ReNews

A PUBLICATION ON DIALYZER REPROCESSING

Volume 4 Number 2
Spring/Summer 1997

How Well Do You Know Your Unit's High Purity Water System?

By Jeff Nidetz

Maintaining patient safety and well-being is the number one priority of every dialysis unit. One of the keys to achieving that goal is the identification and removal of pyrogen and endotoxin particles from your high purity water system. Endotoxins are a lipopolysaccharide component of the cell wall of gram negative bacteria. If present in a dialysis water system, endotoxins can pass through the dialysis membrane and enter a patient's bloodstream, triggering the activation of macrophages. These macrophages release cytokines, causing symptoms such as fevers, chills, nausea, headaches, and hypertension in dialysis patients — otherwise known as a pyrogenic reaction.

How Do You Measure the Presence of Endotoxins?

Most dialysis units use the Limulus Amebocyte Lysate, or LAL, testing method to determine endotoxin levels in their water system. LAL is an aqueous solution of the blood clotting proteins of the horseshoe crab. The horseshoe crab's blood has a very sensitive clotting reaction in the presence of gram negative bacterial endotoxins. The lysate from the crab's blood clots and/or forms a gel in the presence of endotoxins. This method is known as the gel clot LAL test, a qualitative test for monitoring endotoxins in your water system. Variations on the LAL test are also available using chromogenic and turbidimetric methods to determine endotoxin levels. This newer generation of test equipment claims greater sensitivity when compared to the LAL test.

The U.S. Food and Drug Administration (FDA) has established the Endotoxin Unit (EU) as the standard

Continued on page 2

About the Author

Jeff Nidetz, Fibercor's Business Unit Manager, has 17 years of experience in the high purity water industry with industry leading companies such as Culligan, Continental Water Systems, Millipore, and Fibercor. He has a background in mechanical and biomedical engineering and has been with the Fibercor organization for 4 years.

In this Issue

Continued from page 1

measurement to define endotoxin potency. The LAL test shows endotoxin concentrations in EU/ml. In the *AAMI Standards and Recommended Practices: Dialysis*, a recommendation is given for endotoxin concentrations in the water used to dilute sterilants for dialyzer reprocessing.[1] This limit is given as a weight concentration of 1 ng/ml of endotoxin. Based upon the type of endotoxin medical device manufacturers used in making their standards (EU/ml), 1 ng was found to be equivalent to 5 EU for the FDA reference standard endotoxin (1 ng/ml = 5 EU/ml). The standard most dialysis units try to maintain is less than 5 EU/ml, but an effort to tighten this guideline is being considered in the new AAMI standard.

How Do You Remove Endotoxins from Water?

Reverse osmosis (RO) removes dissolved salts and suspended solids from water, and is the most common method used to remove endotoxins. Most dialysis units use RO systems that contain thin film composite polyamide membranes. These polyamide membranes are extremely durable, offer excellent salt rejection, and provide high water flux rates. Unfortunately, they are also very sensitive to chlorine. Chlorine exposure isn't usually a problem in dialysis units, where chlorine is removed from incoming tap water to prevent patient reactions. However, chlorine, which inhibits bacteria growth, provides a measure of protection against bacteria and endotoxins. When it is removed from the feed water source, the RO system is left unprotected against the growth of bacteria on the membrane surfaces. Without a complete disinfection program, and sometimes even with one, the RO can possibly become a source of endotoxins downstream in your water system.

To safeguard your dialysis water supply, the Fibercor division of Minntech Corporation has developed a high purity water cartridge filter that will remove pyrogenic material from dialysis water *at its point of use* . The Fiberflo® Hollow Fiber (HF) Cartridge filter is manufactured from a unique, patented, polysulfone hollow fiber membrane. The asymmetric hollow fiber has an absolute micron ratings of 0.05, 0.1 or 0.2 with verifiable endotoxin removal up to a 5 EU challenge. The Fiberflo® HF is manufactured under GMP guidelines for medical device manufacturing and has marketing clearance through the FDA 510(k) process.

