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UltrOx™
High-Level Disinfectant

For medical devices and instruments

Active ingredient: Hydrogen Peroxide . . . . . 2.0% w/w

INDICATIONS FOR USE: UltrOx 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%. UltrOx 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: UltrOx High-Level Disinfectant 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.

REUSE PERIOD FOR HIGH-LEVEL DISINFECTION: UltrOx High-Level Disinfectant solution has demonstrated disinfection efficacy in the presence of organic soil contamination and microbiological burden during reuse. UltrOx High-Level Disinfectant solution may be reused up to a maximum of 21 days, provided the required conditions of hydrogen peroxide concentration and temperature exist based upon monitoring described in the Directions for Use. DO NOT rely solely on days in use. The hydrogen peroxide concentration of UltrOx High-Level Disinfectant solution during its use-life must be verified before each use with the **UltrOx Test Strip**, which will indicate that the Minimum Recommended Concentration (MRC) of 1.5% hydrogen peroxide has been met.

GENERAL INFORMATION ON SELECTION AND USE

Choose a germicide with the level of antimicrobial activity that is appropriate for the reusable device. Follow the reusable device instructions for use and standard institutional policies. In the absence of complete instructions, use the following process:

For medical devices and instruments, determine whether the reusable device to be reprocessed is a critical or semi-critical device.

Critical devices are defined as devices that come in contact with sterile tissue, blood stream or recirculating body fluids. These include surgical instrumentation, implantable devices and laparoscopes. Sterilization is required. DO NOT use UltrOx High-Level Disinfectant solution as the final treatment prior to use.

Semi-critical devices are devices that come in contact with damaged skin or intact mucus membranes such as the respiratory tract. These include respiratory equipment, surgical mirrors, ultrasound transducers. High-level disinfection is required.

MICROBIAL EFFECTIVENESS

The following indicates the spectrum of activity as demonstrated by testing of UltrOx High-Level Disinfectant solution using prescribed test methods.

VEGETATIVE ORGANISMS:
Pseudomonas aeruginosa (ATCC 15442)
Staphylococcus aureus (ATCC 6538)
Salmonella enterica (ATCC 10708)

SPORES:
Bacillus subtilis (ATCC 19659)
Clostridium sporogenes (ATCC 7955)

FUNGI:
Trychophyton mentagrophytes (ATCC 9533)

VIRUS:
Poliovirus, Chat strain type 1 (ATCC VR-1562)
Herpes Simplex Type 1
Adenovirus Type 5

MYCOBACTERIA:
Mycobacterium terrae (ATCC 15755)

MATERIAL COMPATIBILITY

UltrOx High-Level Disinfectant solution is compatible with manual (bucket and tray) systems made from polypropylene, acrylonitrile-butandienestyrene (ABS), polyethylene, polycarbonate plastics and 316L stainless steel. The use of it in automated ultrasound transducer reprocessors must be part of a validated reprocessing procedure. Product solution may not be suitable for all instruments.

UltrOx High-Level Disinfectant solution has been tested and found to be compatible with the materials shown below.

METALS:	PLASTICS:	ELASTOMERS:
Mild Steel	High Density Polyethylene (HDPE)	Neoprene
Gold Plated Steel	PTFE (Teflon®)	EPDM 42
Chrome Plated Steel	Polyester	Silicone Rubber
302 Stainless Steel	Polystyrene	Viton-A
304 Stainless Steel	Polycarbonate (Lexan®)	Polyurethane
316L Stainless Steel	Polypropylene	Natural Rubber (Red)
410 Stainless Steel	Acrylic	
	Polyvinyl Chloride (PVC)	
	Acrylonitrilebutadiene Styrene (ABS)	
	Nylon	

PRECAUTIONARY STATEMENTS

KEEP OUT OF REACH OF CHILDREN.

WARNING

CONTAINS: Hydrogen Peroxide. Causes mild skin irritation. Causes eye irritation. Wash hands thoroughly after handling. **IF IN EYES:** Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical attention. If skin irritation persists: Get medical attention.

Avoid contamination of food in the use and storage of this product. 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.

Refer to the SDS for additional information.

