ReNews®
A publication on dialyzer reprocessing
volume 8, 2005

Reuse with Renalog® RM

In June of 2005, Minntech Renal Systems upgraded the reprocessing system at five newly acquired DaVita units in Tennessee. The units had been reprocessing using the Renatron II Reprocessing Stations without computers and Renalog software, which required manual labeling and record keeping.

The upgrades consisted of installing the Renalog RM Reprocessing Management software package that includes the Renalog RM software, computer, flat-screen monitor, dedicated label printer, dedicated reports printer, and accessory kit.

This upgrade, which emphasizes safety, efficiency, and ease of use, allowed the facilities to do away with the manual labeling and documentation that is time consuming and more error prone.

Mari Watkins, the Facility Administrator of the DaVita clinic in Bolivar, Tennessee , allowed us to spend some time talking to Michael Coats, the Reprocessing Technician who was trained (inserviced) in using Renalog RM during the time of the upgrade.

We asked Mr. Coats for his thoughts on reprocessing, especially those that reflected on the transition from manual to computerized labeling and record keeping:

Q & A

1. **ReNews:** How long has the center been open?
Michael: "Since 1997."
2. **ReNews:** Who started the center? **Michael:** The Tennessee Kidney Center was opened by Dr. Chary.
3. **ReNews:** When did you start in dialysis? **Michael:** 12 years ago.
4. **ReNews:** How long have you been doing reprocessing?
Michael: Since 1999.
5. **ReNews:** How many patient stations do you have at your facility? **Michael:** 16 chairs.
6. ***ReNews:*** How many patients are on reuse? **Michael:** 45 patients (MWF: 25, TTHS: 20).
7. ***ReNews:*** Have you used systems for reprocessing other than the Renatron?
Michael: No I have not.

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How Perassay® 500 and Renalin® Residual Test Strips Work

Renalin contains hydrogen peroxide (HP) and peracetic acid (PAA). Both substances are oxidizing agents that allow Renalin Cold Sterilant to sterilize hemodialyzers. PAA is the more potent of the two and is predominately responsible for the sterilization.

The Perassay 500 Test Strips are specific for the detection of PAA and are suitable to assure that after storage and before clinical use, the PAA level in a hemodialyzer is sufficient (500 ppm or greater) to achieve sterilization.

The Perassay 500 Test Strips make use of the inorganic chemical iodide. Iodide reacts directly with PAA. Upon reaction, the colorless iodide turns purple-black indicating that after the sterilization period of 11 hours or longer, sufficient PAA is present in a hemodialyzer (PAA concentration of 500 ppm or greater) to have assured sterilization.

The Renalin Residual Test Strips detect both HP and PAA and are suitable for monitoring the effectiveness of the hemodialyzer rinse process before hemodialysis.

The Renalin Residual Test Strip chemistry on the other hand, makes use of enzymes that catalyzes a reaction between HP, PAA and a colorless dye. Upon reaction, the dye turns blue indicating the presence and level of HP and/or PAA. The more intense the blue color, the greater the concentration of HP/PAA. After effective rinsing, a test strip should show a color intensity that is <3 ppm.

For all practical purposes the concentration of chemicals is so low, that only Hydrogen Peroxide is detected, although both chemicals are monitored.

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

MINNTECH® renal systems

SPOTLIGHT ON THE:

The U.S. Area Managers:

Minntech has developed one of the most seasoned groups of U.S. Area Managers in the industry for supporting dialyzer reprocessing, technically and clinically. The following information will provide you with a brief bio of each of the Area Managers so you can get a sense of the depth of skills, knowledge and experience offered by this team.

BILL SINGLEY

Bill Singley heads our sales force and graduated from Southwest Missouri State University with a degree in Education. Bill's teaching career prior to moving into sales gives him a unique perspective in educating his clients, not just selling to them. He has over 26 years of sales experience with 22 years in dialysis. Bill started his dialysis sales career at CD Medical as a Regional Sales Representative and moved to a National Sales Training Position. After spending four years as a Sales Representative with National Medical Care, Bill joined the Minntech team in 1994. He has held positions of Area Territory Manager, US Regional Manager, and is currently Vice President of Sales.