Fiberflo® HF cartridge filters can be easily added to your existing dialysis water system. They are available in all standard filter configurations to fit most filter housings. The Fiberflo® HF is compatible with most disinfecting chemicals, including Minncare®, Renalin® and formaldehyde, so it can be disinfected in line. With its hollow fiber design, the Fiberflo® HF has a large surface area for particle and bacterial retention, excellent flow rate characteristics, and long filter life. For maximum pyrogenic protection in your dialysis water system, Fibercor recommends the Fiberflo® 50 HF filters which will provide endotoxin removal of a 5 EU challenge to less than detectable limits.

Endotoxin testing and removal is critical for water treatment systems in dialysis. Using an RO system followed by a Fiberflo® Hollow Fiber cartridge filter at point-of-use or in the distribution system is a reliable and economical method for removal of endotoxins. The complete RO water treatment system still needs to be regularly cleaned and disinfected, but Fiberflo® HF filters offer a greater measure of patient protection against endotoxins.

If you would like additional information about Fiberflo® HF filters or require application assistance to adapt these filters to your dialysis water system, please contact Fibercor at 1- 800-328-3370.

[1] [AAMI] Association for the Advancement of Medical Instrumentation. 1996. AAMI Standards and Recommended Practices: Dialysis. Vol. 3. Arlington: AAMI. Reuse of hemodialyzers; p. 99.

Kriss Channer, Customer Service Representative, and Jeff Nidetz, Business Unit Manager, are available to answer all of your water quality questions (not pictured are Rick Danforth and Tim Tritch, Regional Sales Representatives). Contact the Fibercor customer service team at 1-800-328-3370 between 8:00 am and 5:00 pm CST.

Important Notice

The following notice was mailed to Renatron® customers on March 14, 1997. Shortly after it was mailed, Clorox notified us that their MSDS on the new formula of 409 was in error, and that both the original and the new anti-bacterial formula are a green liquid (the new formula is not clear). The main diffference between the original and new formula, is that the new formula has an additional ingredient noted on the label as alkyl dimethyl benzyl ammonium chloride and the label will have an anti-bacterial statement such as "now kills bacteria". Please identify a supplier, and continue to use the original Formula 409® All Purpose Cleaner.

March 1997

Dear Renatron Customer,

We have been notified by the Clorox Company that the formulation for Formula 409® All Purpose Cleaner (green liquid) has been changed.

The new formulation of the 409® All Purpose Cleaner states anti-bacterial on the label *and is a clear liquid*. We have also been told that the new formulation will replace the original formula and the original formula will no longer be available to the general public through local retailers as the quantities are sold out.

It will take several weeks minimum to complete testing on the new formulation of 409® All Purpose Cleaner and make any recommendations on using this new formulation for the Renatron® cleaning procedure.

To prevent running out of the original 409® All Purpose Cleaner *(green liquid),* please check your local retailers for the original formula and purchase additional quantities as soon as possible.

Performing periodic cleaning of the internal fluid pathways of the Renatron® with Formula 409® All Purpose Cleaner *(green liquid)*is an important procedure to prevent substance build-up in the fluid pathways of the Renatron®. If substance build-up is allowed to occur the Renatron may give erroneous blood volume readings and pressure fails. The 409® cleaning procedure should be part of the Renatron® System routine maintenance. This procedure should be typically performed every two weeks, however the frequency should be based on the extent of the station use. A guide for the Formula 409® procedure frequency is once every 100 reprocessings; for some centers the Formula 409® cleaning procedure may be needed more often than every two weeks.

If you have any question regarding the Formula 409® All Purpose Cleaner and the Renatron®, cleaning procedure, please contact Renal Systems technical service department at 1-800-328-3324.

