FRESENIUS MEDICAL CARE

GranuFlo® I Version 2 and GranuFlo® II w/ Citrasate® DRY Update Kit

Mixing Training Course
P/N 460030 Rev. D

"Mixing Training Course" P/N 460030 Rev. D
Introduction

COURSE DESCRIPTION
This course is intended to provide dry acid mixing training to inexperienced and experienced operators of the 99 and 132 Gallon Fresenius Medical Care GranuFlo Dissolution Units.

TEXT AND REQUIRED SUPPLIES / EQUIPMENT
- P/N 450368-03 GranuFlo II Citrasate® DRY update kit – Operators Manual
- GranuFlo I or GranuFlo II Ver. 2 (Installed by FMCNA Qualified Technician.)
- Citrasate Dry Acid Update Kit (160157 or 160158)
- Hydrometer and Hydrometer Cylinder
- Thermometer (min. req. 25°C ± 5 °C (68 ° to 86 °F) and accuracy ±1 °C (3.6 °F)
- Bucket/Container (approx. 3.5 gal)
- pHoenix Meter (EMD pH-indicator strips, Cat. #9590 or equivalent)
- PPE Equipment (Eye Protection and Gloves)
- 1 micron filter
Dissolution Units Overview

GranuFlo II Dissolution Unit

GranuFlo I (Ver. 2) Dissolution Unit
There are two (2) pre-programmed cycles:

- **RINSE CYCLE**
- **DISSOLUTION CYCLE**

The **CONTROL PANEL** will display the GranuFlo Dissolution Unit **STATUS** at any given time.

*The* left side of the panel displays the **DISSOLUTION CYCLE**.

The right side of the control panel displays the **RINSE CYCLE**.
INTERNAL COMPONENTS

- Mixer Motor
- Spray Ball
- Final Fill Sensor
- Mid Level Sensor
- 25 Gallon Sensor
- Mixing Jets
- Tank Filter Stand
- Pump Dry Sensor
- Mixer Shaft
- Propellers (2)
Mix Process Overview

Unit Preparation Step #1

Operators Manual Section 5.0

Rinse Cycle Step #2

Operators Manual Section 6.0

Dissolution Cycle Step #3

Operators Manual Section 7.0

Specific Gravity Testing

Pass

Concentrate Disposal

Failed / Residual

Transfer Stage Step #4

Operators Manual Section 7.1

Operators Manual Section 7.2

Operators Manual Section 7.3

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FOR TRAINING PURPOSES ONLY

10/24/2017
UNIT PREPARATION

Step #1

Operators Manual:
Section 5.0
Unit Preparation (Mix Process Step #1)
Operators Manual Section 5.0

- **Power cord** is connected to 120 volts, 60 Hz, single phase 15 amp; GFI protected circuit.
- Be certain the GranuFlo Dissolution Unit **Drain Hose** is over a floor drain and **Transfer Hose** is connected to Transfer Hose Holder.
- **Purified water** source is turned ON.
- **Power** is in the ON position.
- Maximum **Input Water Pressure** is 60 PSI.
RINSE CYCLE
Step #2

Operators Manual: Section 6.0
1. Before initiating the **RINSE CYCLE**, the operator must ensure that:

- Access Port Lid is **IN PLACE**.
- Transfer Valve is in the **CLOSED** position.
- Input water source is in the **ON** position.

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**Rinse Cycle (Mix Process – Step #2)**

**Operators Manual Section 6.0**

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**GranuFlo I Dissolution Unit**

**GranuFlo II Dissolution Unit**
2. Press the Rinse side **START** button.

**FILL** indicator (on rinse cycle side) will illuminate and tank will automatically start to fill up with water until it reaches the 25-Gallon Sensor.
3. Once the 25-Gallon Sensor is reached, the process automatically steps to **RECIRCULATE** operation.

- The recirculate operation will run for **twelve (12) minutes** on the **GranuFlo II Dissolution Unit**.
- The pump and the mixer motor will run for a **ten (10) minute** period for the **GranuFlo I Dissolution Unit**.
- During this time period, follow the procedure outlined to inspect the spray ball (**See Next Slide**).
Rinse Cycle (Mix Process – Step #2)

Operators Manual Section 6.0

GranuFlo II Dissolution Unit

GranuFlo I Dissolution Unit

Use Eye Protection

A. Remove the Small Access Port and look inside to check for the Spray Ball Ring proper rotation.

B. Check the Spray Ball Ring for rotation.

A. If Correct Spray and rotation of the Spray Ball Ring, then proceed to step 4, pg 10.

B. If Spray Ball Ring is dug with the water flow looks like this, then proceed to D.

A. Remove the Small Access Port.

B. Check the Spray Ball for rotation.

A. If Correct Spray Ball spray pattern, then proceed to Step 4 pg 10.

B. If Spray Ball is clogged and not rotating go to C.

FOR TRAINING PURPOSES ONLY

"Mixing Training Course" P/N 460030 Rev. D
Rinse Cycle (Mix Process – Step #2)

Operators Manual Section 6.0

FOR TECHNICAL SERVICE ONLY!

GranuFlo II Dissolution Unit

GranuFlo I Dissolution Unit

C. If the Spray Ball is stationary, push the PAUSE button. RECIRCULATE LED will flash. Turn Main Power Switch OFF.

D. Remove the nut below the Spray Ball to access the Sprayer.

E. Clear the spray holes in both the Spray Ball Ring and sprayer of debris and reassemble.

F. Turn main Power Switch ON. Press RINSE CYCLE START button. PAUSE LED will turn on and RECIRCULATE LED will not flash. Check for proper Spray Ring rotation before proceeding to pg. 10.

C. If the Spray Ball is stationary, push the PAUSE Button. RECIRCULATE light will flash.

D. Remove the nut below the Spray Ball to access the sprayer.
4. When the **RECIRCULATE** operation is complete the GranuFlo Dissolution Unit will switch to **DRAIN** operation and empty rinse water from the GranuFlo Dissolution Unit to the floor drain.

   **Note:** *This is a 10 minute timed cycle for the 132 gal. GranuFlo Dissolution Unit.*

5. At the completion of the **DRAIN** operation, the GranuFlo Unit will refill to the 25-Gallon Sensor. The **Fill** Indicator Light will turn on and the **RINSE** operation will start.

