REPROCESSING PRODUCTS CORP.

Micro-X®
Dialyzer Reprocessing Concentrate

CAUTION:
Federal Law restricts this device to sale by or on the order of a physician. It is important to thoroughly read and understand this manual prior to use of Micro-X® Dialyzer Reprocessing Concentrate

Instructions for Use

Product Description and Indications for Use: Micro-X® Dialyzer Reprocessing Concentrate is a stabilized mixture of hydrogen peroxide and peroxyacetic acid. Micro-X® is indicated for the in vitro cleaning and disinfecting of hollow fiber dialyzers. Micro-X® is intended for use with automated and manual dialyzer reprocessing systems that have been validated by the system manufacturer for use with peracetic acid. Since Micro-X® is formulated to be used only for dialyzer reprocessing, the user should follow the dilution instructions recommended by the reprocessing system manufacturer for the use of peracetic acid concentrates intended for dialyzer reprocessing.

Germicide Level of Activity: Micro-X® is substantially equivalent to Renalin™ (Minntech Corp.), which has been registered by the U.S. Environmental Protection Agency as a sterilant (3.25% for a minimum of 11 hours).

Reuse Period: After dilution, Micro-X® can be used for a period not to exceed seven days, provided the required conditions of the active agent concentrations and temperature exist based on the monitoring, described in "Use and Handling" of Micro-X®. **DO NOT RELY SOLELY ON DAYS IN USE**.

Material Compatibility: When used in accordance with the labeling for these products, peracetic acid-based cleaning and disinfecting agents have been shown to be compatible with the materials commonly used in dialyzers. See the "References" section for literature related to peracetic acid and material compatibility. Consult the "Instructions for Use" from the specific dialyzer's manufacturer if additional information is required concerning material compatibility.

Precleaning Agent Compatibility: When Micro-X® is used in accordance with "Instructions for Use", it is not necessary to use a precleaning agent. Micro-X® can be used for both cleaning and disinfecting of the dialyzer.

Warnings and Precautions

Warnings:

- Federal law (USA) restricts this device to sale by or on the order of a physician.
- Federal law prohibits use of this product in a manner inconsistent with its labeling.
- Danger: Keep out of reach of children.
- Danger: Corrosive. Harmful if swallowed. May cause eye or skin irritation. Do not get in eyes, on skin or on clothing. Wear safety glasses and rubber gloves when handling. Wash with soap and water after exposure. If exposed to concentrations greater then 3.5%, remove clothing and launder before wearing again.
- In case of contact, immediately flush skin or eyes with large amounts of water. For eye contact, prompt medical attention is necessary.
- If swallowed, drink water immediately to dilute, but do not attempt to induce vomiting. Call physician or poison control center immediately. Possible muscosal damage may contraindicate the use of gastric lavage.
- If spilled, flush affected area with large quantities of water.
- For chemical emergencies, call CHEMTREC at 800-424-9300.
- Avoid contact between Micro-X® concentrate or solution and combustible materials.
- Micro-X® undergoes rapid decomposition if allowed to contact metal, dust, or organic materials, or if it is diluted with water failing to meet the Association for the

Advancement of Medical Instrumentation (AAMI) Standards for Hemodialysis Systems (May 14, 1982).

- All diluted Micro-X® should be used within seven days.

Precautions:

- All users should be adequately trained in the decontamination and disinfection of medical devices and the handling of toxic substances such as liquid chemical germicides. All personnel must be thoroughly familiar with the cautions and "Instructions for Use" of Micro-X® before use.
- To avoid contact with skin and eyes, wear gloves, eye covering, and other appropriate protective equipment or clothing.
- A hollow fiber dialyzer that is cleaned, reprocessed, and disinfected with this chemical is filled with a solution of Micro-X® (hydrogen peroxide and peracetic acid). The Micro-X® solution must be thoroughly rinsed from the dialyzer prior to clinical use.
- To optimize the effective reprocessing of dialyzers, use of Micro-X® must be part of a reprocessing procedure validated by the manufacturer of the dialyzer reprocessing system for use with peracetic acid. Since Micro-X® is formulated to be used for dialyzer reprocessing, the user should follow the dilution instructions recommended by the system manufacturer for the use of peracetic acid concentrates intended for dialyzer reprocessing.
- Any modifications of the "Instructions for Use" will affect the safety and effectiveness of Micro-X®. It is the user's responsibility to validate any deviations from the "Instructions for Use". Always store Micro-X® in the original shipping container and shipping box. Never tamper with the vent cap.
- Do not store in direct sunlight. Micro-X® is provided in a translucent container in a shipping carton. Since Micro-X® is light-sensitive, the user must not remove the container from the shipping carton except during dilution prior to use. The container should be replaced in the shipping carton following dilution. Maintain storage temperature at or below 86° F (30° C).

