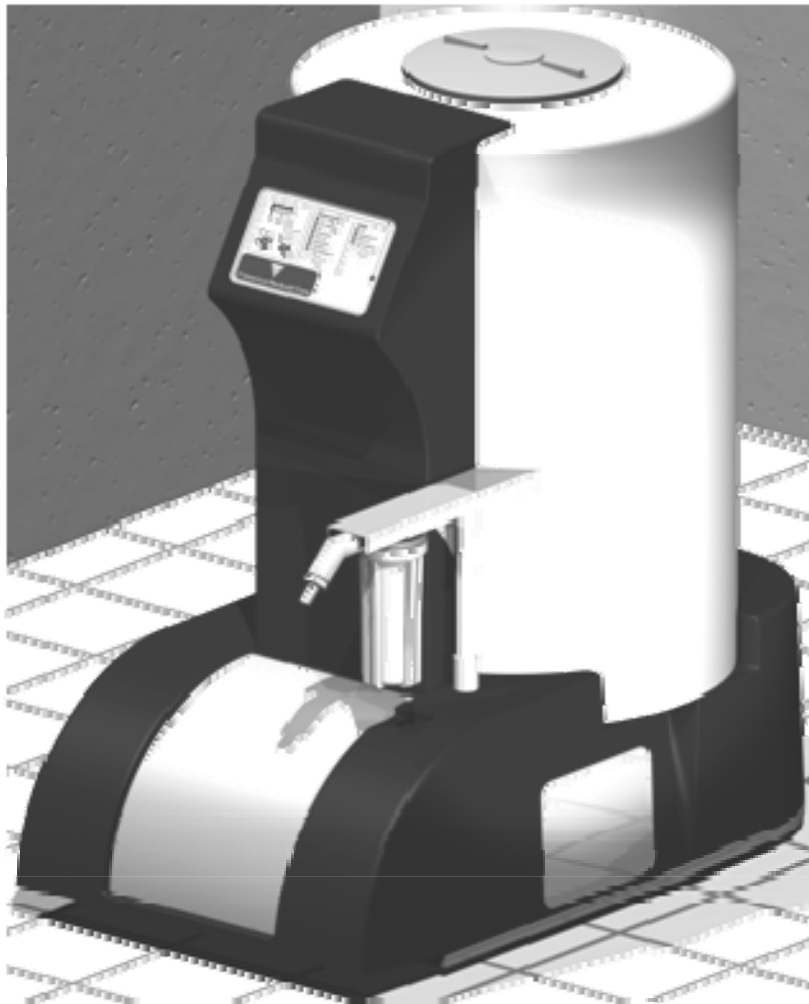




**FRESENIUS
MEDICAL CARE**

**DRY ACID
DISSOLUTION UNIT
99 GALLONS (375 LITERS)**



OPERATORS MANUAL

P/N 460017 REV. C

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Fresenius Medical Care Dry Acid Dissolution Unit: 99 Gallons (375 Liters) Operator's Manual

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

Indications for Use: The Fresenius Medical Care Dry Acid Dissolution Unit mixes Fresenius Medical Care 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.

As part of the Conditions for Coverage, it is the Medical Director's responsibility that the Operators of the Fresenius Medical Care Dry Acid Dissolution Unit must be trained in its operation and thoroughly familiar with the contents of this manual. Operators must be proficient and able to distinguish between normal and abnormal operation.

Assembly, installation, adjustment, or repair is to be performed only by persons authorized by the facility medical director or by Fresenius USA, Inc. Fresenius Medical Care Concentrate Dry Acid Dissolution Unit spare parts manual, PN 460009, Field Service Bulletins, and other documentation are located on the internet at <http://www.fmcna.com>.

