ReNews
A publication on dialyzer reprocessing
volume 7, 2005


# Reprocessing: Valid and Viable

The reprocessing of hollow fiber hemodialyzers continues to be a valid and viable practice both from the standpoint of patient outcomes and economics.

An abstract supporting the efficacy of reprocessing was presented by Wayne Carlson, Director of Renal Clinical Services with Minntech, at the first ever Kidney Disease Economics Conference, "Balancing Economics & Quality in Renal Care," held in Phoenix, Arizona, in February 2005.

The abstract presented at the conference was titled, "Dialyzer Reprocessing: The Ideal Strategy for a Limited Reimbursement Environment." The abstract highlights that reprocessing continues to be a sound approach in dealing with today's environment.

A recent multi-center retrospective analysis of incident dialysis patients, published as an abstract at the 2004 ASN meeting by Nephrology Analytical Services, validated the continued efficacy of dialyzer reprocessing. A slight survival advantage was associated with reuse in unadjusted data while no survival advantage was associated with single use or reuse in the adjusted data.

This contrasts with the results of a retrospective study of prevalent patients converting from reusable dialyzers to single-use dialyzers in Fresenius Medical Care dialysis facilities in the United States.

The NAS analysis is more robust since it includes only data from incident patients and eliminates the inherent practice bias and "chain effect" common to the analysis of data from a single organization.

With no association between reprocessing status and efficacy, the decision to reprocess dialyzers or to dispose of them after every treatment becomes an economic one.

Conservative economic models have demonstrated a dialyzer cost savings beginning at 43% for dialyzer reprocessing when compared to single-use costs.

In an average 70-patient clinic this translates to an annual savings in dialyzers of approximately $43,000.

This savings can then be effectively applied to staff training,

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# Header Cleaning: How to avoid the pitfalls

Some dialyzers come back to the reprocessing area with large amounts of clots and fibrin in the dialyzer headers. This can be related to the header design on specific models of dialyzers or to treatment issues such as inadequate or improper heparinization and low blood flow rates.

In dialyzers with removable headers this problem is sometimes addressed by manual removal and cleaning of the headers. Improper cleaning and disinfection of the header assembly can lead to trapped bacteria

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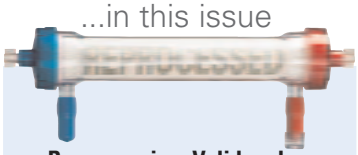



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## Reprocessing: Valid and Viable

increased staff to patient ratios or advanced technologies. When used in this manner, dialyzer reprocessing, as a neutral clinical event, is the ideal method of delivering advanced therapy by removing economic barriers to clinical and technological excellence.

### Conclusion

- Numerous multi-provider studies have validated the efficacy of dialysis using a reprocessed dialyzer.
- It has been established that patient outcomes are not dependent on reuse practice.
- Arguably, no other aspect of dialysis has been as closely scrutinized as dialyzer reprocessing.
- Economic models validate the cost efficacy of maintaining a reprocessing program.
- Recent changes in dialysis reimbursement put even more pressure on the dialysis center to conserve limited financial resources.
- Do you use your limited reimbursement dollars to benefit the patient by reprocessing dialyzers or benefit the supplier by using single-use dialyzers? ■

For more information, see abstract highlights starting on page 6.

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## Header Cleaning: How does this effect your process?

under the O-ring that can be released during subsequent patient treatments. Some patients have experienced a problem called "header sepsis" when manual header cleaning has been improperly performed.

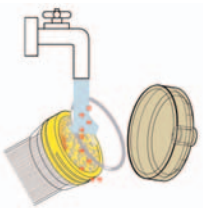
Minntech Renal Systems does not recommend removing or not removing the header caps of dialyzers to be reprocessed; this decision remains with the facility's medical director. Your facility may prohibit header removal or may have a more detailed procedure than the one that follows. Always follow the specific policy and procedure for your facility regarding header removal.The practice of header removal is done to remove residual blood products which accumulate in the headers during dialysis treatments. The removal of header caps in itself is not a problem; the potential of contaminating the exposed components and disinfection and proper reassembly are the major concerns.