Use and Handling of Micro-X®

- The cap on each container is vented to prevent excessive pressure buildup within the container during shipping and storage.
- As with other disinfectants used in dialyzer reprocessing, testing should be performed to show that:
  1. The dialyzer was exposed to the correct disinfectant concentration (peracetic acid potency test); and
  2. The disinfectant has been properly removed (rinsed) from the dialyzer prior to clinical use (residual peroxide reagent test).
- In the concentrated form, Micro-X® stability is maintained for 15 months after date of manufacture. Once diluted, deterioration of the active ingredient commences, and the resulting solution must be used within seven days.
- Use care when disconnecting the dialyzer from the automated reprocessing system or when removing caps from the dialyzer following storage to avoid being sprayed with Micro-X® solution.
- Use only caps specified for use with peracetic acid to close the dialysate and blood ports. Auto-Vent® (P/N 7000-0005) dialysate port caps are recommended for venting pressure from the dialyzer before removal of port caps is attempted. Dialyzer caps should be disinfected with a 1% Micro-X® solution (99 parts AAMI-quality water and 1 part Micro-X®).
- Dialyzers must be completely filled with Micro-X® solution after storage and before rinsing.
- After a minimum storage time of 11 hours and before the dialyzer is rinsed, a solution sample must be taken from the dialysate compartment and tested for the presence of Micro-X®, utilizing peracetic acid reagent strips (Micro-X® Peracetic Acid Potency Test Strips (P/N K100-0105). The test must indicate adequate positive results before the dialyzer is rinsed.
- After rinsing of the dialyzer and prior to clinical use, a rinse sample must be taken from the blood compartment and tested, using a hydrogen peroxide residual test strip (Micro-X® Residual Test Strips (P/N K100-0100). The test must indicate negative results before use of the dialyzer on the patient.

Dilution and Handling Instructions

General Considerations:

- Micro-X® is a single-container germicide. After dilution, mark the proper Micro-X® solution expiration date on the container holding the diluted Micro-X® solution. The expiration date is either 7 days after dilution or the Micro-X® concentrate's expiration date (marked on the shipping carton and on the bottle label), whichever is sooner.
- Replace the Micro-X® container into the original shipping carton, to prevent exposure to light. Do not store Micro-X® concentrate or solution in direct sun light.
- Test the concentration yielded by the reprocessing system with the peracetic acid reagent strips (Micro-X® Peracetic Acid Potency Test Strips (P/N K100-0105) following dilution of each new container of Micro-X®.

Specific Instructions for Manual Systems:

- For cleaning of dialyzers: a 2% solution (1 part Micro-X® and 49 parts AAMI-quality water) is recommended. A stronger concentration of Micro-X® may adversely affect the cleaning of the dialyzer, rather than improve it.
- For disinfecting of dialyzers: a 3.5% solution (1 part Micro-X® and 28.5 parts AAMI-quality water) is recommended.

Specific Instructions for Automated Systems:

Dilute Micro-X® in accordance with the instructions provided by the system manufacturer for peracetic acid-based dialyzer reprocessing germicides.

• For the Renatron/II (excludes Renalin 100 modified) reprocessing system, mix a 21% solution, carefully shaking or stirring to avoid layering. This solution may be attained in either of the following ways:

1. 2 liters of Micro-X® filled to a total volume of 2½ gallons (9463 ml) with AAMI-quality water; OR
2. 800 milliliters of Micro-X® filled to a total volume of 1 gallon (3785 ml) with AAMI-quality water.

• For the Echo reprocessing system, a 2% solution is recommended for dialyzer cleaning and a 3.43% solution is recommended for disinfection. These solutions may be attained in the following ways:

1. A 2% solution is 1 part Micro-X® and 49 parts AAMI-quality water.
   - For 1 gallon, measure 76 ml of Micro-X® and add AAMI-quality water to a total volume of 1 gallon (3785 ml).
   - For 2½ gallons, measure 190 ml of Micro-X® and add AAMI-quality water to a total volume of 2½ gallons (9463 ml).
2. A 3.43% solution is 1 part Micro-X® and 29 parts AAMI-quality water.
   - For 5 gallons, measure 650 ml of Micro-X® and add AAMI-quality water to a total volume of 5 gallons (18,925 ml).
   - For 2½ gallons, measure 325 ml of Micro-X® and add AAMI-quality water to a total volume of 2½ gallons (9463 ml).

• For the Seratronics DRS-4, older models of the DRS-4 use a 33% solution of peracetic acid, while models produced since early 1993 use a 21% solution. Consult and follow the instructions provided in the DRS-4 user's manual.