MIKE KALLAY

Mike Kallay graduated from Ohio University with a degree in Business and Psychology. He has 35 years of medical sales experience, 23 of those in dialysis sales and education. Mike began his career in 1970 with Pfizer in the Orthopaedic Implant Department. He later worked in the cardiovascular surgery and pacemaker markets. Mike has been servicing the western US for Minntech since 1982. Mike has also made numerous presentations at various NANT, CNNT, and National Kidney Foundation meetings.

DENNIS NORDLUND

Dennis Nordlund has 30 years of experience in dialysis sales. He began his career as a teacher and four years later moved into a sales position with a company that sold blood diagnostics and laboratory supplies. In 1975, Dennis joined Cordis Dow and began his dialysis career. Dennis has spent the last 22 years as a member of the Minntech sales team, educating customers and providing quality products and services.

RICH SHAPIRO

Rich Shapiro brings over 16 years of medical sales experience to Minntech. For his first 10 years at Minntech, Rich was an Area Manager for the Cardio Surgery Division, focusing on the hemo-concentrator, blood oxygenator, and hemofiltration product lines. For the last six years, Rich has been involved with Renal Systems, covering the upper mid-west and providing "Back to Basics" Reprocessing Training to his customers.

AMY HALLENBECK

Amy Hallenbeck has 10 years of medical experience. She started her career with Dialysis Clinic, Inc. as a patient/ maintenance technician, and progressed to the training and supervising of laboratory technicians. Prior to joining our sales force nearly three years ago, Amy was with Baxter Healthcare Corporation selling the Continuous Renal Replacement Therapy product line.

