



## A Patient's Guide to Dialyzer Reprocessing: Helping You Help Your Patients

A patient that is new to hemodialysis typically is overwhelmed with information, decisions that need to be made, and consent forms that need to be signed.

The Medical Director and dialysis staff are responsible for fully informing each patient of the facility's practices regarding reuse of dialyzers. Unfortunately, because the patient is immediately flooded with information, the patient merely remembers that their dialyzer will be reused.

The Clinical Services Department at Minntech understands the daily demands in the chronic hemodialysis setting and identified that there was a need for an updated educational

tool to explain dialyzer reuse to the patient.

This educational tool, "A Patient's Guide to Dialyzer Reprocessing," was developed by the Clinical Services Department at Minntech to give the patient and their family valuable information on the history, safety, and economics of reprocessing, along with a detailed look at the individual components that make up a successful dialyzer reprocessing program.

This guide covers a wide variety of information including:

- A description of dialyzer reuse
- How long dialyzer reuse has been practiced
- Why dialysis facilities practice dialyzer reuse
- The safety of dialyzer reuse
- Reuse technician training
- How the entire reprocessing cycle is performed
- How the reprocessed dialyzer is inspected and prepared before each use
- How many times a dialyzer can be reused
- What part the patient plays in the reuse process

### Q & A

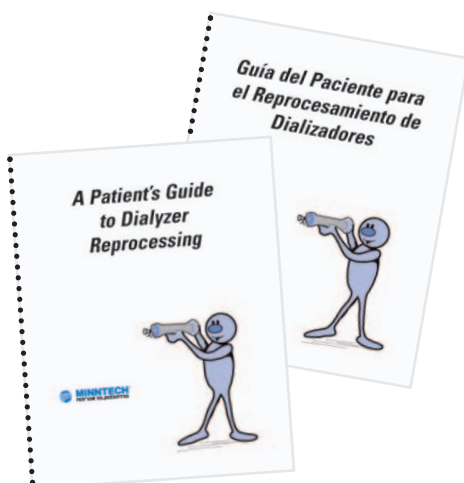
#### "Why does dialyzer potting material sometimes darken after exposure to Renalin?"

The potting material in most dialyzers consists of a highly biocompatible and safe plastic known as polyurethane. During manufacturing, the potting material is introduced as a liquid that rapidly hardens by a cross-linking process. When new, this material appears beige to slightly yellow in color. Like most aging plastics, when polyurethanes are exposed to the oxidizing agents present in Renalin as well as light, they tend to turn some what more yellow-amber in color. This phenomenon is common with many plastics and is the result of continuous reaction of a low quantity of un-reacted residues in the plastic.

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This guide can assist the dialysis staff in explaining and educating patients and their families to your dialyzer reprocessing program and help patients become more active participants in their own dialysis therapy.

"A Patient's Guide to Dialyzer Reprocessing" is written using easy-to-understand non-medical terms and is available in PDF format on a CD, in English as well as Spanish. The PDF format allows you to print hard copies for patients and their families as you need them. Contact your Minntech Area Manager or contact Minntech at (800)328-3345 and ask for Clinical Services to receive a CD and start printing your booklets today!



## SPOTLIGHT ON THE:

### The Minntech Customer Service Department:

The Minntech Customer Service Department collectively has over 45 years of customer service experience. The Customer Service Department fields thousands of calls each month and assists customers with everything from placing orders to tracking deliveries. You may contact the Minntech Customer Service Department at (800)328-3340 from 8:00am until 5:00pm Monday through Friday. After normal business hours, you may still contact the Customer Service Department by calling (800)328-3340 and leaving a message. One of the Customer Service Representatives will call you back.



**JANIS RIOS**

Janis Rios, Customer Service Supervisor, has been with Minntech for 10 years. She has been promoted into different positions through the years, most recently to Supervisor of Customer Service. What she likes most about customer service is “Truly my customers.” Janis enjoys a good book and beading jewelry. She has also given the “gift of life” as a non-related kidney donor.