Both formulas original and new are a green liquid

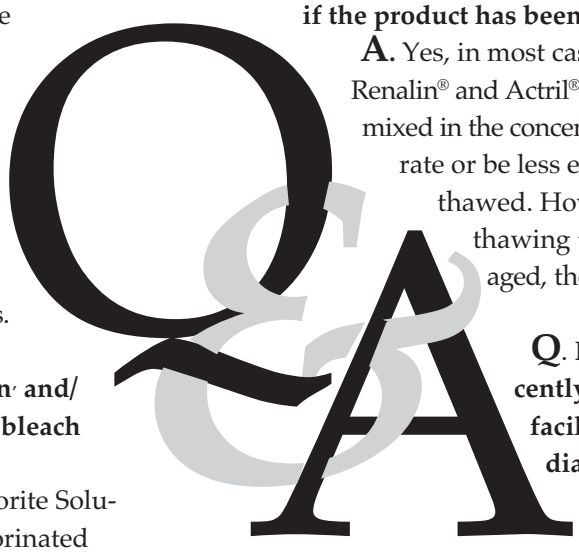
Formula 409® All Purpose Cleaner is a registered trademark of the Clorox Company, of Oakland, CA.

You will be receiving futher updated information regarding the Formula 409® issue.

Q. How long must a preprocessed Renalin® Cold Sterilant-filled dialyzer be stored before rinsing for clinical use?

A. Preprocessing is to "reprocess" an unused drypack dialyzer preparing it for its first patient use. Even though the dialyzer has not had blood contact or patient exposure, the initial sterility of the dialyzer has been affected by the actual preprocessing procedure. In order to achieve "resterilization" the dialyzer must be stored for a minimum of eleven hours after preprocessing. After storage and prior to patient use the dialyzer must pass the Renalin® presence test, be appropriately rinsed, and pass the Renalin® residual test.

Preprocessing dialyzers provides a baseline total cell volume for each individual dialyzer, can help eliminate manufacturing residue from the dialyzer, and allows the facility to use the same rinse procedure on all dialyzers.



Q. Why is it important that Renalin® and/or Actril® Cold Sterilant not mix with bleach (sodium hypochlorite)?

A. Liquid bleach (Sodium Hypochlorite Solution) is the most widely used of all chlorinated bleaches. Uses for liquid bleach include household, laundry, chemical processing, water treatment and general disinfection applications. Bleach is a common chemical found in many hospitals and dialysis units.

The alkalinity or pH of sodium hypochlorite has a direct effect on the stability of the solution. If the sodium hypochlorite solution is acidified (decrease in the pH) it can release toxic chlorine gas. The active ingredient in both Renalin® and Actril® Cold Sterilant is peracetic acid. For this reason, Renalin® and/or Actril® solution should not be allowed to mix with bleach. Both liquid and vapor interaction between the two chemicals (peracetic acid and bleach) can cause a reduction in the pH and could induce chlorine gas vapors.

If Renalin® and/or Actril® sterilants are used in a facility where bleach is also used, some basic precautions can be taken to avoid mixing the two chemicals. If bleach and Renalin® or Actril® solution will be flushing down the same drain, only allow one chemical to drain at a time and flush the drain with copious amounts of water before flushing the next chemical into the drain.

Ideally, both chemicals should be stored in separate areas. If separate storage areas are not an option for your facility, store the two chemicals as far apart as possible. Once a bleach container has been opened, it should not be stored in the area where Renalin® containers are located. Since Renalin® sterilant is packaged in vented containers, storing open or unsealed bleach containers in the same area increases the risk of a liquid or vapor interaction.

Q. Can Renalin® or Actril® Cold Sterilants be used if the product has been frozen and thawed?

A. Yes, in most cases the products can be used. Renalin® and Actril® Cold Sterilants are thoroughly mixed in the concentrate form and will not separate or be less effective when frozen and thawed. However, if due to freezing and thawing the packaging has been damaged, the product should not be used.

Q. I am latex sensitive, and recently started working in a dialysis facility that uses the Renatron® II dialyzer reprocessing system and Primus® dialyzers. Do either of these products contain latex?

A. Renal Systems is aware that sensitivity to latex proteins, or latex allergy, is a growing problem among healthcare workers. Please be assured that our products *do not* contain any known natural or synthetic latex components.