Steps that can be taken to avoid some of the conditions that can lead to header sepsis include:

- Manual header handling and cleaning steps that focus on the areas that decrease the chances of header sepsis.
- The use of automated header cleaning systems, like the RenaClear, that eliminates header removal altogether.

**Problem areas in performing manual header cleaning:**

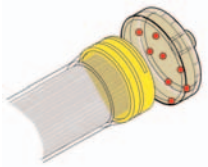
1. Header cleaning exposes previously sealed areas of the dialyzer to potential contamination.



2. Even though the water used to pre-clean and reprocess dialyzers meets AAMI guidelines, it is not sterile.

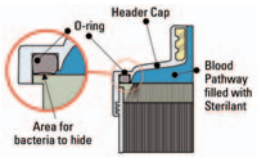
a. Water used to clean header surfaces contains bacteria.

b. When the header is re-assembled bacteria from the rinse water may be trapped under the O-ring.

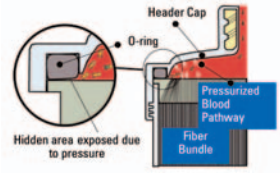


3. Sterilant does not get in all places in the header.

a. The blood pathway is filled with sterilant but it cannot reach the bacteria that may be trapped under the O-ring.




4. Bacteria trapped under the O-ring can be released when the header cap and blood pathway become pressurized during the treatment. This pressurization of the header can cause the O-ring to move,

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## Header Cleaning: How does this effect your process?

exposing the hidden area and possibly release the once trapped bacteria.

**Solving the problem:**

1. Ensure that all header components are properly cleaned and exposed to a 1% Renalin solution (or full strength Actril® Cold Sterilant). This process is necessary to prevent growth of organisms that may be inadvertently introduced into areas that are inaccessible to Renalin solution.

**How is this done?**

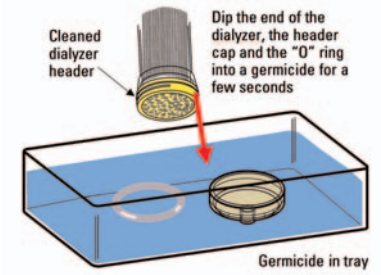
1. Remove one header cap from the dialyzer.

2. Remove the O-ring from the header cap. This can be accomplished by tapping the header cap against the palm of the hand. It is necessary to remove the O-ring to expose the O-ring channel to 1% Renalin solution. (Note: Some models of dialyzers have removable headers with non-removable O-rings. Do not attempt to remove these. Treat the header cap and non-removable O-ring as one unit.)

3. Flush the water source prior to rinsing the components; this removes stagnant water which may contain bacteria and endotoxins.

4. Over a sink, rinse the header cap, O-ring and dialyzer header with a gentle stream of AAMI-quality water, flushing the blood product residue down the drain.

5. Immerse the O-ring, header cap and dialyzer header in a container of 1% Renalin solution.




a. An alternative to immersing the header cap, O-ring and dialyzer header is to use a squirt (not spray) bottle containing fresh 1% Renalin solution (made daily). Fully expose all surfaces of the header cap, O-ring and dialyzer header with a steady stream of 1% Renalin solution.

(NOTE: Do not rinse germicide off of the components as this will defeat the purpose of exposing them to germicide in the first place. Even AAMI quality water contains bacteria that would then be introduced on to the components.)