**TINA BISHOP**

Tina Bishop brings with her over 10 years of customer service experience and has been with Minntech for 1½ years. She is originally from Louisiana, where she lived for over 30 years, and moved to Minnesota in July of

2004. Although she doesn’t think so, her accent gives her away! Tina will be attending school in the spring to complete her accounting degree. Her hobbies include reading, music, cooking, crafts, games, and quiet time at home.



**KIRA SETTERHOLM**

Kira Setterholm, Lead Customer Advocate, came to Minntech six years ago as a graduate from Winona State University with a Bachelor of Science Degree in Health Science. What Kira likes most about working in Customer Service is “The variety of personalities that I come across.” What she likes least about working in customer service is “Rarely getting to meet our customers face to face.” In her free time Kira enjoys traveling and is an avid runner, participating in numerous races around the beautiful lakes of Minneapolis.



**ROBYN PATRI**

Robyn Patri has been with Minntech for 14 years. She supported Renal Systems as an Administrative Assistant for several years before transferring to Customer Service where she has worked for about 1½ years now. Robyn states:

“Minntech is a great place to work and I love working in Customer Service. You really get to know your customers and what their needs are.” She is married and has 3 children, a boy and twin girls. Robyn enjoys traveling, reading, and just relaxing.



**KIM TOLLEFSON**

Kim Tollefson began her career with Minntech 2½ years ago. She is the Customer Service Manager for Renal Systems, MarCor, and Therapeutic Technologies. She also manages the credit and collections functions for all of Minntech, including our International division. She brings with her a total of 19 years in customer service, of which 10 years have been spent in management. Kim enjoys spending time with her family and a good game of golf.

# PREPARING A RENALIN®-PROCESSED DIALYZER FOR PATIENT TREATMENT

## Visually inspect the dialyzer and confirm that:

Best Practice	Rational
The dialyzer information label is intact, affixed properly to the dialyzer, legible, and includes the patient's name, number of previous uses, and the date and time of the last reprocessing cycle.	<p>The reprocessed dialyzer label should not obscure pertinent information on the manufacturer's label such as model number, lot number, and indicators of blood and/or dialysate flow.</p> <p>The patient's name must be clearly printed on the dialyzer information label because each reprocessed dialyzer must be used for only one patient.</p> <p>Verifying the number of previous uses will ensure that the dialyzer is not used beyond your facility's predetermined maximum number of uses.</p> <p>A minimum 11 hour dwell time is required in order to achieve sterilization. Reprocessed dialyzers that exceed your facility's maximum storage time must either be discarded or reprocessed again and stored for at least 11 hours before they are clinically used.</p>
There is no evidence of structural damage or tampering.	Structural damage such as small cracks may not leak until the circuit has been pressurized.
All four dialyzer ports are properly capped, and that there is no evidence of leakage from the ports or other portions of the dialyzer.	<p>Dialysate port caps may be forced off the dialyzer during storage if the pressure within the dialyzer increases. Pressure build-up in a dialyzer reprocessed with proportioned Renalin solution may be related to:</p> <ul style="list-style-type: none"> <li>• The amount of residual blood that may remain in the dialyzer after reprocessing.</li> <li>• Performing the reprocessing procedure with water that exceeds 75°F.</li> <li>• Storing the reprocessed dialyzer at a temperature that exceeds the maximum storage temperature recommendation of 75°F.</li> </ul>
Both dialyzer headers are at least 2/3 full of proportioned Renalin solution.	Both dialyzer headers must be at least 2/3 full, when the dialyzer is viewed horizontally, in order to achieve sterilization.
The cosmetic appearance of the dialyzer is aesthetically acceptable with no more than a few dark clotted fibers, and free of all but small peripheral clots in the headers.	This will satisfy the requirements in V351 and V352 of the CMS Appendix H (Survey Procedures and Interpretive Guidelines for End-Stage Renal Disease Facilities).