If you have been latex sensitive for some time, you probably know that that the best working environment for your condition is a latex-free one. In order to create and maintain a latex-free environment in any medical facility, all gloves, medical accessories, and medical devices used should be evaluated for latex content. The Task Force on Allergic Reactions to Latex, a committee of the American Academy of Allergy and Immunology, recommends that a list of 'safe' products be prepared through contact with medical product manufacturers. Upon request, Renal Systems will provide your facility with a certification letter verifying the latex-free status of our products.

(See *The Facts on Latex Allergies*, p. 5, for more information.)

The Facts on Latex Allergies

Latex, the milky sap produced by the tropical rubber tree, is a common ingredient in gloves, anesthetic gas masks, respiratory devices, catheters, tubing, and adhesive tape. It is also known to cause severe, sometimes life-threatening, allergic reactions in a growing number of healthcare workers worldwide.

Natural latex has been used in medical devices and equipment for many years, yet it is only over the past decade that allergies to the substance have neared epidemic proportions. Although the exact cause of this phenomena cannot be known with certainty, most researchers agree that it is directly connected to latex glove use.

Latex gloves have long been preferred in medical settings because of their durability, ability to stretch thin to facilitate fine manual dexterity, and long-lasting barrier effectiveness. In 1987, when the Center for Disease Control (CDC) mandated that all healthcare workers don gloves to prevent the spread of bloodborne disease like HIV, latex was the natural choice. The institution of 'universal precautions' led to a dramatic rise in latex glove use. Healthcare workers, constantly exposed to the latex proteins that bind to these gloves, became increasingly sensitized to it. The result — an outbreak of hives, skin rashes, conjunctivitis, asthma, and at the extreme, anaphylactic shock, in healthcare workers who have developed a full-blown allergy to natural latex proteins.

Precautions can be taken to prevent latex sensitization. Some latex glove manufacturers have already instituted changes in the manufacturing process, reducing high latex protein levels by increasing the washing or leaching time of the gloves. For those healthcare workers who have already developed a latex allergy, a latex-free work environment is the best option. Synthetic gloves are a possible alternative, although the reduced barrier effectiveness in vinyl and other synthetics may make double-gloving necessary.

Above all, latex-sensitive individuals need to be informed about the presence of latex in the medical devices and equipment they encounter every day. To date, manufacturers of latex products are not required to indicate the presence of latex on their labeling. The issue is further complicated by claims of hypoallergenicity. If a product label reads "hypoallergenic," it does not mean it is latex-free. Current hypoallergenicity testing relates only to chemical sensitivity. The U.S. Food and Drug Administration (FDA) has proposed product labeling changes to eliminate the confusion and safeguard latex-sensitive individuals. In a Federal Register Proposed Rule (Vol 61, 122, June 24, 1996), FDA states that devices containing natural rubber latex should indicate on their labeling that the product contains latex and that the presence of latex may cause allergic reactions. The rule is currently under discussion and is expected to become a final regulation sometime in 1997.

If you would like further information on latex allergy, contact:

E.L.A.S.T.I.C.

Education for Latex Allergy/ Support Team and Information Coalition

196 Pheasant Run Road

West Chester, PA 19380

On the world wide web:

http://pw2.netcom.com/~ecbdmd/elastic.html

Spotlight on Minneapolis, Minnesota: Site of the ANNA and NANT National Symposiums

If you will be traveling to Minneapolis this April to attend the 1997 ANNA or NANT National Symposium, here are 5 good reasons to extend your stay and experience the best the Twin Cities has to offer:

1) Always in season.

Rain or shine, getting around downtown Minneapolis is always a breeze. A climate-controlled skyway system links the Minneapolis Convention Center and Minneapolis Hilton and Towers with 50 blocks of the best shopping, restaurants, and nightlife Minneapolis has to offer. Check your ANNA program or at the hotel front desk for a skyway map.

2) A shopper's paradise.