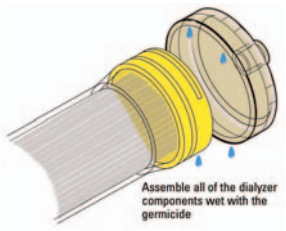
6. Reassemble all of the components wet with germicide. The bacteria that might be under the O-ring will then be exposed to germicide and be destroyed.

a. Invert the header cap.

b. Place the O-ring into the groove.

c. Use your index finger to stabilize the O-ring while pushing the O-ring into position with your other index finger.

d. Replace the header cap and tighten to fit snugly in place.




7. Repeat the above steps for the other header cap if necessary.

8. Proceed to reprocess the dialyzer per your facility's standard procedures. ■

# TROUBLESHOOTING:

## Tank Volume Alarms

**I have never had a Tank Volume Alarm before, what is it?**

Although a very rare occurrence, a Tank Volume Alarm will occur when the Renatron® station either has not filled or emptied the internal tank in the allotted time. Tank Volume Alarms on the Renatron station will most likely happen within the first five steps of the program. Generally, a valve coil failure will cause this alarm.

**How to troubleshoot a Tank Volume Alarm:**

1. Refer to Program Outline PN 20600-610 (for Renalin 100 Renatron stations), and find the step in which the machine has failed. The Program Outline will list coils that should be energized for that step.

2. Check each coil for magnetism. The easiest way to do this is to hold a small metallic object up to the end of the coil; a paper clip usually works best. If the coil is magnetized, the paper clip sticks to the coil.

Note: When the Renatron station goes into Fail mode all coils are de-energized. To check a coil for magnetism the Renatron station must be running.

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## TROUBLESHOOTING: Tank Volume Alarms.

3. Any coils that are not energized in a step that the Program Outline indicates that they should be, should be replaced. If a coil needs to be replaced, you should also make sure that the coil did not damage the power board. Please contact Technical Support at 800-328-3324 for instructions on testing the power board.

4. Once the coil is replaced the machine should function normally.

There are two situations not related to a bad coil that could cause a Tank Volume Alarm in the first five steps. Both of these can cause the alarm because air is pulled into the system at one of the connection sites.

a. The first situation is caused by the reprocessing connectors not being completely inserted into the swivel body on the blood line. This will cause a Tank Volume Alarm in Step 4.

b. The second situation is caused by the dialyzer not being properly attached to the Hansen connectors. This will cause a Tank Volume Alarm in Step 5. ■

Greg Pielow
Senior Technical Service Representative

## CALENDAR OF EVENTS

**BONENT Exam**
August 7, 2005
Montrose, OH

**AKF, American Kidney Fund Regional Conference Series**
**Partnering for Better Outcomes**
August 18, 2005
Atlanta, GA

**AAKP, American Association for Kidney Patients 32nd Annual Convention**
September 1 - 4, 2005
Las Vegas, NV

**BONENT Exam**
September 18, 2005
Toledo, OH

**ANNA Fall Meeting 2005**
September 24 – 26, 2005
Kansas City, MO

**NRAA 2005 Annual Conference**
September 28 – October 1, 2005
Chicago, IL

**BONENT Exam**
October 2, 2005
Columbus, OH

**17th Annual Network Educational Meeting**
**ESRD Network of New England**
October 6, 2005
Sturbridge, MA

**AKF, American Kidney Fund Regional Conference Series**
**Partnering for Better Outcomes**
October 20, 2005
Chicago, IL

**NNCO Exam**
October 22, 2005
Various locations

**ASN, American Society of Nephrology Renal Week 2005**
November 8 – 13, 2005
Philadelphia, PA

## SPOTLIGHT ON THE:

## Clinical Services Team Members

Unlike many providers in the dialysis marketplace, Minntech provides a clinical services group dedicated solely to the dialysis community. The credibility of the clinical services group is unchallenged. The four members that make-up the Clinical Services group collectively has over ninety-five years of medical experience with eighty-nine years of dedicated dialysis experience. The director of the department has been with Minntech for eight years while the newest clinical services specialist joined the group this year. This solid base of working expertise is invaluable when conducting investigations, troubleshooting problems and presenting materials.