6. When the second **RINSE CYCLE** is finished, the GranuFlo Dissolution Unit will go to the **CYCLE COMPLETE** operation. The Rinse Cycle Complete Indicator Light will turn ON and the Drain Valve will remain open, allowing any residual rinse water to go down the drain.
RINSE CYCLE
EXAMPLE
Rinse Cycle (Mix Process – Step #2)

Example

FILL Operation

- The tank fill to the 25 Gallon Sensor.
- The unit will automatically advance to the RECIRCULATE Operation.
Rinse Cycle (Mix Process – Step #2)

Example

RECIRCULATE Operation

- Mixer Motor
- Mixer Shaft
- Propellers(2)
- Spray Ball
- Mixing Jets

"Mixing Training Course" P/N 460030 Rev. D
FOR TRAINING PURPOSES ONLY
Rinse Cycle (Mix Process – Step #2)

Example

DRAIN Operation

- Recirculate Operation will stop and DRAIN valve will open.
Rinse Cycle (Mix Process – Step #2)

Example

FILL Operation

- The tank fill to the 25 Gallon Sensor.
- The unit will automatically advance to the RECIRCULATE Operation.
Rinse Cycle (Mix Process – Step #2)

Example

RECIRCULATE Operation

- Mixer Motor
- Spray Ball
- Mixer Shaft
- Propellers(2)
- Mixing Jets
Rinse Cycle (Mix Process – Step #2)

Example

DRAIN Operation

- Recirculate Operation will stop and DRAIN Valve will open.
Rinse Cycle (Mix Process – Step #2)

Example

CYCLE COMPLETE Operation

- The DRAIN Valve will remain Open.
- The unit will advance to CYCLE COMPLETE Operation.
DISSOLUTION CYCLE
Step #3

Operators Manual:
Section 7.0
**Dissolution Cycle (Mix Process – Step#3)**

Operators Manual Section 7.0

**NOTE:** A COMPLETE FULL RINSE CYCLE IS RECOMMENDED BEFORE MAKING BATCH OF CONCENTRATE.

*(ONLY for the GranuFlo II Unit)*

**NOTE:** A SHORT RINSE CYCLE IS PERFORMED AS PART OF THE DISSOLUTION CYCLE: FILL OPERATION, AND DRAIN IS INITIATED AND COMPLETED WHILE THE FILL INDICATOR LIGHT IS ILLUMINATED. THIS SHORTENED RINSE CYCLE SHOULD NOT BE MISTAKEN FOR A FULL RINSE CYCLE.

The “Short Rinse Cycle” is part of the fill operation.
1. Before initiation of Dissolution Cycle:

- Ensure the tank is empty.
- The 1 micron filter is installed in the concentrate filter housing.
- Check for Propellers are attached to the Mixer Shaft (For 132 Gal. Unit).
- Ensure you have the appropriate Personal Protective Equipment donned.
2. Ensure **Power Switch is ON** and **Water Inlet Open** then place the GranuFlo Dissolution Unit in Dissolution Cycle FILL operation by pressing the Dissolution side **START** button.

**NOTE:** The GranuFlo I Dissolution Unit will be in the **FILL** Operation until the water reaches to the Mid-Level Sensor.

**NOTE:** The GranuFlo II Dissolution Unit will do a short Recirculate Operation with only the Fill Indicator Light illuminated then fill to the Mid-Level Sensor.
3. When the Mid Water Level is reached.
   - The **Water inlet valve** will **Close**.
   - The **Add Granules Light** will begin to **flash**.
   - The Unit is in **PAUSE state** waiting for the operator to **ADD GRANULES**.

---

A) GranuFlo I Dissolution Unit

B) GranuFlo II Dissolution Unit
Dissolution Cycle (Mix Process – Step#3)
Operators Manual Section 7.0

4. Before adding Granules make sure to check the following:
   - Ensure that no water is leaking from underneath or any external connections to and from the GranuFlo Dissolution Unit. In addition, ensure there are no leaks at the end of the Drain Hose.
   - Remove the large access lid and ensure water has stopped at the Mid-Level Sensor.
   - Depending on the input water pressure you may have to wait several minutes to verify the water does not rise above the Mid-Level Sensor.
   - Proceed to ADD GRANULES.
Dissolution Cycle
Add Granules

- Determine how much product is required.

<table>
<thead>
<tr>
<th>FMCNA Dissolution Unit</th>
<th>No. of Cases Needed</th>
</tr>
</thead>
<tbody>
<tr>
<td>GranuFlo II Dissolution Unit</td>
<td>6</td>
</tr>
<tr>
<td>GranuFlo I Dissolution Unit</td>
<td>8</td>
</tr>
</tbody>
</table>

- Check case labels to ensure all cases have the same Catalog Number and Potassium Number.

Recommendation:
1. Group the cases to be used.
2. Separate/isolate the group of cases from other cases that are present to avoid mixing Catalog No./Products.
**Mixing Training Course**

**Add Granules**

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**GranuFlo**

**Product Name:** GRANUFLO

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**Citasate Dry**

**Product Name:** CITRASATE DRY

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### Dissolution Cycle

#### Add Granules

**GranuFlo**

**Product Name:** GRANUFLO

**Label Graphic:** Red

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**Citasate Dry**

**Product Name:** CITRASATE DRY

**Label Graphic:** Yellow
Dissolution Cycle
Add Granules

- Fill in the Production Record Form, attached to the Operators Manual.
- Depending on product, Granuflo or Citrasate Dry Form.

Record the Following Information Depending on the Product.

**CITRASATE DRY BATCH PRODUCTION FORM**

**DRI ACID PRODUCT CAS INFORMATION**

<table>
<thead>
<tr>
<th>OPERATOR (first name):</th>
<th>DATE:</th>
<th>TIME:</th>
<th>BATCH #</th>
</tr>
</thead>
</table>
| CASE 1: Dry Acid Catalog #: | BOX Lot #: | All bag used ✓ box | Potassium # |<br>
| CASE 2: Dry Acid Catalog #: | BOX Lot #: | All bag used ✓ box | Potassium # |<br>
| CASE 3: Dry Acid Catalog #: | BOX Lot #: | All bag used ✓ box | Potassium # |<br>
| CASE 4: Dry Acid Catalog #: | BOX Lot #: | All bag used ✓ box | Potassium # |<br>
| CASE 5: Dry Acid Catalog #: | BOX Lot #: | All bag used ✓ box | Potassium # |<br>
| CASE 6: Dry Acid Catalog #: | BOX Lot #: | All bag used ✓ box | Potassium # |

**SPECIFIC GRAVITY**

<table>
<thead>
<tr>
<th>Measured Temp</th>
<th>Print Catalog Specific Grav.</th>
<th>Measured Specific Gravity</th>
<th>Check Log</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOW:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HIGH:</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**OPERATOR SIGNATURE:**

**VERIFIER SIGNATURE:**
Dissolution Cycle (Mix Process – Step#3)
Add Granules

**PPE**
(Personal Protective Equipment is required/recommended)

**Required**

**Recommended**

For more information refer to the MSDS form of the Dry Acid Product.
Dissolution Cycle (Mix Process – Step#3)
Operators Manual Section 7.0

A) Open a case of Citrasate® DRY / GranuFlo®.
B) Cut off the top of 1 bag just below the bag seal.
C) Remove the GranuFlo Dissolution Unit Small Access Lid and slowly add granules as seen in Figure.
D) Before proceeding with the next case, repeat the steps B and C until all the bags of the case have been added.

Remember:
- Use 6 cases for the 99 Gallon Unit
- Use 8 cases for the 132 Gallon Unit
All cases must have same FMCNA Catalog Number.
5. On the GranuFlo I Dissolution Unit, After the Dry Acid Concentrate has been added, dry off the Upper Level Sensor of any splashing that may have occurred during the add granules process (Figure 10). Then reinstall the Small Access Lid and press the Dissolution START button.

On the GranuFlo II Dissolution Unit, After adding all bags of Dry Acid, reinstall Small Access Lid, then press the Dissolution START button.

Both GranuFlo Dissolution Units will proceed to the MIX operation.
6. For the GranuFlo I Dissolution Unit, during the MIX operation, the solution is mixed for a period of forty-five (45) minutes allowing the granules to completely dissolve. The GranuFlo Dissolution Unit will then automatically step to the DEAERATION Operation.