Only Original Equipment Manufacturer (*OEM*) Fresenius Medical Care parts should be used in the repair or upgrade of the Fresenius Medical Care Dry Acid Dissolution Unit. Although, parts may look similar to parts in various vendor catalogs or brick and mortar stores the Dry Acid Dissolution Unit uses parts that have been specified and tested in accordance to *ANSI/AAMI/ISO* guidelines. The use of non-*OEM* parts will void your warranty and may cause patient harm.

For further information regarding the operation, repair, parts, or maintenance of the Fresenius Medical Care Dry Acid Dissolution Unit, please contact:

Fresenius USA, Inc.
4040 Nelson Avenue.
Concord, CA 94520.

(800) 227-2572

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TABLE OF CONTENTS

SECTION	TOPIC	PAGE
	IMPORTANT SAFETY SYMBOLS AND STATEMENTS	1
SECTION 1:	OVERVIEW.....	2
SECTION 2:	SPECIFICATIONS AND INSTALLATION REQUIREMENTS	3
SECTION 3:	PRODUCT IMPROVEMENT POLICY	4
SECTION 4:	WARNINGS AND CAUTIONS.....	5
	DIAGRAM 1: FRONT PANEL BUTTONS AND INDICATOR LIGHTS/CYCLE PROGRAM OVERVIEW	7
	DIAGRAM 2: EXTERNAL AND INTERNAL 99 GALLON DRY ACID DISSOLUTION UNIT	8
SECTION 5:	DRY ACID DISSOLUTION UNIT PREPARATION	9
SECTION 6:	RINSE CYCLE	10
SECTION 7:	DISSOLUTION CYCLE	13
	7.1 SPECIFIC GRAVITY TEST	15
	7.2 TRANSFER TO STORAGE TANK	21
	7.3 TRANSFER TO INDIVIDUAL CONTAINERS.....	22
SECTION 8:	MAINTENANCE.....	23
	8.1 VISUAL INSPECTION	23
	8.2 CLEANING	23
	8.2.1 PREVENTIVE MAINTENANCE	23
	8.3 SODIUM HYPOCHLORITE (REGULAR BLEACH) DISINFECTION	23
	8.4 UNIT FILTER AND BASE STAND PIPE FILTER MAINTENANCE	25
	8.4.1 FILTER REMOVAL AND REPLACEMENT	26
	8.4.2 BASE STAND PIPE FILTER REMOVAL.....	26
	8.5 SENSOR REPLACEMENT	26
SECTION 9:	MANUAL CONTROL OPERATIONS	27
	9.1 PAUSE STATE.....	27
	9.2 STEP MODE.....	27
	9.3 MAIN POWER DISCONNECT	28
	DIAGRAM 3: TOP VIEW OF VALVE ASSEMBLY	29
	TABLE 1: MAINTENANCE SCHEDULE	30
	FORM 1: GRANUFLO BATCH PRODUCTION RECORD FORM	31
	FORM 2: CITRASATE DRY BATCH PRODUCTION RECORD FORM	32
SECTION 10:	LIMITED WARRANTY	33
SECTION 11:	CUSTOMER SUPPORT	34
SECTION 12:	DEFINITION OF TERMS.....	35
SECTION 13:	DISPOSAL OF CONCENTRATE SOLUTION	37
	13.1 RESIDUAL SOLUTION BUCKET DISPOSAL	37
	13.2 TANK SOLUTION DISPOSAL	37
APPENDIX A:	GRANUFLO® DRY ACID SPECIFIC GRAVITIES TABLE.....	38
APPENDIX B:	CITRASATE DRY SPECIFIC GRAVITIES TABLE.....	39
APPENDIX C:	DRY ACID MIXING INSTRUCTIONS.....	40
APPENDIX D:	FIRST BATCH VERIFICATION INSTRUCTIONS.....	42
BATCH ANALYSIS	FORM.....	43
APPENDIX E:	MANUFACTURER’S EMC DECLARATION	44



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READ ALL INSTRUCTIONS BEFORE USE!