**Wayne Carlson, Director of Clinical Affairs**

**Kendall Larson, Clinical Specialist**

**Tia Sabin, Clinical Specialist**

**Diana Bolton, Clinical Specialist**

In addition to our US-based group we also have three members of Clinical Services that work internationally from Minntech offices in Singapore, Beijing and The Netherlands. ■

## Q & A

**How does Renalin® Cold Sterilant actually work?**

All organisms are made of lipids, DNA, polysaccharides, proteins as well as hybrids of these molecules. Proteins provide structural support, a transport medium and the catalysts (enzymes) that run the cell's machinery. The simplest way to kill an organism is to disrupt its chemical machinery by attacking its lipids, DNA, polysaccharides, and especially its proteins (enzymes in particular). Lipids, DNA, and proteins contain sensitive chemical bonds such as double bonds and sulfur bonds. Agents that react with these bonds can disrupt an organism's chemical processes.

The active ingredients found in Renalin Cold Sterilant are two potent oxidizing agents: hydrogen peroxide ($H_2O_2$) and peracetic acid (PAA). The antimicrobial action of $H_2O_2$ and PAA in Renalin Cold Sterilant is due to its oxidation of sensitive sulfur groups and groups with double bonds found in proteins, DNA, lipids, and surface membrane cell components. HP and PAA disrupts an organism's cell membrane and knockout its transport machinery by rupturing the cell wall. When the cell wall becomes leaky and can no longer control chemical transport and the enzymes are damaged by the oxidation and no longer function as biochemical catalysts, the cell perishes. ■

Bert Walter, PHD
Director of Product Development,
Chemicals & Microbiology

## TECHNICAL SERVICES UPDATE

**Upgraded Renatron station control boards are now available.**

Benefits of the new control board include:

- Incorporation of the expansion board
- Easy to use touch pad calibration instead of potentiometers
- Surface mount technology
- Accommodation of new software enhancements as they become available

Starting August 1, 2005 Technical Services will no longer be able to provide refurbishment and exchange for control boards with part numbers 70136-xxx and 70201-020. This is because the electronics on these boards are no longer available.

Renatron stations with s/n's 10000 and above will be able to be upgraded with the new style control board. Renatron stations below s/n 10000 (Blue boxes) will not be able to be upgraded with the new board.

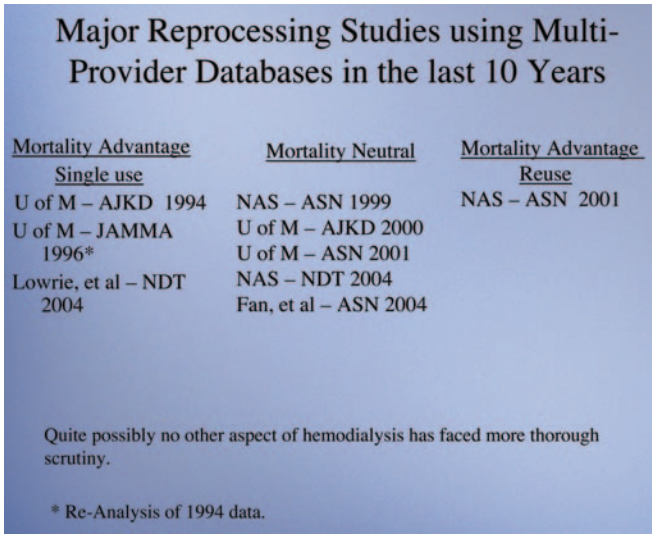
Keep your eyes open for future Renatron enhancements that will make reprocessing even more efficient and convenient.

## PRODUCT UPDATE

The Perassay® 500 test strips give the same test results with a new look.

Perassay 500 test strips have a new green look for clear distinction from white Renalin Residual test strips. The test procedure and reaction pad are the same as before. For more information, contact Minntech customer service at 1-800-328-3340.