Follow Bloodborne Pathogens Universal Precautions, as defined by authorities such as OSHA, WHO, CSA or other appropriate agency, when handling and cleaning soiled devices. When disinfecting devices, use gloves of an appropriate type, and length, and use proper eye protection. Natural or butyl rubber, nitrile or neoprene gloves are recommended.

Contaminated reusable medical devices and instruments, MUST BE THOROUGHLY CLEANED prior to disinfection, since residual contamination with soil or lubricants will decrease the effectiveness of the disinfectant.

The user MUST adhere to the Directions for Use, as modifications to the Directions for Use may affect the safety and effectiveness of the disinfectant.

Use **UltrOx Test Strip** to confirm hydrogen peroxide concentration before each use. Follow the test strip's Directions for Use provided with each box of **UltrOx Test Strips**.

The use of UltrOx High-Level Disinfectant solution in automated transducer reprocessors must be part of a validated reprocessing protocol. The validated automated transducer reprocessor reprocessing protocol must include solution reuse recommendations. The contact conditions for high-level disinfection in the automated transducer reprocessor must be at a minimum of 20°C for 8 minutes. Use the **UltrOx Test Strip** to monitor hydrogen peroxide concentration before each cycle. The use of UltrOx High-Level Disinfectant with semi-critical devices must be part of a validated rinsing procedure as provided by the device manufacturer. See "DIRECTIONS FOR USE RINSING INSTRUCTIONS" below for important information.

NOTICE TO USER:

Please ensure the instruments, equipment or device material to be disinfected is compatible with UltrOx High-Level Disinfectant. If you are uncertain as to material composition of your item, confirm with the 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.

DIRECTIONS FOR USE

CLEANING/DECONTAMINATION: Blood and other body fluids must be thoroughly cleaned from hard, non-porous surfaces of medical devices and instruments before application of the disinfectant. Follow the instrument manufacturer's instructions for disassembly and cleaning. Perform all necessary leak tests as prescribed by the instrument manufacturer prior to immersion of the instrument in the UltrOx High-Level Disinfectant solution. Following thorough cleaning and rinsing, rough dry all instrumentation prior to immersion in UltrOx High-Level Disinfectant solution.

NOTE: Additional fluid carried by devices into the UltrOx High-Level Disinfectant solution may lead to increased dilution.

UltrOx High-Level Disinfectant PREPARATION: If a secondary container (e.g. soak bucket) is used, pour the desired amount of UltrOx High-Level Disinfectant solution from its original container into the secondary container. Ensure that the UltrOx High-Level Disinfectant solution is within expiration. Record the date the original container was opened on the UltrOx High-Level Disinfectant container label, or in a log book. After opening, the solution remaining in the original container may be stored for up to 90 days (provided the 90 days does not extend past the expiration date on the container) until used. Always store remaining solution in its original, closed container.

If a secondary container is used, pour the desired amount of UltrOx High-Level Disinfectant solution from its original container into a secondary container (e.g. soak bucket). Label and record the product name, date dispensed, and expiration date of the solution in the secondary container. The solution in the secondary container can be used for a period up to 21 days. The solution must be discarded after 21 days or sooner as dictated by the **UltrOx Test Strip**. The expiration date of the UltrOx High-Level Disinfectant solution CANNOT be extended even if the test strip indicates passing results.

NOTE: It is recommended to cover the secondary container to prevent spillage or extraneous contamination of the solution.

HIGH-LEVEL DISINFECTION: Place pre-cleaned, rinsed and dried medical device or instrument(s) in solution of undiluted UltrOx High-Level Disinfectant. Follow the instrument manufacturer's instructions for reprocessing and the instructions below to ensure that all of the instrument's surfaces have been fully contacted with UltrOx High-Level Disinfectant solution. Once the instrument has been immersed and all surfaces are in contact with the disinfectant solution, soak the instrument for 8 minutes at 20°C. Monitor the time the instrument is in contact with the solution using a timer.

1. Prior to each use, confirm that the UltrOx High-Level Disinfectant solution meets the minimum recommended concentration using the **UltrOx Test Strip**. Follow the test strip instructions for use and interpretation. If the indicator strip indicates that the concentration is not acceptable, discard the solution and DO NOT process instrumentation.
2. After devices are pre-cleaned, rinsed and excess moisture is removed, place in the solution of undiluted UltrOx High-Level Disinfectant. Ensure that all lumens are filled with fluid. Follow the instrument manufacturer's instructions for flowing the lumens.
3. Set a timer for 8 minutes and allow the device to be immersed in the solution for the entire 8 minute period of time.
4. Upon completion of 8 minutes immersion, remove the instrument from the secondary container. Follow the instrument manufacturer's instructions for draining the lumens prior to rinsing. Follow the rinsing instructions below.

