ReNews

A PUBLICATION ON DIALYZER REPROCESSING

Volume 3 Number 2
Fall/Winter 1995

FDA Prepares to Regulate Dialyzer Reuse Labeling

By LeRoy J. Fischbach
Vice President, Regulatory Affairs
Renal Systems, Division of Minntech Corporation

If your dialysis facility practices reuse, you deal with *resposables* every day. Resposables are products that are labeled as disposable, or single use, yet reused routinely. Since their introduction, dialyzers have been considered a resposable product by many in the dialysis community. Initially, a limited supply of dialyzers prompted reuse. The practice became even more attractive when it was discovered that reprocessing a dialyzer limited first-use reactions for some patients. Today, many facilities reuse dialyzers to save money by minimizing supply costs.

When dialyzer reuse was first practiced, FDA did not require special labeling. At the time, the reuse of disposable dialyzers was intrepreted as a medical practice by FDA, and, therefore did not fall

Continued on page 2

HCFA Adopts 1993 ANSI/AAMI Guidelines

The September 18, 1995 edition of the U.S. *Federal Register* contained a Final Rule by the Health Care Financing Administration (HCFA) concerning standards for quality of water used in dialysis and revised guidelines on reuse of hemodialyzers. This Final Rule went into effect on October 18, 1995. The 1993 ANSI/AAMI guidelines for dialyzer reuse include these important new highlights:

- Total cell volumes are acceptable as an indicator of reused dialyzer performance.
- Clinical outcomes are recognized as the most important indicator of all reuse processes.
- Leak testing is required for each dialyzer with each reuse.
- Reuse of dialyzers from hepatitis B positive patients is prohibited.

Briefly, HCFA has now incorporated by reference the ANSI/AAMI's 1992 water quality requirements and 1993 ANSI/AAMI guidelines for dialyzer reuse into their conditions for coverage.

Previously HCFA had rather ambiguous requirements for dialysis water quality, and it's requirements for dialyzer reprocessing were based on the outdated 1986 AAMI guidelines. With the new Final Rule, both of these discrepancies have been remedied.

The full text of HCFA's new Final Rule can be found in the September 18, 1995 edition of the *Federal Register*, Rules and Regulations, Volume 60, No. 180, pp. 48039-48044. According to the *Federal Register* further information is available from Jackie Sheridan at HCFA, (410)966-4635.

In this Issue

Page

Continued from page 1

within the agency's jurisdiction. But as dialyzer reuse grew, FDA became concerned that reusing dialyzers was actually an off-label use (i.e., used in a way other than what the manufacturer originally intended). In 1986, FDA issued a letter to manufacturers requesting that they relabel their disposable dialyzers and provide directions for reuse. The agency indicated that manufacturers were supporting the practice of reuse while at the same time continuing to label for single use. However, following months of discussion, FDA made a decision to drop their request and the practice of reuse continued.

In October 1992, FDA asked once more that manufacturers label their dialyzers for reuse. Again, the agency claimed that manufacturers were supporting the practice of reuse for their products. FDA cited incidents such as one manufacturer that was selling replacement end caps for its single use dialyzer, and other manufacturers that were giving instructions on how to get the maximum number of reuses from their products. This time FDA did not drop the issue of relabeling resposable dialyzers.

After three years of negotiations with manufacturers and users, FDA is now finalizing a reuse labeling guideline. Preliminary copies of this guideline were released on October 16, 1995. The new reuse guideline will require manufacturers to make a choice—either relabel or stop supporting reuse of their dialyzers. The FDA will require all manufacturers that label dialyzers for reuse to submit test data to support product claims. The agency has promised to put some muscle behind this action. If a manufacturer tries to double market their product, that is, label it for single use and market it for reuse, FDA will take action against the manufacturer and stop the sale of the product in question.

What does this mean for you? First of all, it means the end of resposable dialyzers. A single use label on a disposable dialyzer will mean just that - that the dialyzer meets FDA standards *for single use only* and should not be reprocessed. Conversely, if a dialyzer is labeled for reuse, it will mean that the manufacturer performed testing to support the reusability of the product and it is safe to reprocess following the manufacturer's instructions for use. This should be a win/win situation for dialysis facilities that reuse. They will no longer have to feel as if they are violating the manufacturers' directions for use, and furthermore, can expect support from the manufacturer on the practice of reuse. This will ultimately lead to a better treatment for the patient.

The new reuse guideline will require manufacturers to make a choice—either relabel or stop supporting reuse of their dialyzers.

It took over twenty years to get manufacturers to agree to correct the labeling on dialyzers. It will take several more years for the industry to enact this change and deliver dialyzers labeled for reuse. The FDA is reportedly considering giving manufacturers up to eighteen months to change their labeling practices and develop the necessary support data for reuse labeling, but at the time of this writing the deadline has not yet been set.