## Test the dialyzer for the presence of proportioned Renalin solution:

Best Practice	Rational
Use a Perassay 500 test strip to confirm that there is at least 500ppm of peracetic acid in the processed dialyzer.	To confirm that the concentration of peracetic acid is sufficient to have achieved sterilization. Peracetic acid concentrations as low as 500ppm have been shown to act as a sterilant.

Best Practice	Rational
<p>Store all unused Perassay 500 test strips in their original vial. Store unopened vials between 5°C and 40°C. Once opened, store the vial at room temperature and do not refrigerate.</p>	<p>The test strips are sensitive to moisture. The test strip vial cap has a desiccant (drying agent) to control moisture.</p>
<p>Ensure that the test strips are not expired.</p>	<p>To ensure accuracy, expired test strips must not be used.</p>
<p>Ensure that your glove or hand is clean before removing a strip from the vial. Always replace the cap immediately after removing a test strip from the vial.</p>	<p>The test strips react to oxidants such as Renalin, chlorine, chloramines and hypochlorite. Exposing the test strips to gloves or hands that have been exposed to oxidants, or leaving the vial uncapped near oxidants may cause false positive test results.</p>
<p>Push in the clear plastic shield on the end of the ventable dialysate port cap if it is not already in that position. Squeeze the red portion of the ventable port cap at the base of the clear plastic shield for 2 – 3 seconds to vent the pressure.</p>	<p>The ventable dialysate port cap allows the dialysis staff to release pressure build-up in dialyzers reprocessed with proportioned Renalin solution before any of the port caps are removed from the dialyzer.</p>
<p>Remove one of the dialysate port caps from the dialyzer and collect approximately 1mL of solution. Dip the test strip into the sample, immersing the entire reaction pad. Remove the test strip and gently shake off any excess liquid. Alternatively, your facility's procedure may require allowing a small sample of the solution to drip from the open dialysate port onto the test strip pad, ensuring that the entire test pad is saturated. Gently shake off any excess liquid. Do not insert the test strip into the dialysate port of the dialyzer.</p>	<p>Presence testing must be performed on a sample taken from the dialysate side of the dialyzer. Inserting the test strip into the dialysate port can result in damage to the dialyzer fibers. Additionally, the test strips are not sterile.</p>
<p>After 2 to 5 seconds, observe the reaction pad color development.</p> <ul style="list-style-type: none"> <li>• Blue-grey or blue-black color over the entire reaction pad within 10 seconds, and that does not fade, indicates a peracetic acid level of 500ppm or greater.</li> <li>• No color development, scattered spots of blue-grey or blue-black or brown, or immediate fading of blue-grey or blue-black, indicates a peracetic acid level of less than 500ppm.</li> </ul>	<p>The reaction pad may slowly change or develop color over time after the initial reaction. This is normal and should be ignored for the purpose of test interpretation. Disregard any color changes after the initial 10 seconds. Dialyzers that contain a peracetic acid level less than 500ppm must not be used for patient treatment. Failure to follow the test strip Directions for Use may result in patient injury.</p>

## Prime and rinse the dialyzer:

Best Practice	Rational
<p>Prime the maintenance heparin line with 1cc of heparin and clamp the line as close as possible to the junction with the arterial blood line.</p>	<p>Priming the line will ensure that the patient receives maintenance heparin immediately once the pump is activated and the line is unclamped. Unless the heparin line has been primed, the patient will not receive any maintenance heparin until the air is purged from the line. This may take up to one hour. Clamping the maintenance line as close as possible to the junction with the arterial blood line will ensure that Renalin solution does not migrate into the line during the recirculation cycle.</p>