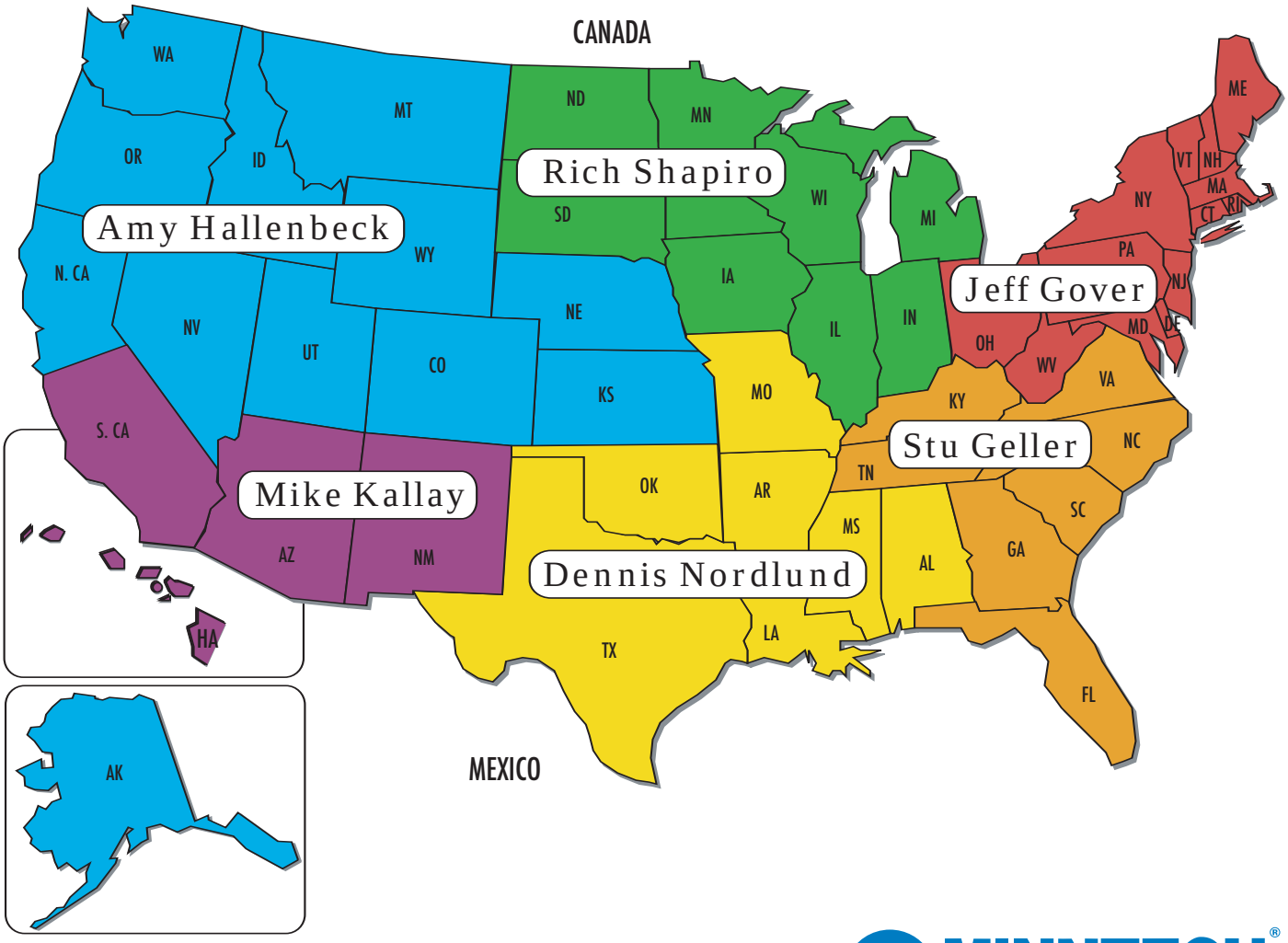
STUART GELLER

Stuart Geller has 18 years of dialysis sales experience with Minntech Renal Systems. He has been active in the local and regional dialysis community by providing training, in-servicing and sales of dialysis reprocessing equipment and ancillary supplies. To date, he has conducted well over 600 training sessions. Stuart has also made numerous presentations at industry meetings regarding the topic of dialyzer reprocessing.

JEFF GOVER

Jeff Gover has 13 years of dialysis sales experience. He started his sales career with Althin Medical selling hemodialysis machines as well as the full range of accessories. Before joining Minntech three years ago, Jeff was with Baxter's Renal Division, selling Continuous Renal Replacement Therapy instrumentation, solutions, blood tubing sets, and hemofilters.

Renal Systems U.S. Territory Structure September 2005



Manual Pre-Cleaning:

A dialyzer that has been used for patient treatment will come back to the reprocessing area with:

- A mixture of blood and saline in the blood compartment
- A mixture of dialysate and waste products in the dialysate compartment

Manually pre-cleaning dialyzers can remove some of the leftover blood and blood clots, and can be a relatively easy and straightforward procedure that consists of:

- A Blood Compartment flush: Flushes blood and clots from dialyzer headers
- RUF- Reverse UltraFiltration:

Reverse Ultrafiltration is a process in which water flows into the dialysate compartment across the dialyzer membrane, and out of the blood compartment.

RUF removes residual blood products from the fiber walls and can effectively restore Beta-2-Microglobulin removal capabilities of High Flux Polysulfone dialyzers.

(Richard A.Ward, Rosemary Ouseph: Impact of Bleach Cleaning on the performance of Dialyzers with High Flux Polysulfone Membranes Processed for Reuse Using Peracetic Acid)

WATER QUALITY

Key Point

Use AAMI quality water for pre-cleaning. The Association for the Advancement of Medical Instrumentation (AAMI) has developed standards and recommendations for the quality of water used in reprocessing.

Rationale

Water used for pre-cleaning must meet the same standards as water used for dialysis treatment and dialyzer reprocessing.

Patient injury could result from the use of unsafe water during the process.

The dialyzer should never be exposed to tap water. Tap water is not of an acceptable quality for either bacteriological or chemical standards.

BLOOD COMPARTMENT FLUSH

Key Point

Position the dialyzer so it does not come into contact with the sink.

Ensure that the blood being flushed from the fibers is directed towards the drain. Do not allow the effluent to contact other dialyzers waiting to be pre-cleaned.

Rationale

To prevent contamination

Key Point

Do not exceed the dialyzer manufacturer's recommended maximum water flow rate and water pressure.

Rationale

Higher water flow rate and pressure may damage the dialyzer fibers.

The DIRECTIONS FOR USE for the dialyzer you are pre-cleaning will have recommendations on maximum water flow rate and water pressure. The manufacturer may also have a maximum time recommendation for the blood compartment flush.

The DIRECTIONS FOR USE can be found in the dialyzer box.

Key Point

If there are clots in the header, orient the flow of water so clots are pushed out of and not into the fibers.

Rationale

To increase effectiveness of the blood compartment flush.

RUF (REVERSE ULTRAFILTRATION)

Key Point

Do not perform the RUF and blood compartment flush at the same time.

Rationale

Performing both procedures simultaneously will cancel-out the effects of the RUF cycle.

Key Point

Do not exceed the dialyzer manufacturer's recommended maximum water flow rate and water pressure.

