or the device accessories as a result of performing approximately up to 1000 reprocessing cycles. With respect to materials used in representative AER systems, compatibility testing of the materials has shown that static immersion causes no functional damage as a result of short and long term exposure. The same can be said for the use of Revital-Ox RESERT HLD for 500 to 1000 reprocessing cycles in the two actual AER systems tested.

6 Biocompatibility Testing

Skin Contact: Toxicity testing of the Revital-Ox 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 assessed to have no corrosive effect on the skin at in-use concentrations, although some irritation may occur in those users who might be sensitive to certain components in the solution.

Cytotoxicity: An in-vitro biocompatibility test was performed by a third party to determine whether the Revital-Ox RESERT HLD potentially degraded materials and/or caused the formation of potentially harmful residues on medical devices that could pose a risk to the patient. A representative medical device was fully immersed for 8 minutes in Revital-Ox RESERT HLD solution to mimic the minimum exposure time as directed on the label. This HLD exposure was followed by soaking in 10 liters of deionized water rinse for 1 minute (with instrument channels flushed with 90 ml of the rinsate). At the conclusion of the HLD and rinse exposures, the device was submerged in a separate bath of deionized water and placed into an incubator at 37°C to extract any potential residues. In addition to testing the extraction samples for in-vitro biocompatibility, they were also assayed to measure the amounts of residual chemicals.

The 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 test confirmed that residues remaining on devices after rinsing were well below the acceptable threshold.

A similar test was performed to determine the risks associated with extended exposure to Revital-Ox RESERT HLD. In this test the representative medical device was fully immersed in Revital-Ox RESERT HLD, rinsed, and subsequently extracted using methods similar to that described above. However, in this test, the device was subjected to two consecutive HLD exposure/rinse cycles and immersed in Revital-Ox RESERT HLD for 30 minutes each time. This was done to simulate extended exposure which could potentially result in an accumulation of disinfectant residues.

The resulting extract from this extended exposure test was evaluated by a third party. The test showed no evidence of cell lysis or toxicity using the iso-elution in-vitro biocompatibility method with mouse fibroblast cells. The test also confirmed that, even with the extended exposure to the HLD solution, the residues remaining on the devices were still well below the acceptable threshold.

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