NOTE: UltrOx High-Level Disinfectant may not be suitable for all instruments. **SEE NOTICE TO USER**.

RINSING INSTRUCTIONS

5. Following removal from UltrOx High-Level Disinfectant solution, thoroughly rinse the medical device by immersing it completely in water. Use sterile water or potable water as required by facility policies. Refer to sections "STERILE WATER RINSE" and "POTABLE WATER RINSE" for further recommendations.
6. Keep the instrument or medical device immersed for a minimum of 1 minute in duration, unless longer is specified by the instrument manufacturer.
7. Manually flush all lumens with large volumes of water (at minimum 100 mL) unless otherwise noted by the instrument manufacturer.
8. Remove device and discard rinse water. Do not reuse the water for rinsing or any other purpose.

NOTE: Refer to the instrument manufacturer's instructions for additional rinsing instructions.

STERILE WATER RINSE: The following instruments or medical devices should be rinsed with sterile water, using aseptic techniques when rinsing and handling:

- Devices intended for use in normally sterile areas of the body.
- Devices intended for use in known immunocompromised patients based on institutional procedures (e.g., high risk population served).

POTABLE WATER RINSE: For all other devices, a sterile water rinse is recommended when practical. Otherwise, potable tap water rinse is acceptable. When using potable water for rinsing, the user should be aware of the increased risk of recontaminating the medical device with microorganisms which may be present in potable water supplies.

TREATED WATER SOURCES:

Water treatment systems, such as softeners or de-ionizers, may add microorganisms to the treated water to the extent that microbial content of the water at the point of use could exceed that of the pretreated drinking water. To ensure proper water quality, adherence to maintenance of the water treatment system is recommended.

The use of a bacterial retentive (0.2 micron) filter system or ultraviolet (UV) systems may eliminate or greatly reduce the amount of these waterborne bacteria from the potable water source. Contact the manufacturer of the filter or UV system for instructions on preventive and maintenance and periodic replacement of the filter to avoid colonization or formation of biofilms in the filter.

DRYING

A device that is not completely dried provides an ideal situation for rapid colonization of bacteria. As these waterborne bacteria are highly resistant to drying, rapid drying will avoid possible colonization but may not result in a device free from these bacteria. A final rinse using a 70% isopropyl alcohol solution (followed by medical air purge if within lumens) may be used to speed the drying process. Follow facility policies. Consult the instrument manufacturer's instructions for recommended rinsing and drying procedure.

POST-PROCESSING HANDLING AND STORAGE OF REUSABLE DEVICES: Disinfected reusable devices are either to be immediately used, or stored in a manner to minimize recontamination. Refer to the reusable device manufacturer's labeling for additional storage and/or handling instructions.

EMERGENCY AND TECHNICAL PRODUCT INFORMATION

For further hazard information refer to Safety Data Sheet. Emergency, safety, or technical information about UltrOx High-Level Disinfectant solution can be obtained from CIVCO Medical Solutions at 319.248.6757, or at WWW.CIVCO.COM.

STORAGE CONDITIONS AND EXPIRATION DATE

UltrOx High-Level Disinfectant should be stored in its original sealed container at controlled room temperature 15 - 30°C (59 - 86°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 the UltrOx High-Level Disinfectant is found on the immediate container.

DISPOSAL

Check state and local disposal regulations. Discard residual solution into drain. Flush drain thoroughly with water. Recommended to triple rinse the container with water, and dispose in accordance with federal, state, provincial and municipal requirements. Do not re-use the empty container.

HOW SUPPLIED

Catalog Number	*Description*	*Case Contains*
610-2473	4L container	4 containers/case

Required Consumables: **UltrOx Test Strip**

CIVCO

Manufactured for:
CIVCO Medical Solutions
102 First Street South
Kalona, IA 52247 USA
319.248.6757
WWW.CIVCO.COM

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Product Made in U.S.A.

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8-1/2"