In the meantime, the FDA has established an interim labeling policy which allows manufacturers to change their labeling without providing supporting test data. Because dialyzer reuse has been so widespread in the past, the FDA has determined that enough data is available to back-up interim label reuse claims until official guidelines are enacted. Renal Systems implemented this interim labeling policy when it introduced the labeled-for-reuse Primus® dialyzer. Along with our Renatron® and Renalin® product lines, the Primus® dialyzer is part of our continuing commitment to support the reuse of hemodialyzers practice.

Reminder

Plan Ahead for Renalin® Concentrate Inventory

Remember, Renalin® Dialyzer Reprocessing Concentrate can only be shipped via ground transportation (airline regulations prohibit air shipment). Planning ahead now to meet your facility's reprocessing needs could prevent shortages this winter, when inclement weather may delay truck shipment delivery of Renalin®.

Renatron® Dialyzer Reprocessing System: The People Behind the Product

In 1982, when the first Renatron® dialyzer reprocessor rolled off the line at Renal Systems, Rose Pierce was there. Today, Rose is still there, as an assembly supervisor in the electronics department - the place where the Renatron® system comes together. Like many of her co-workers, she's been with the product since the beginning. In fact, Rose has been with the *company* since the beginning— twenty years to be exact. But that isn't unusual in her department. The nineteen employees who work in electronics have a combined total of 196 years of experience assembling, supporting, and quality checking the Renatron® system and other Renal Systems products. Electronics manager Tom Olson has a simple explanation for the longevity of these staff members: "Everyone in this department takes tremendous pride in the company. They like what they do, and it shows in every product they put out."

That pride is apparent in the exacting assembly procedures and quality testing the department routinely performs. The Renatron® system enters the electronics department in pieces - circuit boards, wiring, and other system components. The assembly crew begins with the precise hand-soldering of the three circuit boards that are the brains of the unit. After a quality check by an electronics test technician, these circuit boards, along with the other electronic and system subassemblies, are wired together and placed into a Renatron® chassis. The assembled product is then pre-tested to check function and voltage levels. At that point, the unit looks like a dialyzer reprocessor, but it won't be a Renatron® station until it passes a series of stringent quality control checks.

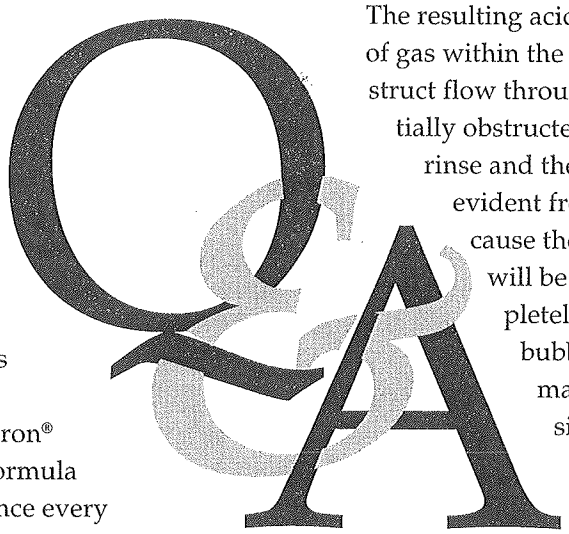
Before a Renatron® system reprocesses a single dialyzer in your facility, it has already been "road-tested" by the electronics staff. Every finished unit must sit on what is called the burn-in bench, where it cycles for twenty-four hours over a three-day period. According to Tom, "If a component is going to fail, mortality tests have shown it will usually happen within the first twenty-four hours of burn-in. Running the unit before it leaves the building lessens the chance of a breakdown in the field." If any part of the unit malfunctions during this process, the Renatron® station is repaired and must withstand another twenty-four hours on the burn-in bench before moving on to calibration and final testing. Quality inspectors periodically conduct audits to ensure that assembly and testing procedures are being followed and the finished product meets Renal Systems' high performance and safety standards. Only after satisfying all of these quality control requirements does a reprocessor earn the Renatron® name.

Renal Systems has made a lot of improvements in the Renatron® system since 1982. It has become a better reprocessor, and Tom says that can be attributed in part to the people in the electronics department. The staff's experience makes them a valuable resource when it comes to product and assembly improvements. "Their insight is great. They are always discussing ways to increase quality and productivity. After all, no one knows their job better than they do" added Tom. For these employees, that job is more than simply putting the pieces together.