For your safety, the information in this manual must be followed to minimize the risk of electrical shock, prevent property damage, personal injury, or loss of life. There are many important safety messages in this manual and on your Dry Acid Dissolution Unit. The following table lists symbols and the criteria of their descriptions, which is used throughout this manual. Your safety and the safety of others are very important. Always read and abide by all safety messages

The Fresenius Medical Care 99 Gallon Dry Acid Dissolution Unit is designed and manufactured in accordance to the requirements of Systems for Mixing Concentrate at a Dialysis Facility listed in Section 5.3 of the *ANSI/AAMI RD61:2006* and Section 5.4 of *ISO 13958:2009* Regulations.

Proper training and demonstrated user competency must be completed and documented before a designated operator can be authorized to use the Fresenius Medical Care Dry Acid Dissolution Unit to make Fresenius Medical Care Dry Acid Concentrate.

SYMBOL	DESCRIPTION
	WARNING! A WARNING IS A STATEMENT THAT IDENTIFIES CONDITIONS OR ACTIONS THAT COULD RESULT IN PERSONAL INJURY OR LOSS OF LIFE. WARNINGS FOUND IN THIS MANUAL OUTSIDE OF THIS SECTION ARE DESIGNATED WITH THE WARNING SYMBOL.
	NOTE: NOTES ARE ADVISORY COMMENTS OR RECOMMENDATIONS REGARDING PRACTICES OR PROCEDURES.
BUTTON	A BUTTON IS A PRESSURE-SENSITIVE, RAISED PAD FOUND ON THE CONTROL PANEL THAT IS USED TO INITIATE AN ACTION OR OPERATION.
<i>ITALICIZED WORDS</i>	ITALICIZED WORDS IN TEXT INDICATES THE WORD IS DEFINED IN SECTION 12: DEFINITION OF TERMS, PAGE 35.

SECTION 1: OVERVIEW

This product is manufactured by:

Fresenius USA, Inc.
4040 Nelson Avenue.
Concord, CA. 94520.

Fresenius USA, Inc. is a wholly owned subsidiary of Fresenius Medical Care Holdings, Inc.







The Fresenius Medical Care Dry Acid Dissolution Unit is automated and is designed to mix a 99 Gallon (375 LITERS) batch of dialysate concentrate with a minimum of operator supervision, and is to be only used for the mixing of Fresenius Medical Care Dry Acid Products.

There are two (2) pre-programmed cycles built into the Fresenius Medical Care Dry Acid Dissolution Unit; the **RINSE CYCLE** and the **DISSOLUTION CYCLE**. The RINSE CYCLE has four operations: FILL, RECIRCULATE, DRAIN, and CYCLE COMPLETE. The first three: FILL, RECIRCULATE, and DRAIN are done twice before it reaches CYCLE COMPLETE Operation. The DISSOLUTION CYCLE has eight operations: FILL, ADD GRANUALES, MIX, DEAERATION, FINAL FILL, HOMOGENIZE, TRANSFER, and CYCLE COMPLETE.

The control panel will display the Dry Acid Dissolution Unit status at any given time, making it easy for the operator to follow the progress of the operations in each cycle. The right side of the panel displays the RINSE CYCLE, and the left side of the panel displays the DISSOLUTION CYCLE.

In addition, a manual PAUSE STATE has been incorporated into the unit. (See Section 9, page 27).

The following components are standard equipment for use with this device:

Description	Part Number
1. Hydrometer	G84-001-60
2. 500ml Hydrometer Cylinder	G79-000-26
3. 1 Micron Filter Cartridge	G84-202-12
4. Base Filter Rod 	260025
5. Filter Housing Wrench 	G84-001-43
6. Tank Nozzle Assembly 	G97-283-08
7. 3/4" Dust CAP 	332107-10-01
8. 3/4" Hose Shank Coupler 	G84-001-57
9. 3/4" Male Adapter 	332107-10

For other Original Equipment Parts see Spare Parts Manual, PN460009, on www.fmcna.com

Prior to operating the Fresenius Medical Care Dry Acid Dissolution Unit: 99 Gallons (375 Liters), adequate power and water connections must be made. The Dry Acid Dissolution Unit, is a computer-controlled electro-mechanical device. The Dry Acid Dissolution Unit must be installed in an appropriate environment (indoors) free from extremes of temperature and humidity, free of the presence of flammable anesthetics, reasonably protected from dust and dirt contamination, liquid splashes, bright sunlight or high intensity lighting.

