ReNews®
A Publication On Dialyzer Reprocessing

Volume 5, Number 2, Fall/Winter 1998

Special Q&A Edition

Top Reprocessing Questions You Weren't Afraid to Ask

Q. What is the recommended maximum number of uses?

A. There is no recommended maximum use. According to the National Surveillance of Dialysis-Associated Diseases in the United States, 1996, during 1976-1986, the percentage of centers that reported reuse of disposable dialyzers increased from 18% to 81%. Among centers that reused disposable dialyzers, the average (median 14) number of reuses changed little during 1991-1996. Sixty-one percent of centers reported using automated systems for reprocessing dialyzers (vs 59% in 1992), 35% only a manual system (vs 33% in 1992), and 4% both systems.

Q. How much Renalin® Cold Sterilant does it take to reprocess a dialyzer using the Renatron® II Dialyzer Reprocessing System?

A. Approximately 156 ml of Proportioned RENALIN Solution for "OO" and "CH" mode, and 248 ml for the "HF" mode.

Q. Is it safe to work with RENALIN Cold Sterilant when you are pregnant?

A. Minntech Renal Systems has, in the past, referred this question to an outside consultant specializing in occupational medicine. The findings of this independent toxicology review do not show any indications of a human reproductive hazard from hydrogen peroxide, peracetic acid or acetic acid, the active ingredients of RENALIN Cold Sterilant. However, the absence of current studies indicating human reproductive hazards from RENALIN Cold Sterilant is not an absolute assurance of its safety. Therefore, Minntech Renal Systems recommends that as a prudent precaution exposure to all chemicals, such as bleach, formaldehyde, household cleaners and RENALIN Cold Sterilant, should be avoided during pregnancy.

Q. Must a RENALIN indicator test be performed on every dialyzer? How often and when do dialyzers need to be tested with the Perassay™ 500 Peracetic Acid Test Strips?

A. Our instructions for use require that each preprocessed or reprocessed dialyzer be tested for the presence of Proportioned RENALIN Solution with the Perassay™ 500 Peracetic Acid Test Strips after storage and before rinsing.

In This Issue:

Q. RENALIN vapors – what must be checked and how often?

A. The two components of RENALIN Cold Sterilant, which are subject to OSHA regulation for maximum airborne levels, are hydrogen peroxide and acetic acid. OSHA specifies that their maximum levels, measured as 8-hour time-weighted averages, are 1 and 10 ppm respectively. For an explanation on how to measure TWA, please refer to the Fall/Winter 1994 issue of ReNews®. OSHA has not established a frequency for monitoring, only that these limits be met. We recommend that initial testing be done when exposure appears greatest, such as when diluting RENALIN Cold Sterilant, to establish the maximum expected levels. If these are found to be below the OSHA limits, routine testing can be infrequent. Testing should always be repeated if processes are changed or if personnel experience discomfort.

Q. Can I use cold AAMI water to process my dialyzers? My heater can't keep up with water demand, and sometimes my water temperature drops below 60°. Your temperature recommendations are higher.

A. Minntech Renal Systems recommends that water used to dilute RENALIN Cold Sterilant to 21%, and water supplied to the RENATRON II System be at a temperature between 59-75°F. The validation of RENALIN Cold Sterilant as a sterilant was carried out at temperatures between 59-75°F . Storing a dialyzer in temperatures outside of this range goes against the manufacturer's recommendations for RENALIN Cold Sterilant.

Q. Do you handle the scanner gun with clean gloves or dirty gloves?

A. The scanner gun is used after the un-reprocessed dialyzer has been placed on the RENATRON II System and is generally handled with dirty gloves.

Q. Is it necessary to store RENALIN solution in the original box once water is added to the concentrate?

A. In order to avoid deterioration of the RENALIN Solution, Minntech Renal Systems recommends that RENALIN Cold Sterilant, RENALIN Solution, as well as preprocessed and reprocessed dialyzers be stored out of direct sunlight. In many locations this is best accomplished by storing both the RENALIN Cold Sterilant and RENALIN Solution in the original shipping container.