Members of the Electronic Manufacturing Department are pictured from left to right (1st row): Diane Weirke, Nettie McDonald, Rose Pierce, Helen Bunich, Jo Herrman, Candy Johnson (2nd row): Gail Weber, Becky Randt, Mary Jansen, Marilyn Hochstedler, Loree Parks (3rd row): Dean Haseltine, Bobbie Lee, Tom Gudaitis, Jim Showalter, Cliff Williams, Brad Bakke, Tom Olson. (Not Pictured: Rollie Jungk)

Q: Why is it necessary to perform the Formula 409® All Purpose Cleaner procedure on the Renatron® and how often should it be done?

A: The internal fluid pathways of the Renatron® station must be cleaned periodically due to a gradual substance build-up inside the blood lines. This build-up is a waxy, denatured substance with a slight yellowish tint that is usually proportional to the extent of the Renatron® station use, the number of dialyzers reprocessed, and such factors as heparin regime and rinseback method. If this substance is allowed to build-up the Renatron® may give erroneous blood volume readings and pressure fails. In order to prevent this substance build up and possible subsequent machine malfunction, the Formula 409® procedure should be part of the Renatron® system routine maintenance.



This procedure should be typically performed every two weeks. However, as stated above, one of the factors in determining the amount of build-up is the extent of Renatron® station use. A guide for the Formula 409® procedure frequency is once every 100 reprocessings; for some centers this may be more often than once every two weeks. The directions for the Formula 409® procedure can be found in the Renatron® Dialyzer Reprocessing System Instruction Manual under the "Removal of Build-Up in the Blood Lines Procedure" section.

Formula 409® All Purpose Cleaner (*green liquid*) is available at most grocery stores in the U.S.A. (European customers should contact our European headquarters at (31) 45 5 471 471 to purchase Formula 409®). **Do not use** substitute chemicals in this procedure. If you have any questions regarding the procedure or Formula 409®All Purpose Cleaner, please contact the technical service department at Renal Systems at 800-328-3324.

Formula 409® All Purpose Cleaner is a registered trademark of the Clorox Company, Oakland, CA.

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® sterilant-filled, 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 Renalin®-filled dialyzers 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.

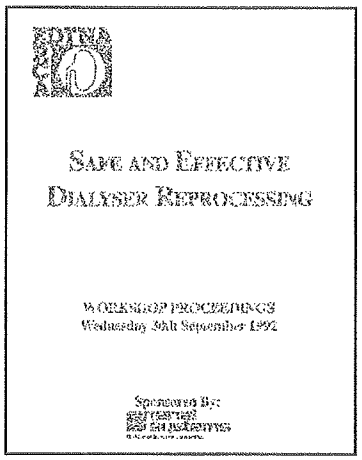
It must be noted that the saline flush is a critical step to avoid potential gas formation within the dialyzer fibers and should be practiced to prevent air obstructed fibers and potential Renalin® residual reactions.

We'd like your feedback

Do you have a story idea or reprocessing question you'd like to see addressed in *ReNews*? We welcome any input our readers have to offer. Please send your comments to *ReNews*, Renal Systems, 14605 28th Avenue North, Minneapolis, MN 55447.

EDTNA/ERCA *Workshop Proceedings*

Stay on top of the latest in European dialyzer reuse with EDTNA Workshop Proceedings. Every year at EDTNA/ERCA, Renal Systems sponsors a workshop to address key issues by leading experts in the field. Each year's proceedings contain both manuscripts and presentation materials of the featured speakers. To order, call toll-free (800) 328-3340 or complete the order form provided below and mail to: Workshop Proceedings, c/o Renal Systems, Division of Minntech Corporation, 14605 28th Ave. N., Minneapolis, MN 55447 U.S.A.



1992—Safe and Effective Dialyzer Reprocessing

Speakers include:

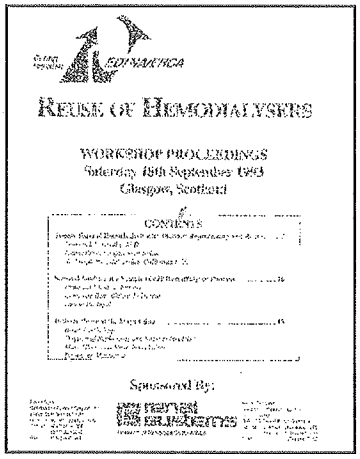
Colin Aldridge
Reuse of Hemodialyzers in Europe

Julie Hartley-Cooper, BSC, RGN
Nursing Management and Dialyzer Reprocessing

Allan J. Collins, M.D.
Long Term Experience With Shortened Therapy and Dialyzer Reuse Compared to EDTA Statistics for Shortened Therapy and No Reuse