For the GranuFlo II Dissolution Unit, during the MIX operation, the solution is mixed for a period of thirty-five (35) minutes allowing the granules to completely dissolve. The GranuFlo Dissolution Unit will then automatically step to the DEAERATION Operation.
7. For the **GranuFlo I Dissolution Unit**, the **DEAERATION** operation runs for **five (5) minutes** during which the entrapped air is allowed to separate out of the solution. Upon completion, the GranuFlo Dissolution Unit will automatically step to FINAL FILL operation and the Final Fill Indicator Light will illuminate.

For the **GranuFlo II Dissolution Unit**, the **DEAERATION** operation runs for **two (2) minutes** during which the entrapped air is allowed to separate out of the solution. Upon completion, the GranuFlo Dissolution Unit will automatically step to FINAL FILL operation and the Final Fill Indicator Light will illuminate.
8. In the **FINAL FILL** operation, the supply water valve will open and GranuFlo Dissolution Unit will fill to the Final Fill sensor.
Dissolution Cycle (Mix Process – Step#3)
Operators Manual Section 7.0

9. When the final water level is reached, the unit will automatically step to HOMOGENIZE operation. Remove the Large Access Lid and ensure the solution level has reached the Final Fill Sensor. Place Large Access Lid onto the GranuFlo Dissolution Unit. Then, CLOSE the water supply valve to the GranuFlo Dissolution Unit.

10. During HOMOGENIZE operation, the mixer motor will stir the solution for ten (10) minutes. When the HOMOGENIZE Operation is complete, the Transfer Indicator Light will flash. Remove Large Access Lid and look into the tank to make sure the granules have dissolved and the solution is colorless. Once you have verified the granules are dissolved and colorless, the solution is ready for Specific Gravity Testing.
Dissolution Cycle (Mix Process – Step#3)  
Example 132 - Gal
Dissolution Cycle (Mix Process – Step#3)

Example 132 - Gal

FILL Operation

- The tank will fill to the Mid Level Sensor.
- The unit will automatically advance to ADD GRANULES Operation.
ADD GRANULES Operation

- Remove the Small Dissolution Tank Lid and slowly add granules.
Dissolution Cycle (Mix Process – Step#3)

Example 132 - Gal

MIX Operation

- Press the START button.
- The mix motor will run for 45 minutes.

NOTE: In the 99 Gallon GranuFlo II Unit the mix will run for 35 minutes.
Dissolution Cycle (Mix Process – Step#3)

Example 132 - Gal

DEAERATION Operation

- DEAERATION Operation
- During this (5) minute operation the Mixer Motor stops to allow air bubbles to separate out of the solution.

NOTE: In the 99 Gallon GranuFlo II Unit the DEAERATION Operation will run for 2 minutes.
FINAL FILL Operation

- FINAL FILL Operation
- During this Operation, the Dissolution Tank is filled with treated water up to the Final Fill Sensor. Then, the unit automatically advance to the HOMOGENIZE Operation.
**HOMOGENIZE Operation**

- **HOMOGENIZE Operation**
- During this ten (10) minute Operation, the Mixer Motor stirs the solution.
- At the end of this Operation, the unit will automatically advance to TRANSFER Operation.
TRANSFER Operation

- TRANSFER light flashing on the front panel.
- The Solution in the tank is ready for Specific Gravity Testing.
SPECIFIC GRAVITY TEST

Operators Manual:
Section 7.1
Once the Transfer Indicator light flashes, the concentrate is ready to be tested. This test is done using a hydrometer which measures the density of the acid in the concentrate. The resultant value is called the "specific gravity". The specific gravity is measured to verify that the concentrate has been properly mixed.

**Requirements for the test:**
- Hydrometer
- Hydrometer Cylinder
- Thermometer*
- Bucket/Container (approx. 3.5 gal)
- pHoenix Meter (EMD pH-indicator strips, Cat. #9590 or equivalent)

*Minimum Requirements: 25°C ±5 °C (68 ° to 86 °F) and accuracy ±1 °C (3.6 °F)
1. Prepare the Hydrometer and the Hydrometer Cylinder.
   - Check Hydrometer for cracks.
   - Do not use a cracked Hydrometer.
   - Always handle the Hydrometer with care. Always hold it vertically by the top, as finger marks lower down can affect the accuracy of the instrument.
   - The Hydrometer should never be held by the stem horizontally.
   - Rinse the hydrometer and the hydrometer cylinder separately with purified water before checking solution for correct density. The purified water source must meet ANSI/AAMI or ISO standards for dialysis currently ANSI/AAMI RD62, or ISO 13959.
   - Once Hydrometer is clean, place the hydrometer onto a clean area.
   - The Hydrometer is fragile and can break easily.
   - Store in a Safe Area.
Specific Gravity Test
Operators Manual Section 7.1

2. Remove Transfer Line from the Transfer Hose Holder and connect the Transfer Line to the Transfer Nozzle.

GranuFlo I

GranuFlo II

With the Transfer Line Connector locking levers open, place the connector onto the end of the Transfer Nozzle and pull back on the levers to lock the Transfer Line Connector in place.
3. Hold the Transfer Nozzle and make sure the Ball Valve on the Transfer Nozzle is CLOSED.

4. Slightly OPEN the Ball Valve next to the Filter Housing.

5. Press Dissolution START button and open slightly the Transfer Nozzle Ball Valve flush approximately 3.5 gallons of solution using a container(s) that will allow for a 3.5 gallon measurement.
   - This removes any solution left in the Transfer Line from a prior batch.
   - Once the 3.5 gallons of solution have been flushed out of the transfer hose, CLOSE the Transfer Nozzle Ball Valve.
Specific Gravity Test  
Operators Manual Section 7.1

6. Fill the Hydrometer Cylinder:
   ▪ Insert the Transfer Nozzle into the Hydrometer Cylinder.
   ▪ Slowly OPEN the Transfer Nozzle Valve until solution starts to slowly accumulate into the Hydrometer Cylinder. Allowing solution to fill down the side of the beaker minimizes the creation of bubbles within the solution (see figure item A).
   ▪ Fill the Hydrometer Cylinder approximately 2/3rd full.
   ▪ Close Transfer Nozzle and the Ball Valve next to the filter housing, then press PAUSE on the Display Panel.
   ▪ Place Transfer Nozzle onto a clean surface.

7. Make sure the solution does not have excessive amount of bubbles. To release excess amount of bubbles from the solution gently tap the Hydrometer Cylinder or gently swirl. (See Adjacent Picture).
8. Place Hydrometer Cylinder on a level table

- *Measure the temperature* of the solution in the Hydrometer and record it on the batch production record form.
- For thermometer requirements refer to appendix A or B.

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CITRASATE DRY BATCH PRODUCTION FORM

<table>
<thead>
<tr>
<th>Operator (Print Name)</th>
<th>Date</th>
<th>Time</th>
<th>Batch</th>
</tr>
</thead>
<tbody>
<tr>
<td>CASE 1: Dry Acid Catalog # (lab or box)</td>
<td>BOX Lot #</td>
<td>4-1/2 bag used</td>
<td>Potassium # (1H, 2H, 3H)</td>
</tr>
<tr>
<td>CASE 2: Dry Acid Catalog #</td>
<td>BOX Lot #</td>
<td>4-1/2 bag used</td>
<td>Potassium #</td>
</tr>
<tr>
<td>CASE 3: Dry Acid Catalog #</td>
<td>BOX Lot #</td>
<td>4-1/2 bag used</td>
<td>Potassium #</td>
</tr>
<tr>
<td>CASE 4: Dry Acid Catalog #</td>
<td>BOX Lot #</td>
<td>4-1/2 bag used</td>
<td>Potassium #</td>
</tr>
<tr>
<td>CASE 5: Dry Acid Catalog #</td>
<td>BOX Lot #</td>
<td>4-1/2 bag used</td>
<td>Potassium #</td>
</tr>
</tbody>
</table>

After Final Fill Level has been reached, turn off valve before the Unit. Once this is done, check the box.

