CRRT Volumetric Balancing Fluid Management for the ICU

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Introduction

High volume continuous renal replacement therapy (>35 mL/kg/hr) is increasingly recognized as better-matched to the metabolic and hemodynamic needs of critically ill patients with acute renal failure (ARF).[1-3] Growing clinical experience also suggests that using continuous renal replacement therapy (CRRT) facilitates metabolic control and fluid balance regulation in hemodynamically unstable ARF patients compared to intermittent hemodialysis (IHD).[4-6] As ICUs seek to deliver the higher volume therapies needed for improved outcomes using CRRT, higher blood pump flows and higher fluid exchange volumes are needed. As volume increases, so does the importance of accurate fluid balancing. NxStage, in response to the unique challenges of high volume CRRT therapy, has developed a novel approach to continuous volumetric balancing that overcomes the limitations of conventional scale-based fluid management.[7]

The Evolution of Volumetric Fluid Balancing

Experience with the Fresenius 2008 series of dialysis machines in the early 80's demonstrated the important advantages of volumetric balancing, including excellent accuracy of fluid control, much tighter ultrafiltration (UF) control and improved clearances. Incorporating two volumetric chambers to balance equal volumes of fresh and waste fluid, accurate volumetric fluid balance could be maintained regardless of K_{uf}, dialysate flow rate or dialysate pressure. The net fluid removed from the patient was removed by a separate pump. As a result of the Fresenius success and refinements to the approach by other companies that followed, volumetric fluid control is today the dominant form of fluid control for the treatment of end-stage renal (ESRD).

Fluid management, utilizing scale-based technology, expanded into the acute care setting in the mid 80's, coinciding with the move to pumped continuous venovenous hemofiltration (CVVH). As with all scale-based systems, the pumps are peristaltic and are typically +/- 10% accurate due to tubing tolerance and pressure effects on pump performance. Each pump must be individually controlled – speed increased or decreased – by the scales. With low fluid volume applications, pump accuracy can be maintained and sterility is easily managed with a single-use fluid path and bagged fluids.

While suitable in low volume use, scale-based systems have shortcomings that are exacerbated in high volume applications. They require the collection of waste fluid (effluent) to monitor fluid balance. Scale capacity limitations require frequent solution and effluent bag changes by an already overloaded nursing staff. In addition, scales are sensitive to user error, movement and other operating environment disturbances. Another approach to fluid control for CRRT was clearly required.

The NxStage® Approach: Continuous Volumetric Balancing Without Scales

In developing a better approach to fluid balancing for high volume renal therapies, NxStage focused on improving performance in a number of key areas: greater accuracy at high fluid volumes; the flexibility to provide multiple therapies, including diffusion, convection and isolated ultrafiltration; reduced requirement for nursing intervention; simplicity of use to reduce operator potential for errors; and enhanced system reliability and serviceability. The result is the System One™ which incorporates a novel continuous volumetric balancing approach that eliminates scales, eliminates the need to collect effluent and reduces the frequency of fluid-related interventions.

The Key Challenge: Designing a Volumetric Balancing Circuit within a Disposable Flow Path

The key design challenge was to develop a system using known volumetric balancing principles, but within a disposable flow path. The approach offers multiple advantages including: no scales; no waste bags to empty; no therapy fluid volume restrictions; accurate fluid control; and fluid that can be pre-hung or added as needed. In addition, the sterile single-use disposable would eliminate the need for disinfection of the flow path and facilitate easy changes between therapies.

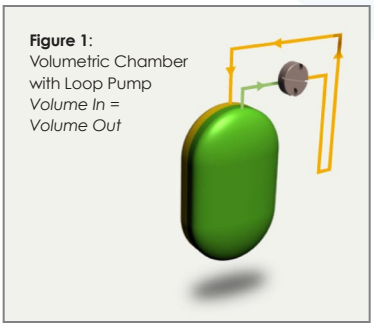

Figure 1: Volumetric Chamber with Loop Pump *Volume In = Volume Out*

The Core Technology: A Single Volumetric Chamber for "Fresh" and "Waste" Dialysate

General volumetric principles of operation apply within the disposable flow path developed by NxStage. Fresh and waste fluid pathways are separated by a membrane that divides the volumetric chamber into halves. Fresh dialysate is always contained within one half of the chamber going to the loop pump while waste dialysate is contained separately within the half returning from the pump. As the loop pump moves fluid out and back into the chamber, the membrane moves across the chamber. The amount of dialysate going in is balanced with the amount of waste dialysate going out. *Volume In = Volume Out.* (See Figure 1)