Best Practice	Rational
<p>Prime the entire arterial blood line with saline before connection to the dialyzer.</p> <ul style="list-style-type: none"> <li>Note: If using the Cobe C3 or Gambro Phoenix dialysis machine, the venous blood line will be primed before connection to the dialyzer.</li> </ul>	<p>To avoid infusing air into the dialyzer. Dialyzer fibers that are fully or partially obstructed with air are more difficult to rinse and increase the possibility of exposing the patient's blood to poorly rinsed surfaces later during dialysis treatment. Air in the dialyzer will also decrease the membrane surface area, and promote clotting once blood is introduced.</p>
<p>Raise the fluid level in the arterial drip bulb/chamber until it is approximately <math>\frac{3}{4}</math> full.</p> <ul style="list-style-type: none"> <li>Note: If using the Cobe C3 or Gambro Phoenix dialysis machine, the fluid in the venous drip bulb/chamber should be raised at this time.</li> </ul>	<p>Raising the fluid level prevents air from being infused into the dialyzer during the priming procedure and/or the recirculation cycle. Overfilling the drip bulb/chamber may result in Renalin solution backing up into the monitor line and possibly the transducer protector during the recirculation cycle. This could result in the Renalin solution not being adequately rinsed out of the extracorporeal circuit and inadvertently expose the patient during treatment. Wet transducer protectors will also result in inaccurate pressure readings.</p>
<p>Prime the circuit with a flow rate no greater than 150mL/min until a minimum of 500mL of saline has drained from the saline bag.</p>	<p>Priming with a flow rate no greater than 150mL/min will help the dialyzer fibers fill evenly and reduce the chances of excessive air in the fibers. The primary recommendation for the saline prime is to prevent the formation of gas bubbles within the dialyzer fibers. This can occur when bicarbonate from the dialysate diffuses into the dialyzer fibers and reacts with the Renalin. Fibers that are fully or partially obstructed with air are more difficult to rinse and increase the possibility of exposing the patient's blood to poorly rinsed surfaces later during dialysis treatment.</p>
<p>Complete the priming procedure with the dialyzer positioned vertically and the venous header facing up.</p> <ul style="list-style-type: none"> <li>Note: If using the Cobe C3 or Gambro Phoenix dialysis machine, the arterial header of the dialyzer will be facing up.</li> </ul>	<p>Positioning the dialyzer vertically will prevent air from being trapped in the dialyzer headers. Priming with the appropriate header facing up will help remove air from the dialyzer.</p>
<p>Raise the fluid level in the venous drip bulb/chamber until it is approximately <math>\frac{3}{4}</math> full. <b>Do not invert the drip bulb/chamber to fill it.</b></p> <ul style="list-style-type: none"> <li>Note: If using the Cobe C3 or Gambro Phoenix dialysis machine, the fluid in the arterial drip bulb/chamber should be raised at this time.</li> </ul>	<p>Raising the fluid level prevents air from being infused into the dialyzer or activating the air/foam detector alarm during the recirculation cycle. Inverting the venous drip bulb/chamber to fill exposes the entire bulb/chamber to Renalin solution. This can result in Renalin solution backing-up into the venous medication administration line and/or the pressure monitor line if the lines are not clamped as close as possible to the junction with the bulb/chamber. Overfilling the drip bulb/chamber may result in Renalin solution backing up into the monitor line and possibly the transducer protector during the recirculation cycle. This could result in the Renalin solution not being adequately rinsed out of the extracorporeal circuit and inadvertently expose the patient during treatment. Wet transducer protectors will also result in inaccurate pressure readings.</p>