**SPECIFIC GRAVITY**

Measured Temp:  
Print Catalog Specific Gravity Value for the Measured Temp listed in Appendix A:  
Measured Specific Gravity Value:  
Check box:  
Pass  
Fail (void section)

Operator Signature:  
Verifier Signature:  

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9. On Appendix A or B
   - Locate the Catalog number of the dry acid product being used (1)
   - Locate the value of the “measured temperature” of the solution (2)
   - Moving across and then down, identify the ‘low’ and ‘high’ specific gravity numbers.
   - These ‘low’ and ‘high’ numbers can be recorded in the appropriate box in the Batch Production Record Form located at the last pages on the manual (3).
10. Obtain the clean hydrometer and slowly lower the hydrometer into the solution until the hydrometer begins to float freely.

11. Hold the top of the hydrometer between your thumb and finger and spin the hydrometer in the Hydrometer Cylinder.

- The slow spinning action of the hydrometer will cause the hydrometer to stay away from the sides of the Hydrometer Cylinder.
- In addition, this will help keep bubbles from forming on the hydrometer.
Specific Gravity Test
Operators Manual Section 7.1

12. Hydrometer will move up and down

- If during the up and down movement of the hydrometer the meniscus is crinkled or dragged out of shape by the motion of the hydrometer, then this indicates that either the hydrometer or the surface of the solution is not clean. Clean the hydrometer and Hydrometer Cylinder again. Then restart the Specific Gravity from step 1.

- If the meniscus remains unchanged as the hydrometer rise and falls, then the hydrometer and liquid surface are clean and a reading can be taken.
13. Allow the hydrometer to settle within the solution. Once the hydrometer is stable, place your head at eye level to the meniscus of the solution as seen in the adjacent Figure.

- The point where the bottom of the meniscus crosses the hydrometer is the correct measuring point.

- Do not take a reading if the hydrometer is touching the side of the hydrometer cylinder.
How to read the Hydrometer

(SCALE)

FULL SCALE
How to read the Hydrometer

(SCALE)

**Notes**
- Every line in the scale represents a value of .002.
Specific Gravity Test
Operators Manual Section 7.1

15. If the results from the Specific Gravity Test are **acceptable** (Measured Value within Low and High Values), check the “Pass” box onto the Citrasate Dry with Acetate Batch Production Record Form. The solution is ready for the **TRANSFER** operation.
16. Pour residual solution from hydrometer cylinder into the solution present in the residual solution bucket.

**Practice Exercise**

**General Instructions:** Read carefully and follow the instructions for this exercise provided on the bottom of this page.

The Operator “X” from the Dialysis Unit “FMCNA #13” located in “Dallas, TX.” is preparing to make his first batch of Citrasate Dry Product Code 0FD1231-DA using a 99 Gallon Dry Acid Dissolution Unit (mixer) with the serial number DA99-123456. The user has several cases of the product with the label shown on the next slide.

Each case of Citrasate Dry contains 4 bags.

It is November 12, 2011 and the time is 9:25 am and the user starts with the mixing process. After mixing, the operator proceeds to test for Specific Gravity.

The results are shown below:

Temperature of Sample: 27°C, Specific Gravity: 1.198

**Instructions:** Using the information provided above and the label shown in the next slide, fill in the batch production record attached to the manual.
Practice Exercise
## Practice Exercise

### PRACTICE EXERCISE RECORD FORM

**FORM 2: CITRASATE® DRY WITH ACETATE PRODUCTION RECORD**

<table>
<thead>
<tr>
<th>Dialysis Unit Name &amp; Location #:</th>
<th>FMCNA #13. Dallas, Tx.</th>
<th>Dry Acid Dissolution Unit Serial #:</th>
<th>DA99-123456</th>
</tr>
</thead>
</table>

### DRY ACID PRODUCT CASE INFORMATION

<table>
<thead>
<tr>
<th>OPERATOR (print name):</th>
<th>DATE:</th>
<th>TIME:</th>
<th>Batch #:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operator X</td>
<td>11/12/2011</td>
<td>9:25 a.m.</td>
<td>1</td>
</tr>
</tbody>
</table>

#### CASE 1: Dry Acid Catalog# (label on box)

- **Box Lot #**: Lot# 12ATGF009
- **4th bag used**: Yes
- **Potassium # (1k, 2k, 3k)**: 1K

#### CASE 2: Dry Acid Catalog#

- **Box Lot #**: Lot# 12ATGF009
- **4th bag used**: Yes
- **Potassium #**: 1K

#### CASE 3: Dry Acid Catalog#

- **Box Lot #**: Lot# 12ATGF009
- **4th bag used**: Yes
- **Potassium #**: 1K

#### CASE 4: Dry Acid Catalog#

- **Box Lot #**: Lot# 12ATGF009
- **4th bag used**: Yes
- **Potassium #**: 1K

#### CASE 5: Dry Acid Catalog#

- **Box Lot #**: Lot# 12ATGF009
- **4th bag used**: Yes
- **Potassium #**: 1K

#### CASE 6: Dry Acid Catalog#

- **Box Lot #**: Lot# 12ATGF009
- **4th bag used**: Yes
- **Potassium #**: 1K

1. After Final Fill Level has been reached, turned OFF water valve to the Unit. Once this is done check the box.

### SPECIFIC GRAVITY

<table>
<thead>
<tr>
<th>Measured Temp</th>
<th>Print Catalog # - Specific Gravity value for the Measured Temp listed in Appendix A:</th>
<th>Measured Specific Gravity Value:</th>
<th>Check one</th>
</tr>
</thead>
<tbody>
<tr>
<td>TEMP: 27°C</td>
<td>LOW: 1.187</td>
<td>1.199</td>
<td>1.198</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>OPERATOR SIGNATURE:</th>
<th>VERIFIER SIGNATURE:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operator X</td>
<td>Verifier Y</td>
</tr>
</tbody>
</table>
**Practice Exercise**

**APPENDIX B: CITRASATE® DRY SPECIFIC GRAVITIES TABLE**

### Specific Gravity Ranges

1:44 PROPORTIONING

<table>
<thead>
<tr>
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<td>1.196</td>
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Minimum Thermometer Specifications: Temperature Range 25°C +/- 5°C (68° to 86°F) and accuracy +/- 1°C (3.5°F)

**What thermometer to use?**
TRANSFER

Step # 4

Operators Manual:
Section 7.2, 7.3
Transfer (Mix Process – Step #4)
Operators Manual Section 7.2 and 7.3

Transfer

Storage Tank

Operators Manual
Section 7.2

Individual Container

Operators Manual
Section 7.3
TRANSFER TO STORAGE TANK (SECTION 7.2, STEPS 1 TO 3)

- After you have obtained a valid specific gravity reading, remove the Transfer Line from the Transfer Nozzle.
- 1st Connect Transfer Line to the storage tank, 2nd open ball valve at the side of the Filter Housing. 3rd Press the Dissolution START button to transfer concentrate into the storage tank.
- Once Transfer of solution is complete, place Transfer line on to the Dissolution Unit Transfer Line Holder. Do not leave Transfer line attached to the Storage Tank.
TRANSFER TO INDIVIDUAL CONTAINER (SECTION 7.3)

- Containers must be properly labeled
- Connect the Transfer Line to the Transfer Nozzle. Place the Transfer Nozzle into the opening of an individual container
- Slightly OPEN the Ball Valve on the top of the Filter Housing.
- With the Transfer light flashing, Press Dissolution START button. The Transfer Pump will start.
- Slowly OPEN Ball Valve on the Transfer Nozzle until the desired rate of flow through the nozzle is achieved.
TRANSFER TO INDIVIDUAL CONTAINER (SECTION 7.3)

- Once the manual TRANSFER Operation has been completed and the individual containers are filled, CLOSE Transfer Nozzle Valve. Press the PAUSE button.