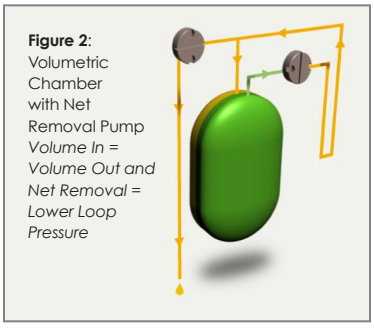

Figure 2: Volumetric Chamber with Net Removal Pump *Volume In = Volume Out and Net Removal = Lower Loop Pressure*

Additional tubing and a net removal pump create the pathway for fluid withdrawal. Withdrawal of fluid from the loop by the net removal pump will lower loop pressure because there is no other route for the fluid to enter or exit the loop. The loop pump moves fluid out and back into the chamber as before and the membrane moves across the chamber. The chamber is always providing the volumetric balance function of: *Volume In = Volume Out and Net Removal = Lower Loop Pressure.* (See Figure 2)

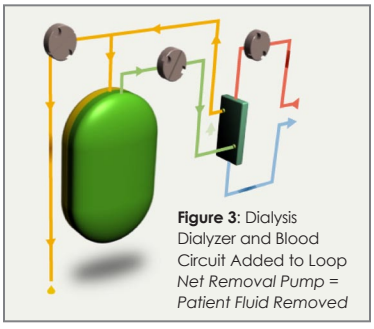

Figure 3: Dialysis Dialyzer and Blood Circuit Added to Loop *Net Removal Pump = Patient Fluid Removed*

When a dialyzer and blood circuit is added to the loop, a pathway for fluid to enter the loop from the blood circuit across the dialyzer membrane is created. The negative pressure in the dialysate chamber relative to the blood circuit creates the gradient needed for ultrafiltration (UF). As a result, net ultrafiltration can be achieved. Again, the chamber connected to the loop is always providing the volumetric balance function of: *Volume In = Volume Out and Net Removal = Patient Fluid Removed.* (See Figure 3)

For continuous flow dialysis, a second chamber fills with fresh dialysate and expels the waste dialysate out the waste line. As the membranes reach the end of travel, the balance chambers switch function. The chamber that was connected to the loop and just finished filling with waste dialysate connects to the source of fresh dialysate and drain. The chamber that was connected to the source of fresh dialysate and drain, and just finished filling with fresh dialysate

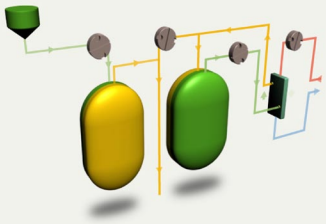

Figure 4: Second chamber
Volume In = Volume Out and Patient Fluid Removed = Net UF Removal Pump.

connects to the volumetric loop. This is done as all open valves close, briefly all valves are closed, and then opposite valves open. The cycle repeats as membranes travel across the chambers and reach end of travel in the opposite direction and valves switch function again. The chamber connected to the loop is always providing the volumetric balance function of: *Volume In = Volume Out and Patient Fluid Removed = Net UF Removal Pump.* (See Figure 4)

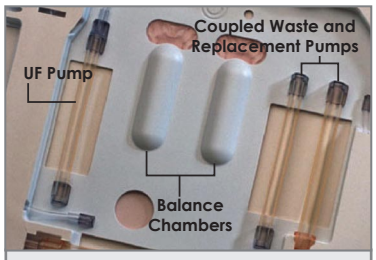

Figure 5: The disposable NxStage Cartridge showing the UF pump and the coupled replacement and waste pumps.

The System One Cartridge: Simplified Format for Accurate Fluid Balancing in CRRT

The NxStage System One is unique in its incorporation of continuous volumetric balancing into a disposable cartridge with two chambers which continuously alternate between filling with fresh dialysate and expelling waste dialysate down the drain. Within the cartridge, each chamber includes separate fluid pathways or "circuits" for fresh and waste dialysate from welded soft plastic. As a result, full separation of fresh and waste dialysate is maintained. In addition to the volumetric balancing chambers, the complete System One cartridge includes UF, replacement fluid and waste pumps. The UF pump performs the net removal of fluid from the patient as programmed by the user. The coupled replacement and waste pumps fill the volumetric balancing chambers. (See Figure 5)