**Highlights from "Dialyzer Reprocessing: The Ideal Strategy for a Limited Reimbursement Environment" abstract continued from other side.** continued from page 1

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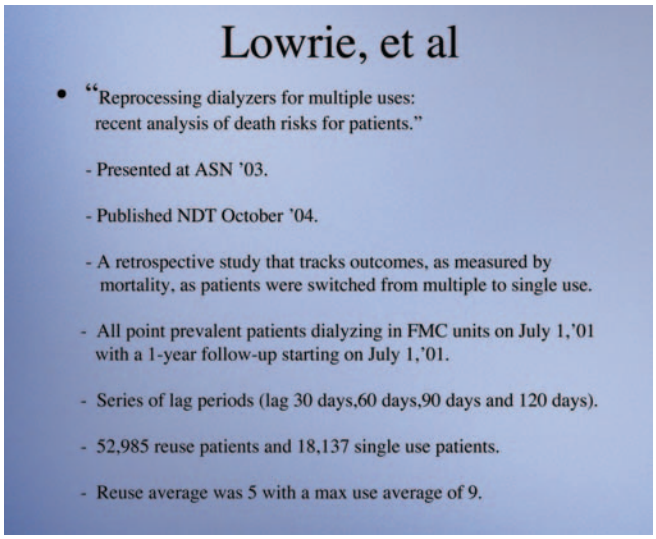


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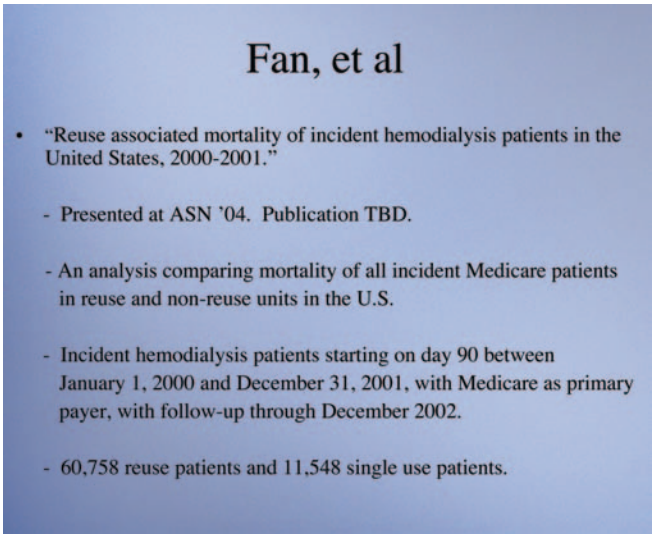


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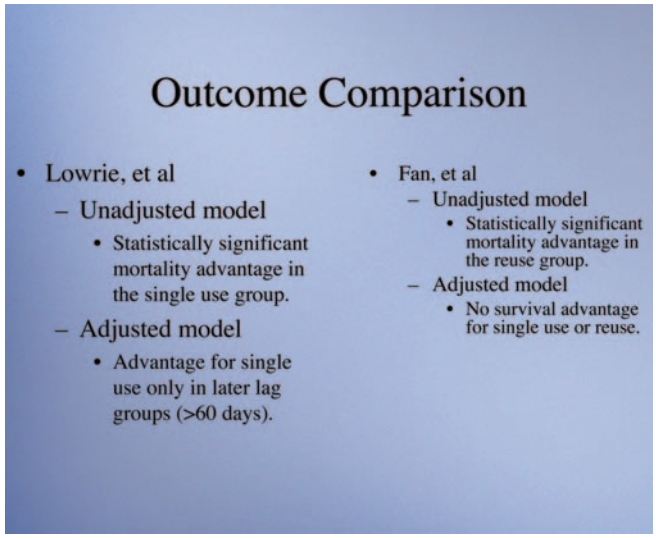



**Slide 4**

**Highlights from "Dialyzer Reprocessing: The Ideal Strategy for a Limited Reimbursement Environment" abstract.** continued from page 6

## Study Comparison Strengths and Weaknesses

### Lowrie, et al Strengths

- Reuse designation is patient-based rather than unit-based.
- Lag periods included to theoretically capture benefit that may lag behind the change to single use.
- Unique opportunity to measure outcomes.