- When the GranuFlo Dissolution Unit is empty, the GranuFlo Dissolution Unit will step to the CYCLE COMPLETE Operation.
Maintenance Program

Operators Manual:
Section 8.0
Maintenance Overview

- Operators Manual
  8.0
- Cleaning and Visual Inspection
- Sodium Hypochlorite (Bleach) Disinfection
- Sensor Filter Base Stand Pipe Filter Replacement
- Operators Manual
  8.1
  8.2
- Operators Manual
  8.3
- Operators Manual
  8.4.1
  8.4.2 (Only for GranuFlo II)
  8.5
Cleaning and Visual Inspection

Operators Manual:
Section 8.1, 8.2
CLEANING

Clean the exterior surface of the GranuFlo Dissolution Unit thoroughly after each batch of concentrate is mixed. If necessary, a mild detergent solution may be used to clean the exterior surface. Care should be taken not to contaminate the system interior. All spills should be wiped off immediately. Spillage at the control panel should be avoided in order to minimize the possibility of electrical malfunction.

VISUAL INSPECTION

Visually inspect the GranuFlo Dissolution Unit prior to each use. The operator should look for any defects which may inhibit the safe or proper operation of the Unit. Items such as:

- Damaged hydraulic hoses or fittings.
- Damaged electrical cables or connections.
- Loose, missing, or damaged hardware.
- Previous process contamination should be corrected prior to the use of the GranuFlo Dissolution Unit.
# Maintenance

## Routine Maintenance Schedule

### GranuFlo 1 Unit

<table>
<thead>
<tr>
<th>PROCEDURE</th>
<th>PER BATCH</th>
<th>MONTH</th>
<th>AS NEEDED</th>
<th>REF. SECTION</th>
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<tr>
<td>Rinse Cycle</td>
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<td>Visual Inspection</td>
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<td>Cleaning Surfaces</td>
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<td>Disinfectant</td>
<td>X</td>
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<td>Filter</td>
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<tr>
<td>Spray Ball</td>
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</table>

* It is recommended to change the Filter after mixing 6 batches or when the 132 Gallon Dry Acid Dissolution Unit Requires Disinfection. If a tank becomes contaminated, the tank will need to be disinfected before a new filter is installed.

** It is recommended that you look for corrosion or salt deposits at the Final Fill Sensor, Propellers and Shaft within the Unit's Tank. Also, look for any corrosion around the connectors at every valve. Any excessive corroded part on the unit should be clean and replaced if needed.

### GranuFlo II Unit

<table>
<thead>
<tr>
<th>PROCEDURE</th>
<th>PER BATCH</th>
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<th>AS NEEDED</th>
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<tr>
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<td>Visual Inspection</td>
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<td>Cleaning Surfaces</td>
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<tr>
<td>Spray Ball</td>
<td>X</td>
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<td>SECTION 6</td>
<td></td>
</tr>
</tbody>
</table>

* It is recommended to change the Filter after mixing 6 batches or when the 99 Gallon Dry Acid Dissolution Unit Requires Disinfection. If a tank becomes contaminated, the tank will need to be disinfected before a new filter is installed.

** It is recommended that you look for corrosion or salt deposits at the Final Fill Sensor and within the Unit's Tank. Also, look for any corrosion around the connectors at every valve. Any excessive corroded part on the unit should be clean and replaced if needed.
Sodium Hypochlorite
“Bleach” DISINFECTION

Operators Manual:
Section 8.3
WARNING! ENSURE THE TRANSFER LINE IS NOT CONNECTED TO A CONCENTRATE STORAGE CONTAINER/TANK.

NOTE: USE ONLY SODIUM HYPOCHLORITE (5% TO 10%) TO DISINFECT THE GranuFlo DISSOLUTION UNIT. MAKE SURE THE BLEACH DOES NOT CONTAIN A CLEANER.
1. Disinfect as required.

2. (A) Remove the Filter Housing and (B) Discard the Filter Element (C) Replace the Filter Housing, but do not insert a replacement Filter at this time. Connect the Transfer Nozzle to the end of the Transfer Line and make sure the Transfer Nozzle Valve is CLOSED.
3. Press the RINSE Start Button. The fill light indicator will turn on and the tank will fill to the 25-Gallon Sensor.

4. Once the water reaches the 25-Gallon Sensor the unit will automatically step to RECIRCULATE operation. Using your safety glasses inspect spray ball operation.

5. The unit will step to DRAIN and FILL Operations again.

6. When the water reaches the 25-Gallon Sensor during the second RINSE, add 0.5 gallons (1.9 liters) of bleach (sodium hypochlorite 5% to 10%) to the rinse water in the Tank and allow it to recirculate for the duration of the RINSE CYCLE.

7. At the completion of the last RINSE operation (to which the bleach has been added), initiate two (2) complete RINSE CYCLES. When completed, Check two (2) areas for residual bleach.

(SEE NEXT PAGE)
Checking from (1) Transfer Hose

- Press Dissolution START button. When water has reached the 25 Gallon Sensor, use **STEP MODE** to skip to TRANSFER operation.

- Press the Dissolution START button. Open the Transfer Valve on the GranuFlo Dissolution Unit. Then, slowly open the Valve on the Transfer Nozzle. Allow water to flow to the drain for 30 seconds and then collect a sample to test for residual bleach. Close Transfer Nozzle Valve.

Checking from (2) Drain Hose

- Using **STEP MODE** skip to CYCLE COMPLETE operation and press Dissolution START Button (132 Gal).

- Using **STEP MODE** skip to DRAIN operation and Press Rinse START Button (99 Gal).

- The Drain Valve will Open. Allow water to drain for 15 seconds and collect a sample from the Drain Hose to test for residual bleach.
8. If residual bleach levels are higher than ANSI/AAMI Standard limit of <0.1 ppm (RD61: 2006), in any of the two areas initiate another complete RINSE operation. After the RINSE CYCLE is complete, start from section 8.3: number 5, to check for residual bleach. Continue the RINSE CYCLE and test procedure until bleach residuals are within ANSI/AAMI Standard limit of <0.1 ppm (RD61:2006) in both places.

9. Once you have attained an acceptable bleach residual reading, connect the Transfer Line back onto the GranuFlo Dissolution Unit Transfer Line Holder.
10. Turn the unit’s power **OFF** and ensure that the main transfer ball valve is **CLOSED**.