Dialyzer Handling Following Reprocessing

1. Disconnect the dialyzer from the automated reprocessing system.
2. High residual amounts of blood products (organic load) indicated by a low total cell volume may reduce Micro-X® below an effective level. Aggressive cleaning, by allowing Micro-X® solution to dwell in the dialyzer and repeating the cleaning and testing cycles, may improve volumes in some dialyzers. Consistently poor results indicate an equipment malfunction or may indicate the need for patient heparin modeling.
3. Place disinfected blood port caps and dialysate port caps on the dialyzer.

NOTE: Dialyzers reprocessed with Micro-X® solution may undergo an internal pressure buildup during storage. An Auto-Vent® (P/N 7000-0005) dialyzer dialysate port cap should be used, which allows the pressure build-up in dialyzers to vent automatically. Refer to Auto-Vent™ port cap instructions for use. Use caution at all times to avoid being sprayed with Micro-X® solution.

4. Store dialyzers with the Auto-Vent® port cap pointing upward. Any gas that develops will rise and escape through the special filter material in the cap. If storing in this manner is not possible, place the dialyzer in a polyethylene plastic bag (P/N 7000-3051) to prevent inadvertent spraying of personnel or equipment. Venting the pressure using the Auto-Vent® port cap will prevent caps from being forced off.

NOTE: Inadvertent disconnection of dialysate port caps due to high internal pressure indicates either the storage conditions are improper or the dialyzer has not been fully cleaned.

Testing Prior to Dialyzer Rinse

Before rinsing the dialyzer after a minimum storage time of 11 hours, the reagent test (Micro-X® Peracetic Acid Potency Test Strips (P/N K100-0105) should be performed to show that the dialyzer was exposed to Micro-X® solution:

1. Check the dialyzer for proper labeling (patient's name, date and reuse number).
2. The dialyzer should be filled at least two-thirds full of Micro-X® solution, even though oxidation will be evident. This two-thirds fill level should be determined by holding the dialyzer parallel to the floor and examining the header of the dialyzer. Dialyzers not meeting this fill level should be refilled with Micro-X® for a minimum time of 11 hours prior to use.
3. Vent pressure from the dialyzer by following Auto-Vent® instructions for use.

NOTE: Some liquid may be released under pressure. Hold away from face and from other personnel.

4. Remove Auto-Vent® cap, siphoning some Micro-X® solution into the cap. Dip the peracetic acid potency strip into the cap and read the results per the test strip instructions for use. An adequate concentration will cause the strip to show a solid brown or black color. This is a positive result for the presence of Micro-X® solution.

Rinse Procedure

CAUTION: To minimize air generation which could create air locks within the fibers, use a saline rinse on the blood side of the dialyzer before attaching the dialysate connectors to the dialyzer.

1. Place the dialyzer into the holder on the dialysis machine. Do not remove the port caps.
2. Prime the arterial blood line with saline, purging all air from the line.
3. Remove the arterial blood port cap from the dialyzer and attach the arterial blood line.
4. Turn the dialyzer, in its holder, until the venous end is up. Remove the venous blood port cap from the dialyzer, then attach the venous blood line to the dialyzer. Prime the dialyzer until a minimum of 500 cc has drained from the saline bag. Collect and dispose of the solution exiting from the venous blood line.

CAUTION: Before continuing, ensure that all air has been purged from the blood circuit using standard priming procedures. Use more saline if necessary.

5. Prepare for recirculation and dialysis to remove the remaining Micro-X® from the extracorporeal circuit. Connect the arterial and venous blood lines at the fistula connectors.

6. Attach the dialysate connectors to the dialyzer. Begin dialyzing and set the blood pump speed to 300 ml/minute. Leave the saline line open to replace any solution removed during this step. An ultra filtration controller should be set at a removal speed of one (1) liter per hour. A negative pressure of 100 mmHg may be used for other dialysis systems. Check the extracorporeal circuit for the presence of air. Once all air is removed, turn the arterial end up into its proper position for more effective dialysis. Complete removal of all solution should be accomplished in less than 10 minutes for cellulose-based membranes; some synthetic membranes, such as polysulfones, may take longer.

Residual Testing Following Rinse Procedure

After completion of the rinse procedure, the dialyzer should be tested to determine the level of residual chemical present.

1. Obtain residual test strips (Micro-X® Peroxide/Peracetic Acid Residual Test Strips (P/N K100-0100).

2. After rinsing the dialyzer for 10 minutes, use a 1 to 3cc syringe and small-bore needle to draw a 1 cc sample of solution from the extracorporeal circuit using the venous injection site. Put solution sample from syringe into a small container that has been rinsed free of contaminants.