Paul van Malderen.
Physical Plant: Technical and Safety Requirements

Douglas Luehmann.
Design and Monitoring of Water Systems



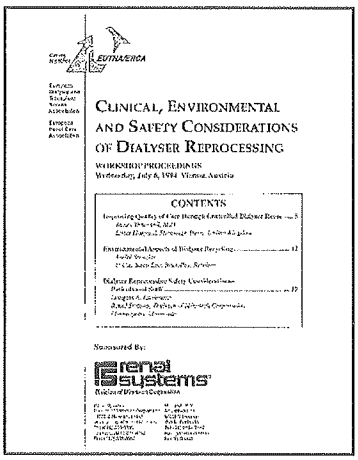
1993—Reuse of Hemodialyzers

Speakers include:

Dominick E. Gentile, M.D.
Twenty Years of Hemodialysis with Dialyzer Reprocessing and Reuse

Pinto dos Santos J, Barbas J.
Survival Analysis of a Sample of 429 Hemodialyzed Patients

Brian J. Schniepp.
Diayzer Reuse at the Mayo Clinic



1994—Clinical, Environmental and Safety Considerations of Dialyzer Reprocessing

Speakers include:

James Tattersall, MDBS, MRCP
Improving Quality of Care Through Controlled Dialyzer Reuse

Andre Stragier
Environmental Aspects of Dialyzer Reuse

Douglas Luehmann
Dialyzer Reprocessing Safety Considerations: Patients and Staff

renal systems®
Division of Minntech Corporation

Please send me the following proceedings:

- ❑ **1992**
  Safe and Effective Dialyzer Reprocessing
- ❑ **1993**
  Reuse of Hemodialyzers
- ❑ **1993**
  Clinical, Environmental and Safety Considerations of Dialyzer Reprocessing

renal systems®
Division of Minntech Corporation

This offer is limited to one copy of each proceeding per customer. Please allow 2-3 weeks for delivery. If you have any questions, contact Renal Systems at (800) 328-3340.

Name_____
Title _____
Facility. _____
Dept. _____
Address _____
City _____ State ____ Zip _____
Telephone ( ) _____

Tribute

The Kidney

There is nothing like the kidney
Cleaning out the blood
Keeping all the sodium and filtering out the crud
For sufficient micturition they won't let you down
For without your kidneys you'd absolutely drown.

They're dependable and they're lendable
They're the organs that make you take a pee
And without a doubt, if you had a drought
You'd develop urethral atrophy, catastrophe.

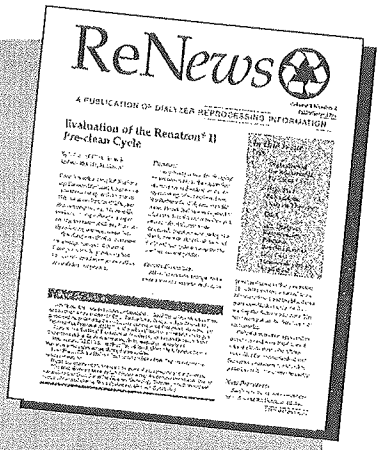
In some textbooks they will tell you
All about the heart
Going into detail about each and every part
But please be heeding while you're reading
They're just slinging mud
The purpose of the heart is just to send the kidneys blood.

John Josselson, M.D.
1944-1992

About the Author:
Dr. John Josselson joined the faculty of the Division of Nephrology at the University of Maryland Hospital in 1977, and was subsequently promoted to Associate Professor of Medicine. Aside from caring for a large renal patient population, Dr. Josselson's colleagues report that his most cherished role was that of teacher to his patients, medical students, house staff, and nephrology trainees.

Dr. Josselson was an active member of the Maryland Commission on Kidney Diseases and the Baltimore City Medical Society. He also served as Physician Director for the Marlboro Center Dialysis Unit, now renamed in his memory as the Josselson Center.

Back Issues


ReNews

Evaluation of the Renatron® II Pre-clean Cycle

To receive a personal copy of future issues, or any of our back issues, call Renal Systems customer service at 1-800-328-3340.

The following back issues of *ReNews* are available free-of-charge. Please limit your order to one per issue.

Vol 1, #1, 1993
"Current Issues in Dialyzer Reuse"
"Key Aspects of the New HCFA Guidelines"

Vol 1, #2, 1993
"Highlights of the New AAMI Reuse Guidelines"
"Reuse in the Nineties - Are We Better Off?"

Vol 2, #1,1994
"Achieving Maximum Use - One Unit's Perspective"
"Endotoxins, Dialysis, and Pyrogen Reactions"

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

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

Renal Systems
Division of Minntech Corporation
14605 28th Avenue North
Minneapolis, MN 55447 U.S.A.
Phone: (612) 553-3300
Toll Free: (800) 328-3340
Fax: (612) 553-3387

renal systems®
Division of Minntech Corporation

Minntech B.V.
Sourethweg 11
6422PC Heerlen
The Netherlands
Tel: (31) 045 5 471471
Fax: (31) 045 5 429695
kvk No 50802

Printed on recycled paper.

P/N 50090-146/A