11. Remove Filter Housing and drain all residual water from the Housing.

12. Install new Filter and tighten Filter Housing into place (See Adjacent Figure).

13. Unhook Transfer Nozzle and place Transfer Line onto the Transfer Line Holder.

14. Immediately after RINSE CYCLE, make a batch of Dry Acid Product. Leaving the GranuFlo Dissolution Unit with only treated water or wetted with only treated water leaves the Unit susceptible to bacterial growth.
### Sodium Hypochlorite (bleach) Disinfection

**Operators Manual Section 8.3**

#### Sodium Hypochlorite (bleach) Disinfection

**Step Summary**

<table>
<thead>
<tr>
<th>Cycle</th>
<th>Operation</th>
<th>Operation #</th>
<th>Comments/Instruction</th>
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</thead>
<tbody>
<tr>
<td>Cycle #0</td>
<td>Rinse Fill</td>
<td>1</td>
<td>Press start on the Rinse Cycle</td>
</tr>
<tr>
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<td>Rinse Recirculate</td>
<td>1</td>
<td>Check for Spray Ball Operation</td>
</tr>
<tr>
<td></td>
<td>Rinse Drain</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Rinse Fill</td>
<td>2</td>
<td>Press pause and add bleach (0.5 Gal or 1.9 L) then press “Rinse Start” to resume.</td>
</tr>
<tr>
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<td>Rinse Recirculate</td>
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<tr>
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<td>Cycle #1</td>
<td>Rinse Fill</td>
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<td>Press Start on Rinse Cycle (2nd Rinse Cycle)</td>
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<td>Rinse Fill</td>
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<td>Rinse Recirculate</td>
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<td>Rinse Drain</td>
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<td>Rinse Cycle Complete</td>
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<td>Cycle #2</td>
<td>Rinse Fill</td>
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<td>Press Start on Rinse Cycle (2nd Rinse Cycle)</td>
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<td>Rinse Recirculate</td>
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<td>Rinse Recirculate</td>
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<td>Transfer</td>
<td>Step Mode</td>
<td>Test from Transfer line**</td>
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<tr>
<td>Dissolution</td>
<td>Cycle Complete</td>
<td>Step Mode</td>
<td>Test from Drain **</td>
</tr>
</tbody>
</table>

**If residual bleach levels of samples are higher than 0.1 ppm. Continue rinse cycle and test until bleach residuals are less than 0.1 ppm.**

After Disinfection is completed, remember to make a batch of Dry Acid product.
Transfer Filter and Base Stand Pipe Filter Replacement

Operators Manual:
Section 8.4
TRANSFER FILTER REPLACEMENT

WHEN?
- The Filter shall be changed AFTER mixing 6 BATCHES.
- When the GranuFlo Dissolution Unit requires DISINFECTION.

NOTE
THE FILTER USED MUST BE COMPATIBLE WITH FRESENIUS MEDICAL CARE DRY ACID PRODUCT AND RATED AT 1 MICRON. FRESENIUS MEDICAL CARE. P/N G84-202-12 IS A POLYPROPYLENE FIBER WOUND ON A POLYPROPYLENE MESH CORE AND MEETS THESE REQUIREMENTS. CELLULOSE FILTERS ARE NOT COMPATIBLE WITH THE FRESENIUS MEDICAL CARE DRY ACID PRODUCT AND WILL BREAK DOWN, CLOGGING AFTER ONLY A FEW BATCHES.
FILTER REPLACEMENT
Operators Manual Section 8.4

TRANSFER FILTER REPLACEMENT

HOW?

- Ensure Mixing Tank is empty
- Power to the GranuFlo Dissolution Unit has been turned off.
- MAIN TRANSFER BALL VALVE is closed.
- Follow the Figure A, B, C, and D for removal and replacement of the filter.
SENSOR REPLACEMENT

Operators Manual:
Section 8.5
SENSOR REPLACEMENT
Operators Manual Section 8.5

Sensor Replacement


(1) Request 2 Empty sample bottles (P/N G83-535-02).

(2) Follow Appendix D

(3) Ship Samples Using BATCH ANALYSIS FORM

Disposal of Concentrate Solution

Operators Manual: Section 13

Residual Solutions
“Bucket Disposal”
Section 13.1

“Tank Disposal”
Section 13.2
DISPOSAL of CONCENTRATE SOLUTION

13.1: Residual Solution Bucket Disposal

There are three occasions that require the need to discard residual solution. Those occasions are described as follows:

- **Filter Housing Residual**: Whenever you have to change out a Filter, then the solution in the Filter Housing shall be poured into the Residual Solution Bucket.

- **Hydrometer Cylinder Residual**: Once you are complete with the Specific Gravity Test, the solution in the Hydrometer Cylinder shall be poured into the Residual Solution Bucket.

- **Initial 3.5 Gallon Transferred Solution**: This is the 3.5 gallons of solution transferred into the Residual Solution Bucket in the beginning part of the Specific Gravity Test, section 7.1.
13.2: Tank Solution Disposal

There are five occasions in which you will need to discard the solution in the Dry Acid Dissolution Unit. Those occasions are described as follows:

- **Expired Solution:** If solution remains in the Dry Acid Dissolution Unit Tank for more than 14 days.

- **Foreign Object:** Any foreign object falling into the Dry Acid Dissolution Unit Tank after the dry acid product has been added.

- **Incorrect Catalog Used:** Any batch preparation with incorrect dry acid product catalog (s) numbers

- **Specific Gravity Out of Range:** Any batch prepared that has been found out of range.

- **Dry Acid Unit Needing Service:** Any Dry Acid Dissolution Unit that contains solution that becomes inoperable.
CONCENTRATE SOLUTION DISPOSAL PROCEDURE:
MIXED DRY ACID CONCENTRATE SOLUTION HAS A PH BELOW 6. THEREFORE, IF YOU MUST DISPOSE OF ACID CONCENTRATE SOLUTION BECAUSE OF ONE OF THE ABOVE SITUATIONS, YOU SHOULD FOLLOW ANY APPLICABLE DISPOSAL REQUIREMENTS OF YOUR LOCAL, STATE, AND/OR FEDERAL AUTHORITIES. SEE CLINIC MANAGER FOR MORE INFORMATION.

WARNING! SOME CHEMICALS USED TO NEUTRALIZE ACID CONCENTRATE SOLUTIONS MAY CAUSE SPLATTERING AND/OR GENERATE DANGEROUS LEVELS OF GASES WHEN COMBINED. FOR EXAMPLE, POTENTIALLY DANGEROUS LEVELS OF CARBON DIOXIDE MAY BE RELEASED WHEN SODIUM BICARBONATE IS USED AS THE NEUTRALIZING AGENT. PLEASE CAREFULLY CONSIDER THESE ISSUES, INCLUDING PROPER VENTILATION, IF NEUTRALIZATION IS REQUIRED.
Immediately after a tank disposal, step unit to CYCLE COMPLETE, press STEP MODE button to turn OFF, then ensure that the water inlet valve is open and perform two (2) RINSE CYCLES by pressing the RINSE CYCLE start button and by pressing it again when the first RINSE CYCLE is completed.

After completing two (2) full RINSE CYCLES visually inspect if there is any powder deposits remaining in the tank. These can be removed by running additional RINSE CYCLES in the unit.

Immediately after rinsing the tank clean, make a batch of Dry Acid Product. Leaving the GranuFlo I Dissolution Unit with only treated water or wetted with only treated water leaves the Unit susceptible to bacterial growth.

