Addressing Acid Concentrate and Bicarbonate Buffer and Alkali Dosing:

Recently, there have been warnings and a recall issued pertaining to Fresenius Medical Care (FMC) and their Granuflo® acid concentrate regarding total alkaline buffer delivered during hemodialysis, related to the acetate contained in acid concentrate and the resulting post-dialysis serum bicarbonate level. For the sake of clarification, Rockwell is providing the following information:

Acid concentrates contain acetic acid, citric acid* or sodium diacetate to maintain the pH of the final dialysate. Sodium diacetate however is different from acetic acid and citric acid. Sodium diacetate is a 1:1 mixture of sodium acetate and acetic acid [$NaH(C_2H_3O_2)_2$]. Each molecule of sodium diacetate generates (2) bicarbonate equivalents, compared to just (1) bicarbonate equivalent generated by acetic acid or citric acid. Bottom line: sodium diacetate significantly increases the amount of bicarbonate delivered to the patient compared to acetic or citric based product. FMC's Granuflo® acid concentrate product contains sodium diacetate.

Rockwell's acid concentrate products do not contain sodium diacetate. Rockwell's acid concentrate products contain only citric acid (CitraPure®) or acetic acid (Dri-Sate® or RenalPure®).

Citric Acid: A bicarbonate-based dialysate containing 2.4 mEq/L of citric acid from the acid concentrate is mixed with 37 mEq/L of sodium bicarbonate from the bicarbonate concentrate to deliver a total of 37 mEq/L of dialysate bicarbonate.

Acetic Acid: A bicarbonate-based dialysate containing 4 mEq/L of acetic acid from the acid concentrate is mixed with 37 mEq/L of sodium bicarbonate from the bicarbonate concentrate to deliver a total of 37 mEq/L of dialysate bicarbonate.

Sodium Diacetate: A bicarbonate-based dialysate containing 4 mmol/L of diacetate (generating 8 mEq/L acetate) in the acid concentrate is mixed with 37 mEq/L of sodium bicarbonate in the bicarbonate concentrate to deliver a total of 41 mEq/L of dialysate bicarbonate. This extra delivery of bicarbonate is generated only by FMC's Granuflo® product.

NOTE: An adjustment to the bicarbonate setting on the dialysis machine to compensate for the extra acetate delivered by Granuflo® (e.g. lowering the bicarbonate setting to 33 mEq/L) will consequently deliver more K, Ca and Mg than the patient was actually prescribed.

Rockwell's acid concentrate products contain only citric acid (CitraPure®) or acetic acid (Dri-Sate® or RenalPure®) and we are committed to providing high-quality dialysates that are safe for and benefit dialysis patients.

*Dialysate containing citric acid only (with no acetate present) has demonstrated clinical advantages for dialysis patients.