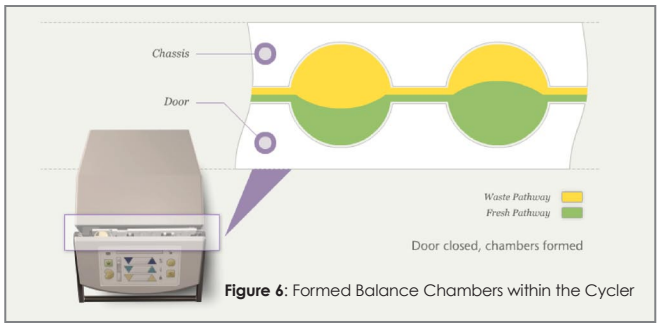

Figure 6: Formed Balance Chambers within the Cycler

When the cartridge is loaded into the NxStage System One, the fluid pathways attach to the cartridge tray and are overlaid so that the balance chamber areas align. The cycler door plates are rigid and each door contains ½ of the balance chambers. After the cartridge is loaded, the door is closed and when fluid is introduced, the plastic portions of the fluid pathways form into the rigid pocket walls, much like a pool liner and a complete balance chamber with a fixed volume is formed. The sides of the plastic portions in contact with each other form the moving membrane of the chamber while separating fresh and waste fluids. (See Figure 6)

Continuous "Fresh" and "Waste" Dialysate Balancing

During operation the replacement fluid pump pushes fresh dialysate into one chamber, displacing effluent into the waste line. At the same time, the waste pump pushes the effluent into the waste portion of the other chamber, displacing fresh dialysate into the replacement fluid line to the filter. As the membranes reach the end of their travel, with one chamber full of effluent and the other full of fresh dialysate, the balance chambers switch function. Continuous flow volumetric balancing is thus physically linked and happens on a 1:1 basis.

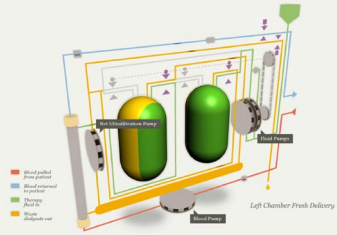

Figure 7: Synchronized pump and valve function.

Timing of the volumetric balancing cycle is controlled through sets of pinch valves synchronized to the combined replacement fluid and waste pumps (fluid balance pump). Thus, the opening and closing of the pinch valves is sequenced to the pumping of the fresh and waste fluids into the chambers. At the end of a cycle, all open valves close, all valves remain briefly closed, and then opposite valves open. The fluid balance pump speed determines the equal exchange rate of fresh and waste fluids. Net UF is removed though the separate UF pump and is equal to the net patient fluid loss. (See Figure 7)

Automated System Sensors Reduce Potential for Errors

The volumetric design of the System One includes a system of self-checks and alarms that reduce the potential for user error and assure greater patient safety. Pressure sensing, fluid sensing, and blood leak detectors are engaged when the cartridge is loaded and the cycler door is closed. They are also tested during the alarm test phase following prime. The pressure and fluid sensors determine when flow is restricted to or from the balance chambers. When this occurs, fluid balancing is stopped and not allowed to continue until the situation is corrected. In addition, the volumetric fluid management system (VFMS), conducts self tests during the alarm test phase and the treatment phase at specified intervals to ensure proper machine function.

Performance Testing of the NxStage System One

The System One volumetric fluid management system has been extensively tested under controlled laboratory conditions required to assess long duration/high accuracy fluid systems. The System One has demonstrated consistent accuracy during CVVHD and CVVH and is equivalent in accuracy to scale based systems.

Summary

The continuous volumetric balancing approach of the NxStage System One is well-matched to the safety, accuracy, and operational simplicity needs of ICUs for the delivery high volume renal therapies. The System One has demonstrated the ability to deliver volumes of up to 600 mL/Min (Q_B) and 14.4 mL/hour (Q_{UF}). By incorporating continuous volumetric balancing in the disposable cartridge, not only is the System One designed to be safe and highly accurate, but it also eliminates restrictions of prescription fluid that can be connected—all while allowing for continuous drainage of effluent. This simple approach to renal care eliminates the traditional challenges associated with scale-based systems, such as annoying scale alarms and waste bags to empty. Importantly, the disposable System One cartridge simplifies set-up and maintenance.

The NxStage System One enables the ICU to meet their goals of economically delivering more intensive renal replacement therapies while reducing the strain on overburdened critical care staff and resources, thereby allowing nurses to spend more time with their patients.

References

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