Q. How often do we have to change the clean/dirty cap container solution?

A. If you are using 1% RENALIN Solution, the solution should be mixed fresh once every 24 hours. If using Actril® Cold Sterilant, the solution can be used for up to 14 days, as long as it has been verified with an indicator test strip. The ACTRIL Solution should be checked every morning with an ACTRIL Indicator Test Strip to verify the presence of ACTRIL.

Q. If a cap blows off the reprocessed dialyzer and it is then tested and found positive for Proportioned RENALIN Solution, do we have to reprocess the dialyzer again?

A. Minntech Renal Systems recommends that if a cap blows off of a reprocessed dialyzer, it indicates that the dialyzer may still contain residual blood products or the storage conditions have not been optimal. The dialyzer should be reprocessed and stored a minimum of 11 hours before using.

Q. What causes large bubbles within the dialyzer following reprocessing?

A. RENALIN Cold Sterilant will produce oxygen gas when it is exposed to residual blood products remaining in a dialyzer after it has been used. To reduce this phenomenon, you may consider using the pre-clean cycle on the RENATRON II System. You may also wish to analyze the dialyzer handling practices in your dialysis unit that may influence the amount of clotting that may occur during and after a dialysis treatment.

Q. What is the purpose of the ventable port caps and how are they properly used?

A. When RENALIN Cold Sterilant and the residual protein in the dialyzer mix, they produce oxygen gas. The ventable caps act as a release for this gas. Always be sure to point the dialyzer port and ventable cap upward and *away from eyes,* and make sure the clear deflection shield is in the out position. Squeeze the red portion of the ventable cap at the top rounded part of the cap, under the deflection shield. Squeezing the cap twice for 2-3 seconds should vent the pressure properly. For storage, the cap shield is to be fully extended in the "out" position. Repeat these steps after storage and prior to removal of port caps.

Q. What reaction takes place when a patient comes into contact with Proportioned RENALIN Solution remaining in a dialyzer?

A. A patient may respond to a small RENALIN Cold Sterilant exposure just as they would to an exposure to any foreign substance. Some of the symptoms observed in patients that have been exposed to small amounts of RENALIN Cold Sterilant are the following:

- Burning in extremities
- Itching
- Sensation or warmth
- Chest pain or tightness
- Hypotension
- Numbness/tingling sensation
- Dizziness
- Nausea
- Vomiting
- Facial flushing
- Sweating

Have You Heard

About the

NANT

Essentials of Dialysis Regional Meeting

Designed for technicians, nurses and LPN/LVN's, this meeting features 17 contact hours over two days, covering the essentials of dialysis and troubleshooting the hemodialysis machine. $50 for NANT members, $95 for non members.

October 22-23, St. Louis, MO
November 5-6, Yonkers, NY

For a meeting brochure contact NANT
(937) 586-3705 or fax address to (937)-586-3699

Q. Is RENALIN Cold Sterilant a known carcinogen?

A. No. Neither RENALIN Cold Sterilant, nor any of its components, are known carcinogens.

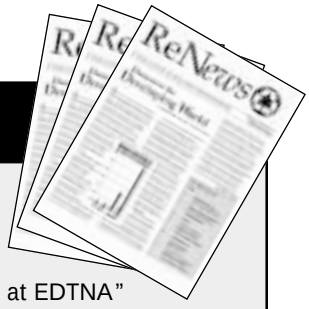
Q. Can a dye be added to RENALIN Cold Sterilant?

A. No. The oxidizing nature of RENALIN Cold Sterilant would render any dye colorless in a very short period of time. Many dialysis centers that use Formalin to disinfect dialyzers use a color to verify that the Formalin solution was in the dialyzer. Unfortunately, the presence of colored dye is not an assurance of the proper levels of Formalin in the dialyzer. Our recommended indicator test performed just prior to the use of the dialyzer is a positive assurance of the presence of Proportioned RENALIN Solution at the proper concentration.