Rationale

Higher water flow rate and pressure may damage the dialyzer fibers. The DIRECTIONS FOR USE for the dialyzer you are pre-cleaning will have recommendations on maximum water flow rate and water pressure. The manufacturer may also have a maximum time recommendation for the blood compartment flush.

Key Point

Purge air from the dialysate compartment before starting RUF cycle.

Rationale

If not purged, air will be forced across the dialyzer membrane and cleaning effectiveness will be diminished. RUF will only take place where water in the dialysate compartment is in contact with the membrane. No RUF will take place in areas that are filled with air.

Key Point

Unless otherwise noted in your facility Policy and Procedure, follow the manufacturer's recommendations for maximum RUF time.

Rationale

The manufacturer may have a maximum time recommendation for the RUF in the dialyzer DIRECTIONS FOR USE.

Key Point

Blood that is flushed from the fibers should not be allowed to run over the exterior of the dialyzer being pre-cleaned or dialyzers waiting to be pre-cleaned.

Rationale

To prevent contamination, the dialyzer should not come in contact with the sink. Effluent from the dialyzer, running over the dialyzer jacket could contaminate the outside of the dialyzer or any dialyzers immediately nearby.

Key Point

Post RUF fiber re-inflation is recommended for some dialyzers. Post RUF re-inflation of the fibers is accomplished by performing a blood compartment flush on the dialyzer after RUF.

Rationale

The RUF cycle may cause the fibers of some dialyzer models to collapse, and a blood compartment flush will re-inflate the fibers. Collapsed fibers may lead to inaccurately low total cell volumes and the possibility of prematurely failing dialyzers.

HEADER REMOVAL

Key Point

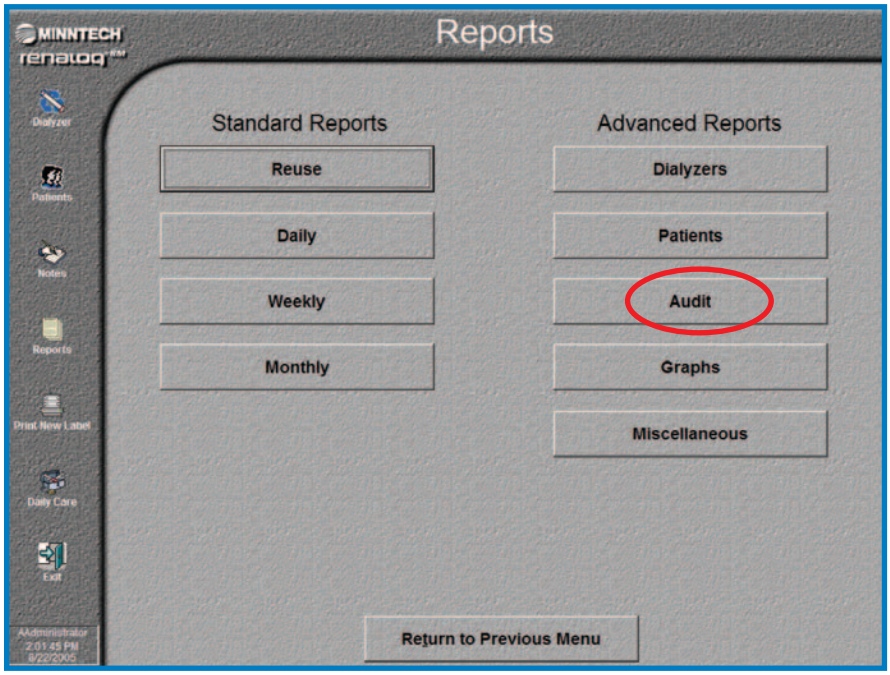
The practice of header removal as part of the pre-cleaning process is determined by the Medical Director of each facility.

If your facility removes headers, care should be taken to follow your facilities Policies and Procedures regarding header removal.