Take a stroll down Nicollet Mall, where there's no sales tax on clothing and 12 blocks of shops, boutiques, and malls to explore. If you're the "shop till you drop" type, no trip to Minneapolis would be complete without a journey to the Mall of America - the largest fully-

Continued on page 6

Continued from page 5

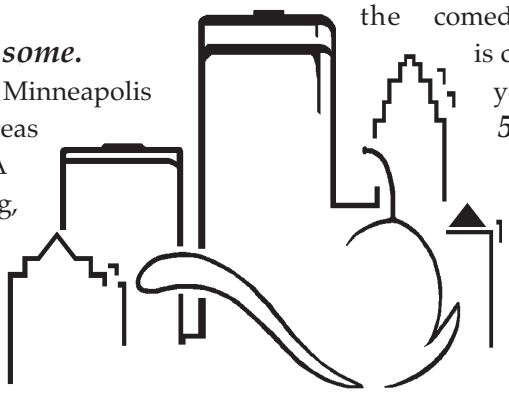
enclosed retail complex in the U.S. With over 400 stores, a walk-through aquarium, and an entire amusement park under one roof, the mega-mall (as Minnesotans like to call it) has something for everyone. Mall of America is only 10 miles from downtown Minneapolis. Call the Mall at 883-8800 for information on hours and transportation.

3) Ten thousand lakes, and then some.

Whether you're into boating or biking, Minneapolis offers plenty of parks and recreation areas to satisfy the outdoorsperson in you. A 55-mile system of paved biking, jogging, and walking paths connects the 22 lakes and 170 parks throughout Minneapolis, and the mighty Mississippi river winds through Minneapolis and sister-city, St. Paul.

4) More fun than you can shake a stethoscope at.

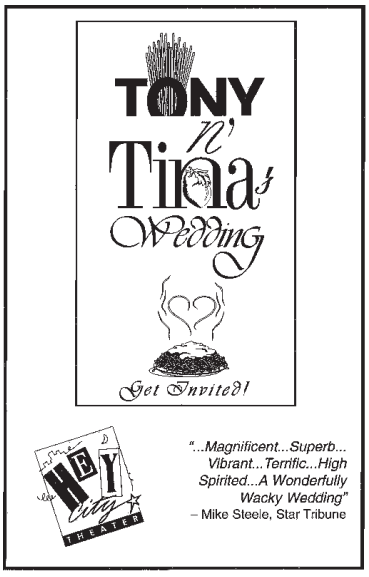
Have sports fever or an artistic itch? Minneapolis has the cure for you. Catch Twins baseball in the Metrodome, or stroll through the 11-acre outdoor sculpture garden at the Walker Art Center. Minneapolis is home to three major league sports teams and dozens of live music venues, galleries, nightclubs, museums, and theaters. The two-block Hennepin Avenue Theatre District incorporates The Historic State and Orpheum Theatres and the new Hey City Theater, where the comedy improv hit *Tony n' Tina's Wedding* is currently in its second successful year



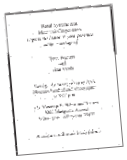
5) Home sweet home.

Minneapolis, Minnesota is the world headquarters of Renal Systems. We're proud to have the opportunity to welcome you to our home state. Please stop by the Renal Systems booth (#400) at ANNA and say hello.

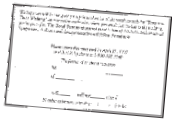
For more information on Minneapolis events and attractions, contact the Greater Minneapolis Convention & Visitors Association at 1-612-348-7000 or on the World Wide Web at http://www.minneapolis.org



Renal Systems and Minntech Corporation request the honor of your presence at the marriage of



Tony Nunzio
and
Tina Vitale



We hope you will be our guest for a private showing of the smash comedy hit "Tony and Tina's Wedding" an interactive celebration where you aren't just invited to the wedding and reception, you're part of it.

Watch for your invitation in the mail! Return your reply card by April 15, 1997 or RSVP by phone at 1-800-328-3340.