Q. Do I need special venting in the reuse area to evacuate RENALIN Cold Sterilant fumes during reuse?

A. As a result of the closed system design of the RENATRON II System, exhaust fans that provide the reuse room with five room exchanges per hour will meet OSHA requirements and provide a comfortable working atmosphere for staff. When planning ventilation design, the ducts, grills and other air handling equipment should be made of nonmetallic construction to avoid later problems with corrosion. The exhaust vents should not be placed in the ceiling. As RENALIN vapors are heavier than air, preferred placement of vents is at counter-top height just behind the RENATRON II System or immediately adjacent to areas where RENALIN Cold Sterilant is used and mixed.

Back Issues of ReNews



To receive a personal copy of future issues, or any of our back issues, call Minntech Renal Systems Customer Service at:

1-800-328-3340

The following back issues of ReNews are available free-of-charge.

Volume 5, Number 1, 1997
"Dialysis in the Developing World"
"Meet Renal Systems' Technical Service Department"

Volume 4, Number 2, 1997
"How Well Do You Know Your Unit's High Purity Water System?"
"The Facts on Latex Allergies"

Volume 4, Number 1, 1996
"Mortality Data and Reuse Presented at EDTNA"
"Interview: Allan Collins, M.D., FACP"

Volume 3, Number 2, 1995
"Reuse Labeling"
"Renatron: The People Behind the Product"

Volume 3, Number 1, 1995
"The Impact of Anticoagulation Techniques on Dialyzer Reuse"
"What IS a Sterilant, Anyway?"

Volume 2, Number 2, 1994
"Evaluation of the Renatron® II Pre-Clean Cycle"
"Is a Dialyzer Reprocessing Program Beneficial When Low Cost Hemodialyzers are Available?"

Q. Why does Minntech Renal Systems recommend a flow of six liters per minute per RENATRON II Dialyzer Reprocessing System?

A. Reliability was a major consideration when the RENATRON II System was developed. The RENATRON II System uses a jet pump rather than an electromechanical pump as a component of the operating system. While this design permits a maximum 6 liters/minute flow rate, it allows the RENATRON II System to operate with maximum reliability and efficiency and minimizes electrical requirements. Many dialyzer reprocessing areas have a minimum amount of space for equipment. Should a breakdown occur, it can seriously disrupt the routine for the reprocessing and technical staff. In addition, this disruption can cause dialyzers to be discarded, which will increase the cost of providing dialysis. In extreme circumstances this may deplete dialyzers to a serious level. Installation of adequate water volume and pressure to the reuse area is a small cost to invest to guarantee the dialysis center a smooth and uninterrupted treatment of patients.

Q. What is a RENALIN Certification Agreement?

A. As directed by the US Food and Drug Administration, (FDA) in their 518(a) order, Minntech Renal Systems is required to obtain a signed agreement by all dialysis facilities using RENALIN Cold Sterilant, to ensure that they conform with the 1986 Association for the Advancement of Medical Instrumentation Recommended Practice for Reuse of Hemodialyzers (AAMIROH-1986) and Minntech Renal System's guidelines. The FDA prohibits the sale of RENALIN Cold Sterilant to dialysis facilities which have not returned a signed copy of this agreement. The agreement covers five different categories of RENALIN Cold Sterilant usage. The customer needs to determine which category or categories accurately describe their RENALIN Cold Sterilant usage.

All centers that are RENALIN customers as of April 1, 1993 have a signed Certification Agreement on file. New customers are requested to send a Certification Agreement, signed by their Medical Director or Administrator.

Q. A 1% RENALIN Solution can be used for port cap disinfection. What is the formula for making a 1% RENALIN Solution from a 21% RENALIN Solution?

