GranuFlo® Acid Concentrate

GranuFlo Acid Mixing Procedure Card

This card is intended to be a supplement to the Fresenius Renal Technologies Dry Acid Dissolution Unit Operator's Manual and the GranuFlo Operator's Manual and product labels. Refer to the Fresenius Renal Technologies Dry Acid Dissolution Unit Operator's Manual and the GranuFlo acid concentrate product labels for a complete description of mixing instructions, hazards, contraindications and precautions.

Preparation for Dissolution Cycle

Note: GranuFlo Concentrate Dissolution Units are designed for use with GranuFlo acid product only.
Dry Acid Dissolution Units are designed for use with Citrasate® Dry acid or GranuFlo acid products only.
Note: Do not use GranuFlo acid concentrate cases if package is opened or damaged.

1. **Determine how much product is required for mixing (See Table 1 below).**

Dry Acid Dissolution Unit	No. of Cases Needed
99 gallon mixer	6
132 gallon mixer	8

Table 1: GranuFlo Acid Concentrate Case Requirements

2. **Check case labels to ensure all cases are of the same catalog number.**

3. **Complete the Dry Acid Batch Production Record form.**

4. **Use water that meets or exceeds ANSI/AAMI RD62 or ISO 13959 hemodialysis water quality standards. Water temperature should be 20°C-30°C (68°F-86°F) for proper dissolution.**

Instructions for Dissolution

Note: The contents in the GranuFlo acid cases may clump or harden. This does not affect the chemical composition of the product. While the images below depict the Granuflo Dissolution Unit, the following instructions are for GranuFlo Concentrate Dissolution Units and Dry Acid Dissolution Units.

Rinse cycle must be completed prior to initiating the batch of concentrate.

1. **Ensure access port lid is in place, main transfer ball valve is closed and Input Water Source is On.**

2. **Press the RINSE START button.**

3. **Begin the Fill Cycle on the Dry Acid Dissolution Unit by pressing the DISSOLUTION START button.**

4. **Wait for the ADD GRANULES light prior to adding dry acid product.**

5. **Using eye protection and gloves is recommended. If contact with eyes occurs, flush immediately for 15 minutes. If contact with skin occurs, rinse with plenty of soap and water.**

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Instructions for Dissolution (Continued)

6 Remove small access lid on Granuflo Dissolution Unit or Dry Acid (Dissolution Unit).

7 Open a case of GranuFlo concentrate and cut off the tops of all bags just below the bag seal, leaving as much extra bag length as possible.

8 Gather extra bag material at the top with your thumb facing down. This will allow the proper hand position when the bag is inverted.

9 Grab the flap on the bottom of the bag and invert the bag. Insert the gathered end into the small opening in Dissolution Unit.

10 Release the gathered end of the bag and allow the contents to empty into the tank. Once all of the powder has transferred to the dissolution unit remove and discard the empty bag.

11 Repeat steps 7-10 until the correct number of bags have been emptied into the Dissolution Unit.

Note: Each case contains three bags. The contents of the bags in each case are different. All bags must be used.

12 **Dry off the Final Fill Sensors.**

Label the Dissolution Unit with contents and dates prepared.

13 **Replace the small access lid and press the DISSOLUTION START button. The Dissolution Unit will proceed to the Mix Operation. Follow the instructions to complete the mixing process as directed by the Operator's Manual for your specific Dissolution Unit.**

14 **Once the Transfer Indicator Light flashes, the concentrate can be tested for the specific gravity.**

15 **After the specific gravity value is within recommended limits, follow the instructions in your operators manual to transfer the solution to appropriate storage containers.**

Note: Reconstituted acid concentrate should not be stored in the Dissolution Unit tank for longer than two weeks from the date of dissolution.

Indications for Use: GranuFlo dry acid concentrate is indicated in the treatment of acute and chronic renal failure during the hemodialysis procedure. This concentrate is formulated to be used with a three stream hemodialysis machine which is calibrated for acid and bicarbonate concentrates. The Dry Acid Dissolution Unit mixes Fresenius Renal Technologies distributed dry acid concentrate products with hemodialysis quality water. The resulting liquid acid concentrates are intended for use in three stream hemodialysis machines calibrated for acid and bicarbonate concentrates.

Caution: Federal (US) law restricts this device to sale by or on the order of a physician.

Note: Read the Instructions for Use for safe and proper use of this device. For a complete description of hazards, contraindications, side effects and precautions, see full package labeling at www.fmcna.com.

Warning: This acid concentrate product is for use as one component in mixing dialysate bath. This product contains sodium diacetate and, after mixing, yields 8 milliequivalents per liter of acetate in the dialysate. After diffusion across the dialyzer membrane, acetate is metabolized by the liver to serum bicarbonate and adds to the serum bicarbonate that separately results from the diffusion of dialysate bicarbonate across the dialyzer membrane. During dialysis, the dynamic of diffusion and concentration gradients prevent serum bicarbonate concentration from exceeding the dialysate bicarbonate concentration. The bicarbonate concentration of the dialysate is the "bicarbonate" setting on the dialysis machine, and is the bicarbonate dose prescribed by the physician. On 2008® series hemodialysis machines, the bicarbonate dose may be set in a range between 20 and 40 milliequivalents per liter, but may be set in different ranges in other machines.

When the dialysis session terminates, acetate that has not yet metabolized may remain in the blood and will be converted to serum bicarbonate after diffusion ceases, without possibility of diffusion out of the blood. The post dialysis metabolism of acetate could thus briefly increase serum bicarbonate concentration above the prescribed bicarbonate concentration of the dialysate. Physicians should consider this possibility in prescribing bicarbonate dose.

Prescription of insufficient bicarbonate may contribute to metabolic acidosis; excessive bicarbonate may contribute to metabolic alkalosis. Both conditions are associated with poor patient outcomes, including increased mortality risk.

Customer Service: 800-323-5188 • Technical Support: 800-227-2572

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