NOTE: The venous and arterial lines may be separated if properly clamped and the blood pump is stopped, but a false positive may occur from Micro-X® residue on the fistula connector using this method.

3. Dip a test strip briefly (approximately 1 second) into test solution. After 2 seconds, shake off the excess. If no color is immediately apparent on the test strip, there is less than 1 part per million (ppm) of Micro-X® remaining and no further rinsing is required. Refer to test strip instructions for use for additional information on the use of the test strips.

4. If the result is 3ppm or higher, further rinsing is necessary. If the residual Micro-X® is acceptable but the patient is not ready to begin dialysis, continue recirculating the dialyzer at blood pump settings of 100 ml per minute and zero negative pressure, to conserve saline, until the patient is ready to be connected to the dialysis machine.

Product Specifications

Materials:

Hydrogen peroxide	27.0 %
Peroxyacetic acid	4.50 %
Inert Ingredients	68.5 %

(Nominal concentrations)

Packaging Options:

- 1-gallon (3000 ml) container:
  Shipping carton (case of 4 containers).
  Kit includes: 300 Micro-X® Residual & Potency Test Strips

Dilution Requirements:

- Water used for dilution must meet or exceed AAMI Standards for Hemodialysis Systems (May 14, 1982), and AAMI Recommended Practice, Reuse of Hemodialyzers (July 1986).
- Water must be produced by reverse osmosis or pre-filtered through a 1.2 micron or smaller filter. Water temperature must be 59EF-75EF (15EC-24EC).

Storage Conditions (Concentrate and Use-Dilution):

- Store in shipping containers to protect from light.
- Store upright to prevent leaking from vented caps.

Store at temperature between 86°F (30°C) and 32°F (0°C). **DO NOT FREEZE.**

Shelf Life and Expiration Date

- In concentrated form, stability is maintained for 15 months after date of manufacture. An expiration date is assigned at the time of manufacture.
- Once diluted per instructions, the resulting solution must be used within 7 days or by the concentrate's expiration date, whichever is sooner. The use period is a maximum limit and the solution must not be used when the maximum concentration of the active ingredient has dropped below the minimum effective concentration regardless of the number of days in use.
- Following dilution, Micro-X® solution exhibits a gradual loss of potency at a rate such that 50% of the active ingredients remain after a 7-day period. This deterioration has been considered when listing concentrations of active ingredients and when calculating the amount of Micro-X® placed in the dialyzer.

Disposal:
Heavily diluted Micro-X® may be safely disposed of in sewer systems and normal waste removal facilities. Empty containers should be triple rinsed and recycled or directed to approved landfills or incinerator sites.

Test Strips:
Micro-X® Peroxide/Peracetic Acid Residual Test Strips
Product Number K100-0100
Micro-X® Peracetic Acid Potency Test Strips
Product Number K100-0105

Emergency and Additional Information

For chemical emergency call CHEMTREC at 800-424-9300. For Material Safety Data Sheet (MSDS) and a complete listing of information on Micro-X® Dialyzer Reprocessing Concentrate, contact Reprocessing Products Corp.

References

1. Dumler, F.; Zasuwa, G; Levin, N. Effect of dialyzer reprocessing methods on complement activation and hemodialyzer-related symptoms. *Artif. Organs* 1987 April; 11(2): 128-31.
2. DiRaimondo, C.R.; Pollack, V.E.: Beta 2 micro-globulin kinetics in maintenance hemodialysis: a comparison of conventional and high-flux dialyzers and the effect of dialyzer reuse. *Am. J. Kidney Dis*. May 1989; 13(5):390-5.
3. Fleming S.J.; et al. Dialyzer reprocessing with Renalin. *Am. J. Nephrol*. 1991; 11 (1):27-31.
4. Goldman, M.; et al. Adsorption of Beta 2 microglobulin on dialysis membranes: comparison of different dialyzers and effects of reuse procedures. Int. J. *Artif Organs*. Jun 1989; 12 (6): 373-8.
5. Kuwahara, T.; Market, M.; Wauters, JP. Biocompatibility aspects of dialyzer reprocessing: a comparison of 3 re-use methods and 3 membranes. *Clin. Nephrol*. Sep. 1989; 32(3): 139-43.
6. Vanholder, R; Ringoir, S. Influence of use and reuse sterilants on the first-use syndrome. *Artif. Organs*. April 1987; 11(2):137-9.

Order Information

Description	Order #
Micro-X® Gallons (4/cs)	MX-30004
Micro-X® Gallons Kits (4/cs + 300 of ea. Strip)	MX-30004TS
Micro-X® Peroxide/Peracetic Acid Residual Test Strips (100/bottle)	K100-0100
Micro-X® Peracetic Acid Potency Test Strips (100/bottle)	K100-0105

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