A. 21% RENALIN Cold Sterilant is the concentration of the RENALIN Solution in a 2.5 gallon container with two liters of RENALIN concentrate properly diluted for use with the RENATRON II System.

A 1% RENALIN Solution can be made from the 21% RENALIN Solution by using 48mls of the 21% RENALIN Solution and adding 952 mls of AAMI quality water and mixing well. This will deliver one liter of 1% RENALIN Solution for port cap disinfection. (Fresh 1% RENALIN Solution should be made daily.)

Q. What is the rationale for rinsing the blood compartment of a RENALIN sterilant-reprocessed dialyzer with 500 ml of sterile normal saline to drain before initiating dialysate flow to the dialyzer?

A. The RENALIN dialyzer-rinse procedure recommends a 500 ml saline flush to drain through the blood compartment prior to commencing dialysate flow and the ultrafiltration phase of the rinse procedure. The primary recommendation for this saline flush is to prevent formation of gas bubbles within the dialyzer's hollow fibers. This can occur when bicarbonate (base) from the dialysate diffuses into RENALIN-filled (peracetic acid) fibers. The resulting acid-base reaction results in liberation of gas within the fibers, which may subsequently obstruct flow through these fibers. Fibers fully or partially obstructed with air are more difficult to rinse and the phenomenon may not be clearly evident from residual test procedures, because the bulk of saline being recirculated will be from unobstructed, more completely rinsed, fibers. In addition, gas bubbles trapped in the dialyzer fibers may be dislodged later during dialysis, exposing poorly rinsed surfaces to the patient's blood.

This rinse procedure recommendation for a RENALIN-filled dialyzer may differ from the method for rinsing a formaldehyde-filled dialyzer. Often, the dialysate flow is initiated prior to rinsing the blood compartment of a formaldehyde-filled dialyzer.

It must be noted that the saline flush is a critical step to avoid potential gas formation within the dialyzer fibers and should be practiced to prevent air obstructed fibers and potential RENALIN residual reactions.

Q. Can dialyzers from patients testing positive with hepatitis B or hepatitis C surface antigens be reprocessed?

A. The 1993 edition of the AAMI guidelines on "Reuse of Hemodialyzers" (which was adopted by HCFA as Final Rule in October of 1995) states in Section 6, "dialyzers should not be reprocessed from patients who have tested positive with hepatitis B surface antigens." According to the Federal Register Vol. 60, No. 180, this decision to prohibit the reuse of dialyzers from patients testing positive for hepatitis B was developed by the medical community and reflects the general concern of most professionals that extreme caution is necessary in treating patients with the disease.

The Centers for Disease Control state, in the National Surveillance of Dialysis Associated Diseases in the United States, 1996, that dialysis patients with non-A, non-B hepatitis should be treated with the same precautions used for all patients, following the 1996 standard precautions. The CDC also noted that patients who are positive for anti-C HCV or have a diagnosis of non-A, non-B hepatitis do not have to be isolated from other patients or dialyzed separately on dedicated machines, and may participate in a dialyzer reuse program.

Calendar Of Events

Event	Date	Location	Contact
NKF 48th Annual Meeting	October 22 - 25, 1998	Philadelphia, PA	NKF at 800-622-9010 www.kidney.org
NANT, Essentials of Dialysis Regional Meeting	October 22 - 23, 1998	Holiday Inn Select St. Louis, MO	NANT at 937-586-3705 Fax: 937-586-3699
ASN 31st Annual Scientific Meeting	October 25 - 28, 1998	Philadelphia Convention Center, Philadelphia, PA	ASN at 202-857-1190 www.asn-online.com
Renal Systems Renatron Service & Maintenance Seminar	November 3 & 4, November 5 & 6	Las Vegas	Minntech Renal Systems Amy Erickson: 800-328-3345 ext. 504
NANT, Essentials of Dialysis Regional Meeting	November 5 - 6, 1998	Royal Regency Hotel Yonkers, NY	NANT at 937-586-3705 Fax: 937-586-3699