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14th Annual NANT National Symposium Schedule

Saturday April 26,1997	
8:00 - 12:00 noon	NNTCB Exam
8:00 - 11:30 am	NANT Board of Directors Meeting
1:00 - 2:00 pm	Professionalism/Empowerment Keynote Speaker ***Susan Hanson***
2:00 - 3:00 pm	Using Today's Technology Today ***Elizabeth Lindley***
3:00 - 3:15 pm	Refreshment Break
3:15 - 4:15 pm	How to use AAMI Standards ***Jim Boag***
4:15 - 5:00 pm	NANT State of the Association/Awards Presentations
5:15 - 7:00 pm	Presidential Reception sponsored by Fresenius
7:00 - 10:00 pm	Opening Night Party sponsored by Spectra Labs/ Renal Systems, Division of Minntech

Sunday April 27, 1997		
8:30 - 12:00 noon	NANT/ANNA Joint Session	
12:00 - 1:30 pm	Luncheon on own	
	Concurrent Sessions:	
	Technology	**Quality Improvement**
1:30 - 2:25 pm	Introduction to Computers ***John Sweeny***	Introduction to CQI ***Lori Orleanski***
2:30 - 3:25 pm	Introduction to Spreadsheets ***Robert Levin***	Demos of CQI Projects ***Lori Orleanski***
3:25 - 4:00 pm	Refreshment Break	
4:00 - 4:55 pm	Using Spreadsheets in Dialysis ***Robert Levin***	Practical aspects of CQI ***Lori Orleanski***
5:00 - 6:00 pm	NANT Chapter Workshop	So you want to take the NNTCB Exam
7:00 - 9:00 pm	**ANNA Exhibits/reception**	
9:00 - 12:00 midnight	Opening Reception sponsored by	Baxter/AMGEN

Monday April 28, 1997			
	Concurrent Sessions		
	Clinical	**Biomedical**	**Computer**
8:00 - 8:55 am	Heparinization ***Merryn Jolkovsky***	Water Quality ***Willie Burcham***	Introduction to the Powers of Access™ ***John Hyte***
8:55 - 9:30 am	Refreshments		
8:30 - 10:00 am	ANNA exhibits open		
9:30 - 10:25 am	Vascular Acess ***John N. Graber***	Reuse: If RD47 is standard ***Paul Duke***	Database Utilization for Renal Therapy ***Cathy Sandmann***
10:30 - 11:30 am	Infection control ***Rosalie Long***	Current Dialyzer Reuse Issues ***Andre Stagier***	Paperless Unit ***Anna Corea***
11:30 - 1:00 pm	Luncheon on own		
1:00 - 2:30 pm	General Session:Internet	***Franklin W. Maddux***	
2:30 - 4:00 pm	European Panel /	Town Hall	
2:15 - 3:45 pm	ANNA exhibits open		

Renal Systems Welcomes NANT to Minneapolis for the 14th NANT National Symposium. Visit the Renal Systems display (booths 400 - 406) and check out our winning combination — The Renatron® II Automated Reprocessing System and Renalin® Cold Sterilant — and pick up your personal combination card. Try your luck opening our prize case. You may win a Raymond Weil watch.

Renal Systems Sponsored Events

Renal Systems and Spectra Labs will sponsor a Casino night on Saturday evening, April 26th. See you there!

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kvk No 14050802

Saturday April 26, 1997	Program Event
12:30 - 4:30 pm	NNCB Examination
7:30 - 4:00 pm	Leadership Development Workshop
4:00 - 7:00 pm	Registration Opens
5:30 - 7:30 pm	Practicing Quality: Working with the Clinical Practice Guidelines

Sunday April 27, 1997	Program Event
12:00 noon - 7:00 pm	Registration Open
4:45 - 5:45 pm	Opening Ceremonies
5:45 - 6:45 pm	Opening Ceremonies General Session (sponsored by Abbott Laboratories)
7:00 - 9:00 pm	Opening of Exhibits Hall
9:00 pm - 12:30 am	Opening Reception (sponsored by ANNA and Amgen, Inc.)

