ReNews®
A publication on dialyzer reprocessing
volume 14, 2008

Renatron® Station Upgrades – *How They Work*

The upgraded Renatron II 100 Series Dialyzer Reprocessing station brings enhancements to make reprocessing even more efficient and effective. The upgrades feature a dedicated Service Clean/Rinse Cycle, a Water Culture Sample Collection Cycle, a Volume-Fail Retest Limit, and a Header Leak Test. The dedicated Service Clean/Rinse Cycle and the Water Culture Sample Collection Cycle can be accessed by simply pressing a button sequence on the front display panel. The Volume-Fail Retest Limit and the Header Leak Test are fully automated.

Dedicated Service Clean/Rinse Cycle

The dedicated Service Clean/Rinse Cycle is an alternate and more aggressive cycle than the regular Service Clean/Rinse and can be used for heavily deposited lines on the Renatron station. This feature adds a button sequence that will draw a larger amount of *For Institutional Use Formula 409® NQF* into the Renatron hydraulics. This cycle will draw approximately five times more Formula 409 into the Renatron station than the traditional Service Clean/Rinse procedure.

To activate the dedicated Service Clean/Rinse Cycle, do the following:

- Turn on the Renatron station.
- Use MUTE ALARM and RESET to change to the HF mode.
- Press the following buttons in sequence: MUTE ALARM, RESET, and DISPLAY.
- The Volume display will read "409" and the Program Step display will read "SC."

- Press the START SANITIZE button to begin the Service Clean/Rinse cycle and follow the instructions provided in the Renatron II 100 Series Instruction Manual to complete the cycle.

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Q&A

Formula 409®

Q: Can I buy Formula 409® from a grocery store and use it for the Renatron station's Formula 409 Service Cleaning procedure?

A: No, the *For Institutional Use Formula 409 NQF* (non-quaternary formula) product that is to be used when performing the Service Clean/Rinse procedure is not available in grocery stores or commercial outlets but is available through Minntech Corporation.

For Institutional Use Formula 409® NQF

At one time, Formula 409 cleaner/degreaser was a stand-alone product, but today the Clorox Company has a wide-range of cleaning products under the brand name Formula 409, such as: glass cleaners, stone countertop cleaners, carpet cleaners, and all-purpose cleaners.

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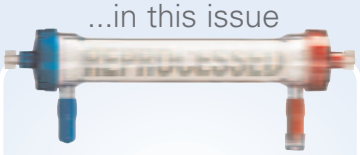

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Water Culture Sample Collection Cycle

A separate cycle has been added to ease the task of obtaining water samples collected for performing bacteriological and endotoxin tests. The Water Culture Sample Collection Cycle will flush the Renalin® solution from the Renatron station and fill the calibration cell with water to be sampled. Samples for testing can be obtained after a minimum six-hour sanitization has taken place.

- Turn on the Renatron station.
- Use MUTE ALARM and RESET to change to the CH mode.
- Press the following buttons in sequence: MUTE ALARM, RESET, and DISPLAY.
- The Volume display will read "CUL" and the Program Step display will read "CC."

- Press START PROCESS button to begin the cycle.
- At the conclusion of Step 9, the "PROCESS COMPLETE" message will illuminate and "CUL" and "SA" will be displayed on the front panel.

- The calibration cell is filled with the sample to be tested.
- After the sample has been collected, press the "RESET" button. The Renatron II 100 Series Station is now ready for calibration verification and then for reprocessing dialyzers.

Volume-Fail Retesting Limits

Each time a volume-fail alarm occurs and the RETEST button is pressed, the Renatron station applies a negative pressure in an attempt to pull more fluid from the blood compartment. Repeated testing of a volume-failed dialyzer could potentially lead to an artificially high volume that could allow a failed dialyzer to pass the volume test. This may occur because the dialyzer has a semipermeable membrane and repeated testing may pull additional fluid from the dialysate compartment. By limiting the number of retests to two, the volume measured should not include fluid that is in the dialysate compartment.

The volume-fail retesting will be performed as follows:

- If the volume test fails, the operator can repeat the test by pressing the START PROCESS button and retest two additional times.
- If the test fails a third time, the light on the START PROCESS button extinguishes and the button is deactivated.
- The only option available is for the operator to press the RESET button which sends a "Volume Fail" error code to the Renalog (software) system.

Header Leak Test

This is a diagnostic test to verify that the header is secured with the O-ring in place. This differs from the Pressure test in Step 39 which tests for broken fibers.

Leaks from the header cap may be caused by:

- Failure to replace the O-ring back into the header cap.
- Failure to tighten the header cap.
- Cracks in the header cap caused by over tightening.

The Header Leak Test is automatically performed between Steps 2 and 3 of the Reprocessing and Preclean Cycles. If the test fails, the dialyzer can be retested by pressing the START PROCESS button. The operator should confirm that the O-ring has been properly placed and that the header cap is secured correctly and completely. If the operator presses the RESET button, it returns a "Pressure Fail" error to the Renalog software. Since this failure has exactly the same failure message produced in Step 39 (which checks for broken fibers) the operator should keep track of the step in which the error occurred.

The Renatron station upgrades have been customer driven. The dedicated Service Clean/Rinse Cycle and the Water Culture Sample Collection Cycle are easy to use and access. The volume fail testing limit and Header Leak Test are automated. These Renatron upgrades have made reprocessing even more efficient and effective.

Use the Pre-Clean Cycle on the Renatron® Station

When the term "precleaning" is used in the reuse room, it is often associated with manual precleaning of the dialyzer. Manual pre-cleaning may include header removal and reassembly, blood compartment flushing, and manual reverse ultrafiltration (RUF). Manual precleaning can be very effective for removing blood and clots from the dialyzer before the dialyzer is placed on the Renatron station for complete reprocessing.