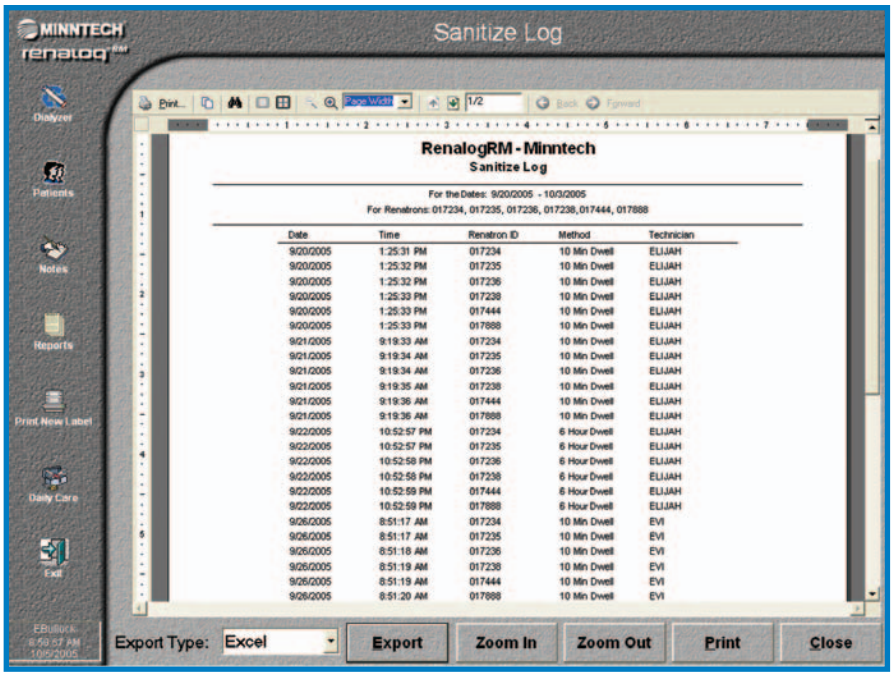
Rationale

If header removal is performed, steps should be taken to decrease the chances of header sepsis(see ReNews article" Header Cleaning: How to avoid the pitfalls" volume 7, 2005)

Renalog RM: Focus on Reports

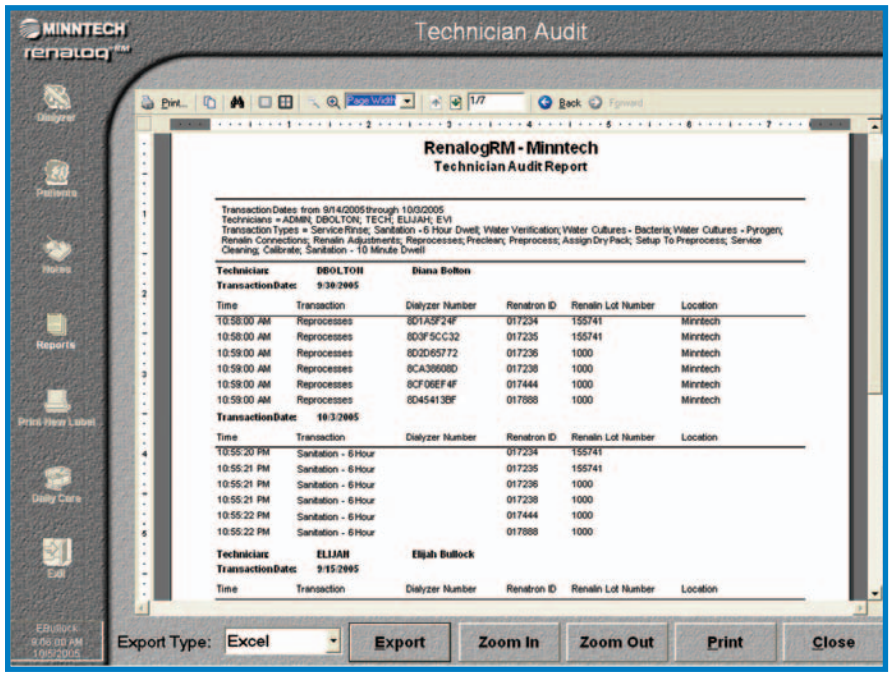


Reports allow you to track a variety of very important reprocessing activities, and electronic tracking of these activities can help ease your QA/QC responsibilities. In addition to the reports found in Renalog Version III, Renalog RM has enhanced reporting capabilities. Three of these very useful new reports, the Sanitize Log: Calibration Verification Log; and the Technician Audit, are found under the Audit section of Advanced Reports.