CAUTION! **Do not allow the Unit to remain full of water without the addition of Fresenius Medical Care Dry Acid Product. Bacterial growth may occur.**
Manual Control Operations
MANUAL CONTROL OPERATIONS

Manual Control Operations

Pause State

Step Mode

Main Power Disconnect

Operators Manual
Section 9.0

Operators Manual
Section 9.1

Operators Manual
Section 9.2

Operators Manual
Section 9.3
MANUAL CONTROL OPERATIONS

- **Step Mode:** ON/OFF Button
- **Power ON Indicator**
- **Cycle PAUSE Push Button**
- **Cycle STEP Push Button**
- **Dissolution Cycle START Push Button**
- **Rinse Cycle START Push Button**
- **Time Remaining Indicator**
- **Dissolution Cycle status Indicators**
- **Rinse Cycle Status Indicators**

GRANUFLO® DISSOLUTION UNIT

GRANUFLO® DISSOLUTION UNIT
PAUSE STATE

If at any time the operator needs to PAUSE a timed operation during the cycle, the PAUSE button may be pressed.

- This will cause the Indicating light for the current step of the operation to flash.
- In the PAUSE state Pressing the PAUSE button or placing the control into the STEP MODE will disable the pump, agitators, drains, fill valves, etc.
- To continue the cycle, press the START button and the timers will resume.
MANUAL CONTROL OPERATIONS

Step Mode

When to Use it?
The STEP MODE function is intended to be used during the Disinfection operation or when it is necessary to discard an incorrectly mixed batch of solution.

How To Use it?
- Press the **STEP MODE ON/OFF** button
- The step Mode Indicator light will illuminate.
- System will enter STEP MODE and all operations will be suspended.

- Press **STEP** button to skip to desired operation. (operation indicator light will illuminate)
- Press the **STEP MODE ON/OFF** button and the operation is continued.
MANUAL CONTROL OPERATIONS
Main Power Disconnect

MAIN POWER DISCONNECT

The MAIN POWER Switch is provided to allow the operator to completely shut down the power to the GranuFlo Dissolution Unit.

The Main Power Disconnect Switch should be switched to the OFF position when the GranuFlo Dissolution Unit is not in use or in case of an emergency.

Remove POWER PLUG from wall receptacle to disconnect power. A 'LOCKOUT' device may be used to prevent unauthorized start up.
Appendix and Forms
### Specific Gravity Ranges

#### 1:44 Proportioning

<table>
<thead>
<tr>
<th>Catalog Number</th>
<th>17°C to 21°C</th>
<th>22°C to 26°C</th>
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</tbody>
</table>

Thermometer Specifications: Temperature Range 25°C +/-5°C (68° to 86° F) and accuracy +/- 1°C (3.6 °F)

For Reference Only.
See Appendix A in Operator’s Manual
### Specific Gravity Ranges

1:44 Proportioning

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<td>1.194</td>
<td>1.206</td>
<td>1.190</td>
</tr>
<tr>
<td>3K</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0FD3231-DA</td>
<td>1.195</td>
<td>1.207</td>
<td>1.190</td>
</tr>
<tr>
<td>0FD3251-DA</td>
<td>1.195</td>
<td>1.207</td>
<td>1.191</td>
</tr>
<tr>
<td>0FD3301-DA</td>
<td>1.196</td>
<td>1.208</td>
<td>1.192</td>
</tr>
</tbody>
</table>

Minimum Thermometer Specifications: Temperature Range 25°C ±5°C (68°F to 86°F) and accuracy ±1°C (3.6°F)

For reference only.
See Appendix B in Operator’s Manual
Preparation for Dissolution Cycle

Note: FMONA Dry Acid Dissolution Units are designed for use with Citrasate Dry or Granuflo products only. Do not use Granuflo or Citrasate Dry cases if package is open or damaged

Step 1
Determine how much product is required for mixing (see Table 1 below).

<table>
<thead>
<tr>
<th>FMONA Dry Acid Dissolution Unit</th>
<th>No. of Cases Needed</th>
</tr>
</thead>
<tbody>
<tr>
<td>49 gallon mixer</td>
<td>6</td>
</tr>
<tr>
<td>132 gallon mixer</td>
<td>8</td>
</tr>
</tbody>
</table>

Table 1: Citrasate Dry | Granuflo to Cases Required

Step 2
Check case labels to ensure all cases are of the same catalogue number.

Step 3
Complete the Dry Acid Batch Production Record form.

Step 4
Use water that meets or exceeds ANSI/ASTM D360 or ISO 13959 hemodialysis water quality standards. Water temperature should be 20°C to 30°C (68°F to 86°F) for proper dissolution.

Instructions for Dissolution

Note: The contents in the Granuflo or Citrasate Dry cases may clump or harden. This does not affect the chemical composition of the product.

Rinse Cycle must be completed prior to initiating the batch of concentrate

Step 1
Ensure Access Port Lid is in place, Transfer Valve is closed and Input Water Source is On.

Step 2
Press the RINSE START button.

Step 3
Begin the Rinse Cycle on the FMONA Dry Acid Dissolution Unit by pressing the DISSOLUTION START button.

Step 4
Wait for the ADD GRANULES light to turn off adding dry acid product.

Step 5
Put on PPE.

Step 6
Remove small access lid on FMONA Dry Acid Dissolution Unit.

Step 7
Open a case of Granuflo/Citrasate Dry and cut off the tops of all bags just below the bag seal leaving as much extra bag length as possible. When using Citrasate Dry, do not cut off top of small, orange acetate bag until immediately prior to adding.

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

Step 9
Grab the flap on the bottom of the bag and invert the bag, insert the gathered end into the small opening in the FMONA Dry Acid Dissolution Unit.

Step 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.

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

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

Step 12
Dry off the Upper Level Sensors.

Step 13
Label the FMONA Dry Acid Dissolution Unit with contents and dates prepared.

Step 14
Replace the small access lid and press the DISSOLUTION START button. The Dissolution Unit will proceed to the Mix Operation. Follow the FMONA Dry Acid Dissolution Unit Operator's Manual for instruction to complete the mixing process.

Step 15
Once the Transfer Indicator Light flashes, the concentrate can be tested for the specific gravity.

Step 16
After the specific gravity value is found to be acceptable, follow the FMONA Dry Acid Dissolution Unit Operator's Manual to transfer the solution to appropriate storage containers.

Note: Reconstituted acid concentrate should not be stored in the Dry Acid Dissolution tank for longer than two weeks from the date of dissolution.
APPENDIX D: FIRST BATCH VERIFICATION INSTRUCTIONS

1. Once the Final Fill Sensor is replaced or unit relocated and the empty sample bottles are available, plug in the power cord. Turn treated water on. Turn the power switch ON (red switch on the right side of the GranuFlo® Dissolution Unit). Verify the power light activates.

2. As per the Operators Manual section 6.0, secure the tank lid and initiate the RINSE CYCLE.

3. As per the Operators Manual section 7.0, run a DISSOLUTION CYCLE by pressing the DISSOLUTION Start Button. When the ADD GRANULES light flashes check to make sure water has reached the Mid-Level Sensor, and then add the eight (8) boxes of GranuFlo® or Citrasate® DRY product.

   NOTE: Make sure to fill the production batch record form attached to this manual with the product information.