Effective precleaning can also be accomplished using the Renatron station. The Renatron station has a precleaning cycle that is very easy to use and incorporates an automated blood-compartment flush and automated reverse ultrafiltration cycle.

During the scanning sequence, the operator scans the Pre-Clean barcode on the front panel instead of the barcode with the Renatron Serial Number.

This will set the program for a precleaning cycle for the dialyzer. The preclean cycle follows the same initial 18 steps of the regular

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Q&A

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These products differ in composition from the original Formula 409 cleaner/degreaser.

The *For Institutional Use Formula 409 NQF* cleaner/degreaser is the original Formula 409 formulation which is no longer available in commercial outlets, and is the only Formula 409 formulation that is validated as a system cleaning agent for the Renatron stations.

No other Formula 409 products should be used in the Renatron station because they contain ingredients which have not been validated for use in the reprocessing system, could damage the Renatron station, and may not work as effectively as the *For Institutional Use Formula 409 NQF* cleaner/degreaser.

Dialyzer Storage

Q: How long can a reprocessed dialyzer be stored?

A: It is up to the facility to establish a maximum storage time for reprocessed dialyzers, and they will be surveyed to that policy. Under the guidance for CMS survey tag V356 in Appendix H: Survey Procedures and Interpretive Guidelines for End-Stage Renal Disease, surveyors are instructed to, "Look at the dates of reprocessing; are these within the storage limits set by the facility?" Maximum storage time observed in many facilities is commonly 7 to 14 days.

AAMI Standards RD47 2002, Reuse of Hemodialyzers, doesn't specify a maximum time limit but does state in section 11.7 that, "Prolonged storage (greater than 1 month) should be documented to be safe and effective. Dialyzers that have exceeded the facility's maximum storage time shall be reprocessed or discarded."

Minntech does call for a minimum dwell time of 11 hours and requires that each Renalin-reprocessed dialyzer be tested after storage and prior to patient use with a Perassay® 500 Peracetic Acid test strip. A positive test result indicates that the dialyzer has been instilled with a solution adequate to have sterilized the dialyzer.

Caps and Connectors

Q: Why do new reprocessing caps and connectors need to be disinfected before using them for the first time?

A: Even though new reprocessing caps and connectors look very clean, they have not been disinfected. Disinfection of the caps and connectors before use is required to avoid contamination of the dialyzer and, ultimately, injury to the patient.

MINNTECH® renal systems

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Use the Pre-Clean Cycle on the Renatron® Station

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The Pre-Clean Cycle Label on the Renatron Station

reprocessing cycle but automatically stops the cycle in Step 18 after the blood fibers have been flushed with water and a 2% Renalin® solution has filled the dialyzer and a reverse ultrafiltration cycle has begun. If the dialyzer is not removed from the Renatron station and the RESET button has not been pressed, the station will vent the dialyzer every 10 seconds to prevent pressure build up. The length of time between the end of the preclean cycle and starting a full reprocessing cycle will vary from dialyzer to dialyzer, depending on how clean the dialyzer appears. Maximum effectiveness of the pre-clean mode is attained in two hours.

After the preclean waiting period is finished, the operator must press the RESET button, which will print one PRECLEAN label and reset the Renatron station back to its ready mode. The dialyzer must go through a complete reprocessing cycle before being placed in storage.

The operator can also press the RESET button, remove the dialyzer from the station, label the dialyzer with the automatically printed PRECLEAN label and set the dialyzer aside for an additional soak/dwell cleaning period (consult your facility's Policies and Procedures for specifics). The precleaned dialyzer has not been volume or pressure tested, nor has it been filled with the required concentration of Renalin solution. It is important that all dialyzers which have been precleaned, either manually or using the Renatron station, go through a complete reprocessing cycle before being stored and used again by the patient.

Archival issues of ReNews are available at www.minntech.com

Seymour Jones and the Temple of Chronic Kidney Disease

Watch Seymour Jones and the Temple of Chronic Kidney Disease at www.RSNhope.org!

This very funny video, produced by Renal Support Network, eloquently illustrates the early warning signs of CKD and should be shared with patients, family members, friends and other groups. At a time when 26 million Americans have CKD and another 20 million are at risk, it's never too early to check for the warning signs.

Listen to *KidneyTalk!* online at:
RSNhope.org
Renal Support Network
Service to those affected by chronic kidney disease.

You won't just watch it once!

Calendar of Events *2008*

June

National Foundation for Infectious Diseases (NFID) 2008 Annual Conference on Antimicrobial Resistance
(www.nfid.org)
June 23-25, 2008
Bethesda, MD

July

XVII World Transplant Games
(www.kidney.org)
July 11-16, 2008
Pittsburgh, PA

August

National Kidney Awareness and Education Week
(www.annanurse.org)
August 4-8, 2008

17th World Transplant Games
(www.worldtransplantgames09.com),
August 22, 2008
Gold Coast, Australia

September

Nephrology Nurses Week
(www.annanurse.org)
September 14-20, 2008

MeritCare - NBT Symposium
(www.meritcare.com)
September 17-18, 2008
Fargo, ND

National Renal Administrators Association (NRAA) 31st Annual Fall Conference
(www.nraa.org)
September 24-26, 2008 Cleveland, OH

ANNA Fall Meeting 2008
(www.annanurse.org)
September 27-29, 2008
Chicago, IL

October

CANNT Annual National Symposium
(www.cannt.ca)
October 23-26, 2008
Quebec City, Quebec

November

American Society of Nephrology (ASN) Renal Week 2008
(www.asn-online.org)
November 4-9, 2008
Philadelphia, PA

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