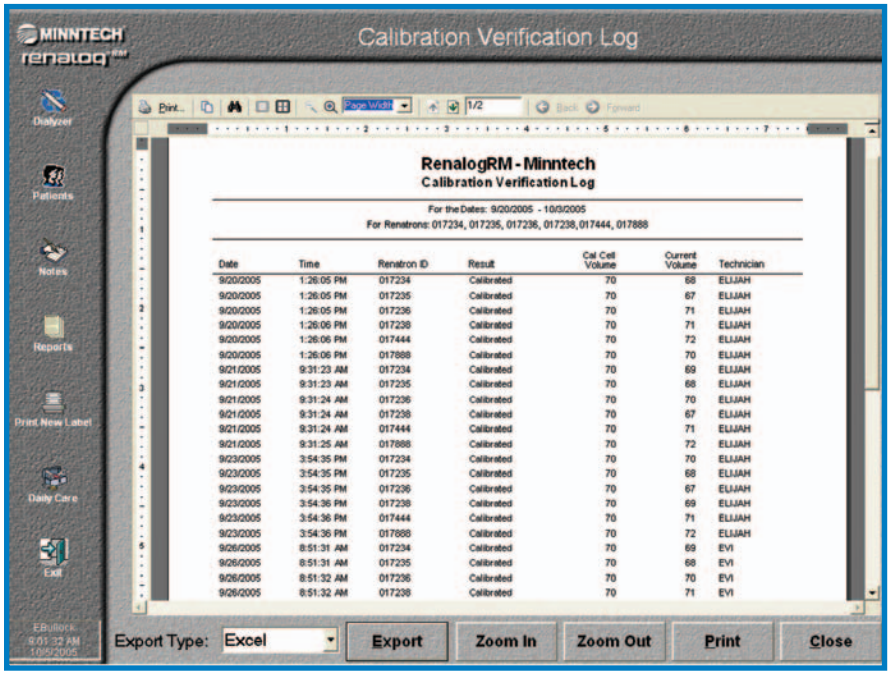


The Sanitize Log will display the date and time that each selected Renatron station was documented as being sanitized. Along with the name of the technician who is logged in at the time of the documentation, it also shows if either the "10 Minute Sanitization" or the "6 Hour Sanitization" was performed.

These reports can be utilized to document the sanitization and calibration verification of the specified Renatron reprocessing stations and the activities of technicians. Additionally, as with the other reports, they can be printed if hard copies are desired.



The Technician Audit report details all the reprocessing-related activities performed by the selected technician during the selected date range. The search criteria in this report allows you to narrow your search to an individual technician and/ or specific reprocessing related activities. This may include: who was logged in when the sanitization procedure was documented; which individual processed a specific dialyzer; and who was logged in when the Service Clean procedure was documented.



The Calibration Verification Log will display the date and time the Calibration Verification was performed for each Renatron Station, the corresponding volume, along with the name of the technician who is logged in at the time of documentation

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Q & A continued

8. ***ReNews:*** What issues (difficulties) did you previously have with manual labeling and record keeping?
Michael: Manual labeling and record keeping could lead to legibility issues and reprocessing use numbers being incorrectly recorded.

9. **ReNews:** Was the transition to *Renalog* RM smooth? **Michael:** Yes.

10. **ReNews:** Was the training helpful and useful?
Michael: Yes, and I found the system user-friendly and easy to pick up and understand.

11. **ReNews:** Did the upgrade make your life easier or worse?
Michael: A lot easier.

12. **ReNews:** Describe the best part of upgrading to *Renalog* RM?
Michael: Having automatically printed labels for both the dialyzer logs and the dialyzer. No more handwritten logs and labels and this saves a lot of time.

13. **ReNews:** What was the biggest challenge in upgrading to *Renalog* RM? **Michael:** No challenges were encountered.

14. **ReNews:** How would you compare reprocessing before the upgrade, to your job now that *Renalog* RM has been installed?
Michael: Reprocessing is now quicker, smoother and there is less potential for error.

15. **Renews:** What has been the reaction of the staff on the clinic floor to the upgrade?
Michael: No complaints from the staff. The transition to the new labels went smoothly.

16. **ReNews:** Has the staff on the floor found the new computer printed labels easier to use and decipher than the older manually printed labels?
Michael: Absolutely. They find the new labels easier to read. With the old manual labels the staff would have to spend time tracking me down if they found information on the label illegible. Also, they no longer have to manually input the reprocessing information on the patient's treatment sheet; they just put on a copy of the information label.

17. **ReNews:** Would you go back to reprocessing without *Renalog* RM?
Michael: I would hate to work without it.

MINNTECH renal systems

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