Monday April 28, 1997	Program Event
6:45 - 7:15 am	Continental Breakfast
7:00 am - 5:30 pm	Registration Open
7:15 - 8:30 am	ROUNDTABLE CLINICAL SIGs
Session 1	Hemodialysis
2	Peritoneal Dialysis
3	Pediatric Nephrology
4	Transplant
5	Clinical Practice
8:30 - 10:00 am	Coffee Break Poster Presentations
10:00 - 11:15 am	Keynote Address (Sponsored by Abbott Laboratories)
11:15 am - 12:45 pm	Lunch Break Poster Presentations
12:45 - 2:15 pm	CONCURRENT SESSIONS
Session 6	Collaboration-Pt. 1
7	Communication
8	Research
9	Functional Status
10	Role Change Management
11	Coordinate Care Pathways-Pt. 1
2:15 - 3:45 pm	Break/Poster Presentations
3:45 - 5:00 pm	SIG NETWORKING SESSIONS
Session 12	Clinical Practice
13	Education
14	Research
15	Administration
16	Corporate/Government
17	Advanced Practice
5:15 - 6:15 pm	Regional Receptions
8:00 - 9:00 pm	Preconcert Refreshments (sponsored by Fresenius)
9:00 - 10:30 pm	ANNA's Rock & Roll Revival with Three Dog Night & The Turtles

ANNA at a Glance

Renal Systems at ANNA

Visit Renal Systems at ANNA's 28th National Symposium in Minneapolis (booths 400 - 406) and let us unlock the potential of your reuse program with our winning reprocessing combination - the Renatron® II Automated Reprocessing System and Renalin® Cold Sterilant. While you're there, try your luck at opening our prize case. Watch your mailbox for your personal combination card and bring it to ANNA for your chance to win a Raymond Weil watch.

Renal Systems-sponsored events

Congress of Chapters Reception
(by invitation only to All Chapter Officers)
Saturday, April 26, 5:30 - 7:00 p.m.

Tony & Tina's Wedding
A Renal Systems "Special Event"
Tuesday, April 29, 8:00 - 11:00 p.m.
Minneapolis Hilton Hotel & Towers
(see p. 6 for details)

Tuesday April 29, 1997	Program Event
7:15 - 9:30 am	Amgen Breakfast Symposium
8:00 am - 5:30 pm	Registration Open
9:30 - 11:00 am	Break Poster Session
11:00 am - 12:30 pm	CONCURRENT SESSIONS
Session 18	Collaboration-Pt. 2
19	Hemodialysis
20	Peritoneal Dialysis
21	Transplant
22	Pediatrics
23	Coordinate Care Pathways-Pt. 2
12:45 - 2:30 pm	Nephrology Nurse Day Luncheon
2:30 - 4:00 pm	Break Poster Presentations
4:00 - 5:15 pm	Sessions A1-A6 Abstract Presentations
6:00 - 7:30 pm	ANNA & NNCB Salute Our More Than 4,000 CNNs (sponsored by NNCB & ANNA)
8:00 - 11:00 pm	SPECIAL EVENT "Tony & Tina's Wedding" - An evening of interactive comedy (sponsored by Renal Systems)

Wednesday April 30, 1997	Program Event
7:00 - 7:30 am	Continental Breakfast
7:30 - 8:45 am	CORPORATE-SPONSORED CONCURRENT SESSIONS
Session 1	Emerging Trends for Dialytic Therapy (Fresenius USA, Inc.)
2	Nurse Leadership in Iron Management (Schein Pharmaceuticals)
3	Drug Dosing and Compliance in the Dialysis Patient (Boehringer Ingelheim)
4	Measuring Hemodialysis Adequacy (NMC, LifeChem)
8:45 - 9:15 am	Break
9:15 - 11:00 am	CONCURRENT SESSIONS
Session 24	Collaboration-Pt. 3
25	Journal
26	Related Therapies - CRRT
27	Alternate Areas of Practice
28	Workplace Violence
29	Coordinate Care Pathways-Pt. 3
11:15 am	Adjourn

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