### Fan, et al Strengths

- Incident rather than prevalent patients.
- Data from the standard 7-chain affiliations as well as all free-standing and hospital-based units.

### Lowrie, et al Weaknesses

- Retrospective study.
- Prevalent patient data.
- Change to single use began in '00 yet lag 0 was set at 7/1/01.
- No description of selection process for switch to single use (administrative decision).
- Data from only one provider.
- Dialyzers of only one membrane type from one manufacturer.

### Fan, et al Weaknesses

- Retrospective study.
- Reuse status is unit-based rather then patient-based.
- Biochemical data from the entry period not included.

**Slide 5**

## Outcome Significance

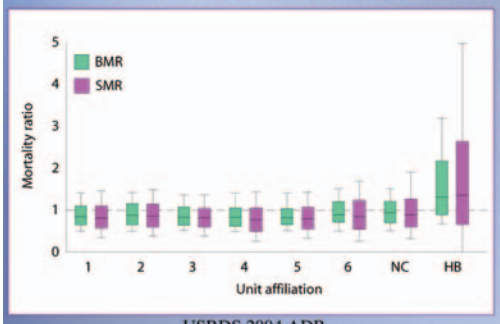
– Lowrie, et al study outcomes based solely on the practice of one provider.

– Low reuse average noted in Lowrie, et al study (5) gives insight into the management of the reuse program. The last national reuse average published by the CDC was 17 and there is no indication that the number has fallen. The low reuse average of clinics that switched indicates that they are not representative of reprocessing units as a whole.

– Lowrie, et al study may provide insight into reuse practice within the Fresenius organization.

**Slide 6**

## Confirmation of Fan, et al Findings




Chain 1 - Fresenius
Chain 2 - Gambro
Chain 3 - DaVita
Chain 4 - Renal Care Group
Chain 5 - Dialysis Clinics, Inc.
Chain 6 - Nat'l Nephrology Assoc.
NC - Non-chain units
HB - Hospital-based units
U - Unknown affiliation

USRDS 2004 ADR

Prevalent dialysis patients, 2002, in all dialysis providers. Adjusted for age, gender, race, primary diagnosis, & vintage.

When comparing outcomes from independent dialysis providers, multi-provider databases and the USRDS it is evident that dialyzer reuse is not associated with negative clinical results. Furthermore, outcomes were virtually equivalent despite reprocessing status.

**Slide 7**

## Dialysis Center Comparison of Medium Center and Large Center

| 70 Patients | Cost/Rx | Annual Cost |
|---|---|---|
| Single Use | $9.111 | $99,489 |
| Reprocessing | $5.141 | $56,143 |
| Savings | $3.969 | $43,346 |

| 150 Patients | Cost/Rx | Annual Cost |
|---|---|---|
| Single Use | $8.612 | $201,513 |
| Reprocessing | $4.796 | $112,224 |
| Savings | $3.816 | $89,289 |

S.U. Dialyzer - $ 8.50 M.U. Dialyzer -$ 18.50

Financial Aspect

46,000,000RX/yr@$8.50 dialyzer
$391,000,000
46,000,000RX/15 uses@$20 dialyzer
$61,300,000
$329,700,000 (This represents a decrease in dialyzer purchases by dialysis centers and a loss of revenue for dialyzer manufacturers).

Center Model costs:

- Dialyzer cost/testing/rinsing/misc.
- Biohazardous waste removal
- Equipment cost
-Amortization schedule
-Supply cost
-Salary/benefits
-Space allocation
-Overhead

**Slide 8**



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