

GENERAL DESCRIPTION

Revital-Ox RESERT High Level Disinfectant is a ready to use liquid chemical germicide. The product is a 2.0% nominal hydrogen peroxide solution. The minimum recommended concentration (MRC) is 1.5%. Revital-Ox RESERT HLD is intended to be used by health care practitioners in clinical settings as a ready to use liquid chemical disinfectant for the high level disinfection of semi-critical medical devices for which alternative methods of terminal processing are not suitable or available.

High Level Disinfectant: Revital-Ox RESERT HLD is a high level disinfectant when used or reused undiluted for a maximum of 21 days at a minimum temperature of 20°C (68°F) for a minimum immersion time of 8 minutes. Passing MRC test results should be obtained using the Revital-Ox™ RESERT™ R60 Solution Test Strip prior to each use.

Revital-Ox RESERT High Level Disinfectant solution is compatible with manual (bucket and tray) systems made from polypropylene, acrylonitrile-butadienestyrene (ABS), polyethylene, polycarbonate plastics, and 316L stainless steel. Revital-Ox RESERT HLD can replace aldehydes in select applications. The use of Revital-Ox RESERT HLD in open architecture automated endoscope reprocessors (AER) must be part of a validated reprocessing procedure. Product solution may not be suitable for all instruments. Always refer to the medical device manufacturer's instructions for use.

For medical devices and instruments, determine whether the reusable device to be reprocessed is a critical or semi-critical device. Critical devices are devices that are introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body. Sterilization is required. DO NOT use Revital-Ox RESERT HLD as the final treatment prior to use for critical devices. Semi-critical devices are medical devices and instruments that come in contact with intact skin or mucous membrane (which are not normally considered to be sterile) such as respiratory equipment, surgical mirrors, or flexible endoscopes. A minimum of high level disinfection is required for semi-critical devices.

FEATURES

BENEFITS

Fast-acting high level disinfectant	Broad-spectrum kill against viruses, fungus, and bacteria, including mycobacteria
Minimum of 8-minute contact time at ≥ 20°C (68°F)	Fast microbiocidal activity
Oxidative chemistry (hydrogen peroxide)	Safe alternative to aldehydes (e.g., glutaraldehyde and orthophthaldehyde [OPA])
Lower hydrogen peroxide (2%) as compared to other hydrogen peroxide based chemistries (7.5%)	Improved compatibility with flexible endoscopes
Ready to use	Removes potential for mixing/dilution errors and saves time
Easily rinsed from instruments	Leaves no toxic fixatives or residues after one rinse
No Volatile Organic Carbons (VOC)	Virtually odorless, requiring no special room ventilation equipment
Non-foaming	Can be used in manual soaking or open architecture automated endoscope reprocessors with a validated process
Does not require deactivation/detoxification	Eliminates the requirement for additional chemicals and saves time
21-day reuse while MRC test passes	Stable in the presence of residual patient fluids

TYPICAL PHYSICAL PROPERTIES

Form.....	Liquid
Color.....	Colorless to light straw
Typical pH	2.2 – 2.6
Typical specific gravity.....	1.02

DIRECTIONS FOR USE

Cleaning/Decontamination

Blood and other body fluids must be thoroughly cleaned from surfaces of medical devices and instruments before application of the high level disinfectant. For complete high level disinfection of medical instruments and equipment, thoroughly clean, rinse, and rough dry objects before immersion into Revital-Ox RESERT HLD. Clean and rinse the lumens of hollow instruments before filling with Revital-Ox RESERT HLD.

Refer to the reusable device or instrument manufacturer's instructions for disassembly, decontamination, cleaning, and leak testing (where applicable) of their equipment.

High Level Disinfection

Place pre-cleaned, rinsed, and dried instruments in solution of undiluted Revital-Ox RESERT HLD. Follow the instrument manufacturer's instructions for reprocessing and the Revital-Ox RESERT HLD instructions for use to ensure all the instrument's surfaces have been fully contacted with Revital-Ox RESERT HLD. Once the instrument has been immersed and all surfaces in contact with the disinfectant solution, soak the instrument for eight minutes at $\geq 20^{\circ}\text{C}$ (68°F). Monitor the time the instrument is in contact with the solution using a timer. Rinse the instrument with sterile water or potable tap water (see package insert for details). Revital-Ox RESERT HLD may not be suitable for all instruments.

SEE NOTICE TO USER AND PACKAGE INSERT FOR DETAILED INSTRUCTIONS ON USE WITH AUTOMATED ENDOSCOPE REPROCESSING.

Reuse Period for Disinfection

Revital-Ox RESERT HLD has demonstrated disinfection efficacy in the presence of organic soil contamination and microbiological burden during reuse. The hydrogen peroxide concentration of Revital-Ox RESERT HLD during its use-life must be verified using the Revital-Ox RESERT R60 Solution Test Strip for solutions prior to each use, to determine that the MRC of 1.5% is present. Revital-Ox RESERT HLD may be used and reused within the limitations indicated above for up to a maximum of 21 days. Revital-Ox RESERT HLD must be discarded after 21 days, even if the test strip indicates a concentration above the MRC. The Revital-Ox RESERT HLD in its original packaging is good until the date of expiry.

STORAGE AND DISPOSAL

Storage: Revital-Ox RESERT HLD should be stored in its original sealed container at controlled room temperature $15\text{-}30^{\circ}\text{C}$ ($59\text{-}86^{\circ}\text{F}$). Do not store in food processing areas. Store in dry, well ventilated area away from chemicals, direct light, heat, or open flame. Do not mix with other cleaning or disinfecting products. The expiration date of Revital-Ox RESERT HLD is found on the immediate container.

Disposal: Dispose in accordance with local, state, and federal regulations. Discard residual solution into drain. Flush drain thoroughly with water. Triple rinse the container with water and dispose in accordance with local, state, and federal requirements. Do not use empty containers for other purposes.

NOTICE TO USER

STERIS offers support through STERIS Device Testing – an ISO 17025 accredited testing program that performs material compatibility and efficacy testing on reusable medical devices with products such as Revital-Ox RESERT HLD. Prior to using Revital-Ox RESERT HLD, confirm device compatibility through the Revital-Ox RESERT HLD Device Matrix which is located on the product webpage. If a medical device is not listed on the Device Compatibility Matrix, reference the Revital-Ox RESERT HLD Technical Data Monograph for additional material compatibility information. If you are uncertain as to the material composition of your item, confirm with the medical device manufacturer before proceeding.

CAUTION: Corrosive to copper, brass, tungsten carbide, Monel S, silver, chromium-plated brass, and nickel-plated steel. May be corrosive to aluminum under prolonged immersion.

For further information, contact:



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