   WARNING: DO NOT USE ANY BOX OF GRANUFLO® OR CITRASATE® DRY CONCENTRATE that has been opened or tampered with. It is important that the entire contents of each box are emptied into the DISSOLUTION TANK.

   WARNING! The use of eye protection, dust mask and gloves is recommended when handling dry acid product. If contact with eyes, rinse immediately for 15 minutes. If contact with skin, flush with plenty of soap and water. See Material Safety Data Sheets (MSDS) for the dry acid product being used for further Personal Protective Equipment (PPE) or emergency requirements/instructions.

4. As per the Operators Manual section 7.1, perform the Specific Gravity Test and record the results on the production batch record form.

5. Collect a sample of the final product(s) using the (2) sample bottles (P/N G83-535-02). The product sample(s) will be analyzed in accordance to manufacturer's product specifications. If only one product code is being used, collect two (2) samples of that product to be analyzed.

6. Place the sample bottles and the following completed forms into a shipping box:
   - Copy of Batch Production Record Form (Operator's Manual – Form 1 or Form 2)
   - Batch Analysis Form (Operator's Manual pg 43)

7. Cutout and affix the pre-printed mailing label from the Batch Analysis Form to the box. It is the responsibility of the RES to ship the samples to the “Ship To” address on the Batch Analysis Form. Contact Fresenius Medical Care Laboratory at (872) -929-7291 for results.

8. NOTICE: The composition of the first batch of GranuFlo® / Citrasate® DRY product must be tested by a qualified testing laboratory to ensure that the resulting product meets the GranuFlo® / Citrasate® DRY product specifications. If final solution did not meet final batch criteria for use, the batch of concentrate must be discarded (See Section 11: Concentrate Solution Disposal Procedures, page 37).
# FORM 1: GranuFlo® Batch Production Record

**Operator:** [print name]

<table>
<thead>
<tr>
<th>Dialysis Unit Name &amp; Location #:</th>
<th>GranuFlo I Dissolution Unit Serial #:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>DRY ACID PRODUCT CASE INFORMATION</strong></td>
<td><strong>Batch #:</strong></td>
</tr>
<tr>
<td>CASE 1: Dry Acid Catalog #: [label on box]</td>
<td>BOX Lot #:</td>
</tr>
<tr>
<td>CASE 2: Dry Acid Catalog #:</td>
<td>BOX Lot #:</td>
</tr>
<tr>
<td>CASE 3: Dry Acid Catalog #:</td>
<td>BOX Lot #:</td>
</tr>
<tr>
<td>CASE 4: Dry Acid Catalog #:</td>
<td>BOX Lot #:</td>
</tr>
<tr>
<td>CASE 5: Dry Acid Catalog #:</td>
<td>BOX Lot #:</td>
</tr>
<tr>
<td>CASE 6: Dry Acid Catalog #:</td>
<td>BOX Lot #:</td>
</tr>
<tr>
<td>CASE 7: Dry Acid Catalog #:</td>
<td>BOX Lot #:</td>
</tr>
<tr>
<td>CASE 8: Dry Acid Catalog #:</td>
<td>BOX Lot #:</td>
</tr>
</tbody>
</table>

1. After final fill level has been reached, close water supply valve to the unit. Once this is done check the box:

**SPECIFIC GRAVITY**

<table>
<thead>
<tr>
<th>Measured Temp</th>
<th>Print Catalog # Specific Gravity Value for the Measured Temp Listed in Appendix A</th>
<th>Measured Specific Gravity Value</th>
<th>Check one</th>
</tr>
</thead>
<tbody>
<tr>
<td>TEMP: LOW:</td>
<td>HIGH:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**OPERATOR SIGNATURE:**

**VERIFIER SIGNATURE:**

---

**For Reference Only.**

**See form in Operator’s Manual**

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"Mixing Training Course" P/N 460030 Rev. D

**FOR TRAINING PURPOSES ONLY**
**OPERATORS MANUAL**

**FORM 2: Citrasate® DRY Batch Production Record**

---

**FORM 2: CITRASATE® DRY WITH ACETATE PRODUCTION RECORD**

<table>
<thead>
<tr>
<th>DIALYSIS UNIT NAME &amp; LOCATION #:</th>
<th>GranuFlo I Dissolution Unit Serial #:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**DRY ACID PRODUCT CASE INFORMATION**

<table>
<thead>
<tr>
<th>OPERATOR (print name):</th>
<th>DATE:</th>
<th>TIME:</th>
<th>Batch #:</th>
</tr>
</thead>
<tbody>
<tr>
<td>CASE 1: Dry Acid Catalog # (label on box)</td>
<td>BOI Lot #:</td>
<td>4th beg used □</td>
<td>Yes □ Potassium #: (1K, 2K, 3K)</td>
</tr>
<tr>
<td>CASE 2: Dry Acid Catalog #</td>
<td>BOI Lot #:</td>
<td>4th beg used □</td>
<td>Yes □ Potassium #:</td>
</tr>
<tr>
<td>CASE 3: Dry Acid Catalog #</td>
<td>BOI Lot #:</td>
<td>4th beg used □</td>
<td>Yes □ Potassium #:</td>
</tr>
<tr>
<td>CASE 4: Dry Acid Catalog #</td>
<td>BOI Lot #:</td>
<td>4th beg used □</td>
<td>Yes □ Potassium #:</td>
</tr>
<tr>
<td>CASE 5: Dry Acid Catalog #</td>
<td>BOI Lot #:</td>
<td>4th beg used □</td>
<td>Yes □ Potassium #:</td>
</tr>
<tr>
<td>CASE 6: Dry Acid Catalog #</td>
<td>BOI Lot #:</td>
<td>4th beg used □</td>
<td>Yes □ Potassium #:</td>
</tr>
<tr>
<td>CASE 7: Dry Acid Catalog #</td>
<td>BOI Lot #:</td>
<td>4th beg used □</td>
<td>Yes □ Potassium #:</td>
</tr>
<tr>
<td>CASE 8: Dry Acid catalog #</td>
<td>BOI Lot #:</td>
<td>4th beg used □</td>
<td>Yes □ Potassium #:</td>
</tr>
</tbody>
</table>

**SPECIFIC GRAVITY**

<table>
<thead>
<tr>
<th>Measured Temp</th>
<th>Print Catalog #: Specific Gravity Value for the Measured Temp listed in Appendix A:</th>
<th>Measured Specific Gravity Value:</th>
<th>Check one</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOW:</td>
<td></td>
<td></td>
<td>Pass □</td>
</tr>
<tr>
<td>HIGH:</td>
<td></td>
<td></td>
<td>Fail (void section) □</td>
</tr>
</tbody>
</table>

1. After Final Fill Level has been reached, CLOSE water supply valve to the Unit. Once this is done check the box □

OPERATOR SIGNATURE: VERIFIER SIGNATURE:

---

For Reference Only.
See form in Operator’s Manual
BASE STAND PIPE FILTER REMOVAL

- Using Base Filter Rod, P/N 260025 (A)
- Reach into the tank and connect the small end of the shaft into the Screw Nut of Base Filter (B).
- Turn the Screw Nut Counter Clockwise until the Base Stand Pipe Filter is no longer attached to the tank.
- Use the Base Filter Rod to help lift the Base Stand Pipe Filter out of Tank.

After Removing the Base Stand Pipe Filter:
- Clean with purified water
- Re-install
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