Best Practice	Rational
<p>Verify that the conductivity, pH, and temperature of the dialysate are within safe limits. (This is not part of the rinse procedure, but it is critically important that this be done before patient treatment is initiated).</p> <p>Connect the dialysate hoses to the dialyzer and initiate a dialysate flow of at least 500mL/min after completing the initial prime.</p> <ul style="list-style-type: none"> <li>Note: Some Gambro Phoenix dialysis machines have software that allows the dialysate hoses to be connected to the dialyzer during the initial prime. If the dialysate hoses are connected either before or during the initial prime, ensure that the dialysate is in bypass.</li> </ul>	<p>Connecting the dialysate hoses to the dialyzer and initiating dialysate flow prior to priming approximately 500mL of saline through the circuit may cause the dialyzer fibers to air-lock. This can occur when bicarbonate from the dialysate diffuses into the dialyzer fibers and reacts with the Renalin.</p>
<p>Allow the dialysate to completely fill the dialyzer from bottom to top.</p> <p>Verify that there is an adequate amount of saline remaining in the bag to complete the recirculation cycle.</p>	<p>Filling the dialysate compartment from bottom to top will purge air from the dialysate compartment.</p> <p>Allowing the saline bag to empty during the recirculation cycle can result in a large bolus of air being infused into the dialyzer.</p>
<p>Recirculate with a blood flow rate of approximately 300mL/min for at least 10 minutes with a fluid removal rate of 2L/hr.</p>	<p>Recirculating with a flow rate no greater than 300mL/min will minimize the chance of pulling air into the pre-pump segment. Recirculating for at least 10 minutes with a fluid removal rate of 2L/hr will effectively rinse the dialyzer.</p>
<p>Continue to recirculate, and maintain a minimal ultrafiltration rate between rinsing the dialyzer and initiating patient treatment.</p>	<p>This process will prevent germicide rebound. If flow is interrupted after the dialyzer has been rinsed, germicide may diffuse from the dialyzer materials into the blood compartment resulting in germicide rebound.</p>

## Identify the dialyzer and the patient:

Best Practice	Rational
<p>Verify that the patient name on the information label corresponds with the patient name on the dialyzer barcode label.</p>	<p>To confirm that the dialyzer was not labeled incorrectly. It is critical to compare the two labels because the information label is updated and replaced after each reprocessing cycle.</p>
<p>Verify that the dialyzer number on the information label corresponds with the dialyzer number on the barcode label.</p>	<p>To confirm that the dialyzer was not labeled incorrectly. A patient may have more than one dialyzer assigned to them.</p>
<p>Verify that the dialyzer model listed on the information label corresponds with that of the dialyzer.</p> <p>Verify that the dialyzer model corresponds with what was ordered by the physician.</p>	<p>To ensure that the appropriate dialyzer model is used for patient treatment as ordered by the physician.</p>
<p>Two staff members or one staff member and the patient should verify that the dialyzer belongs to the patient present at the station.</p> <ul style="list-style-type: none"> <li>Note: This procedure should be documented before treatment is initiated.</li> </ul>	<p>To confirm that the correct dialyzer will be used to treat the patient.</p>

## Test the dialyzer for residual Renalin after it has been rinsed:

Best Practice	Rational
<p>After rinsing the dialyzer and immediately before patient treatment is initiated, use a Renalin® Residual test strip to confirm that there is less than 3ppm of hydrogen peroxide present.</p> <ul style="list-style-type: none"> <li>Note: Refer to your facility policy regarding acceptable residual Renalin test results.</li> </ul>	<p>To ensure that the Renalin solution has been rinsed down to a safe level before patient treatment is initiated. The symptoms of exposure to residual Renalin can range from mild to severe depending on the Renalin concentration and the patient's sensitivity.</p>
<p>Store all unused Renalin Residual test strips in their original vial. Store the vials in a cool and dry place without refrigerating.</p>	<p>The test strips are sensitive to moisture. The test strip vial cap has a desiccant (drying agent) to control moisture. Failure to store the test strips properly may result in inaccurate readings.</p>
<p>Ensure that the test strips are not expired.</p>	<p>To ensure accuracy, expired test strips must not be used.</p>
<p>Ensure that your glove or hand is clean before removing a strip from the vial. Always replace the cap immediately after removing a test strip from the vial.</p>	<p>The test strips react to oxidants such as Renalin, chlorine, chloramines and hypochlorite. Exposing the test strips to gloves or hands that have been exposed to oxidants, or leaving the vial uncapped near oxidants may cause inaccurate test results.</p>
<p>Turn off the blood pump and clamp both the arterial and venous blood line at the patient end. Separate the blood lines and allow enough saline to drip from the end of the venous blood line to completely saturate the test strip pad. Take care not to contaminate the end of either blood line. Gently shake off the excess liquid.</p> <ul style="list-style-type: none"> <li>Note: Your facility procedure may require using a needle and syringe to draw a sample from one of the blood line sample ports. If this procedure is performed, ensure that the sample port is disinfected before obtaining the sample.</li> </ul>	<p>Residual Renalin testing must be performed on a sample taken from the blood circuit to ensure that the Renalin has been rinsed down to a safe level before patient treatment is initiated. Contaminating the end of either blood line or not disinfecting the sample port before penetrating the circuit can contaminate the circuit and jeopardize the patient's safety.</p>
<p>Compare the test pad with the color scale on the test strip vial between 5 and 10 seconds after exposure.</p> <ul style="list-style-type: none"> <li>If the test strip indicates less than 3ppm the dialyzer is safe for patient use. However, your facility policy may require a lower result.</li> <li>If the result is 3ppm or greater, re-connect the arterial and venous blood lines and continue rinsing the dialyzer. Repeat the residual test procedure until the result indicates that the dialyzer has been rinsed adequately.</li> </ul>	<p>Patient treatment must not be initiated if the circuit contains a residual Renalin level of 3ppm or greater. The symptoms of exposure to residual Renalin can range from mild to severe depending on the Renalin concentration and the patient's sensitivity. Failure to follow the test strip Directions for Use may result in patient injury.</p>
<p>Discard the saline bag, spike a new bag, and flush the extracorporeal circuit with fresh saline immediately before initiating patient treatment.</p> <p><b>Do not infuse recirculated saline into the patient as a volume enhancer.</b></p>	<p>Fresh saline should always be used to replace the rinse saline within the circuit before treatment is initiated. This will minimize exposure to manufacturing residues from the blood tubing and dialyzer, and germicide that may have rebounded in the circuit and/or migrated into the saline administration line and the saline bag.</p>

## CALENDAR OF EVENTS:

### Annual Dialysis Conference

February 26-28, 2006  
San Francisco, CA

### The Renal Network, Inc.: 2006 Nephrology Conference

March 1-3, 2006  
Chicago, IL

### NANT 23rd Annual Symposium

March 7-9, 2006  
Las Vegas, NV

### Renatron Service/Maintenance Seminar

March 14-15, 2006 &  
March 16-17, 2006  
Cleveland, OH

### RPA, Renal Physicians Association Annual Meeting

March 18-20, 2006  
Baltimore, MD

### ANNA 37th National Symposium

April 2-5, 2006  
Nashville, TN

### NKF 2006 Spring Clinical Nephrology Meetings

April 19-23, 2006  
Chicago, IL

### NRAA Annual Spring Meeting 2006

April 27, 2006  
Palm Springs, CA

### California Dialysis Council 24th Annual Educational Conference

April 27-29, 2006  
Palm Springs, CA

### Renatron Service/Maintenance Seminar

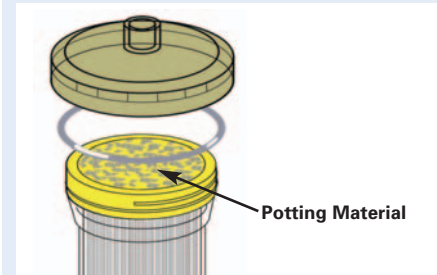
May 9-10, 2006 &  
May 11-12, 2006  
Las Vegas, NV

## Q & A

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This is accelerated by both light and Renalin. The exhaustion of residues creates a more dense cross-linked material. When the cross-link density increases, the optical characteristics of the material changes where the spectrum of light it originally reflected (beige to slight yellow) is a slightly more deep yellow amber color.

Bert Walter, PHD  
Director of Product Development,  
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