The Fresenius Medical Care Dry Acid Dissolution Unit: 99 Gallons (375 Liters) is in compliance with the electrical requirements of *ISO 13958:2009 (E) / IEC 60601-1*.

Failure to install the Dry Acid Dissolution Unit according to these guidelines may result in improper operation or early failure of the device or its components. Direct sunlight may cause discoloration of the polyethylene tank, lid, or electronic housing.

The Dry Acid Dissolution Unit needs to be set up using the following parameters:

1. A 15 amp *GFI* duplex outlet is required. The Dry Acid Dissolution Unit requires 120 VAC, 60 Hz, single phase power. The Dry Acid Dissolution Unit uses approximately 9 amperes total. Electrical service should meet all applicable national, state and local code requirements.
2. The electrical power cord, input water hose, and output drain hose shall be properly routed away from high traffic areas and installed in such a way that does not cause any electrical or safety hazards.



NOTE: THE DRY ACID DISSOLUTION UNIT'S TANK IS MADE OF NON-FERROUS MATERIAL.

3. The treated water source must meet *ANSI/AAMI* or *ISO* requirements for water for hemodialysis, currently *ANSI/AMMI RD62*, or *ISO 13959*. Plumbing service must meet all national, state and local plumbing codes. The Dry Acid Dissolution Unit uses approximately 99 gallons (375 liters) of water per batch of product.



WARNING! DO NOT PERMANENTLY INSTALL TRANSFER HOSE TO A STORAGE TANK/CONTAINER.

4. Supply Water Treatment System should be capable of a minimum flow rate of ½ gallon per minute. The maximum input water pressure is 60psi. The water temperature should be 20°-30°C (68°-86°F) for dissolution mixing conditions.
5. Height from the floor to the top of the Dry Acid Dissolution Unit is approximately 56 inches.
6. Platform for the Dry Acid Dissolution Unit is 50 inches long by 28 inches wide.
7. Transfer Filter Housing is equipped with a ¾" hose barb fitting.
8. There is a ¾" hose barb inlet fitting, and another for the drain outlet.
9. The Dry Acid Dissolution Unit must be level.
10. The Dry Acid Dissolution Unit weight is 200 lbs. empty and 1025 lbs. filled.



CAUTION! THE FLOOR MUST BE CAPABLE OF WITHSTANDING THE MAXIMUM WEIGHT OF 1025 POUNDS.

11. A floor drain emptying into a sewer line must be in the immediate area of the Dry Acid Dissolution Unit.

The Dry Acid Dissolution Unit is designed and built to comply with its product specifications. It is the intention of Fresenius Medical Care to pursue product development that may result in modifications or improvements to specifications or equipment produced in the future. Such product improvements shall not force similar changes and improvements to equipment produced prior to the changes. Product development may or may not be applicable or usable with previously produced equipment. Where possible, improvements will be made available at reasonable prices. These improvements shall not be construed as corrections of any deficiency.



WARNING! NEVER PUT YOUR HEAD INTO THE DRY ACID DISSOLUTION UNIT TANK. THIS MAY RESULT IN OPERATOR FALLING INTO TANK.



WARNING! IN THE EVENT OF A FOREIGN OBJECT FALLING INTO THE TANK DURING ANY ACTIVE OPERATION, THE OPERATION SHOULD BE PAUSED. IF NEEDED, USE STEP MODE TO PLACE UNIT INTO A DRAIN OPERATION TO EMPTY THE TANK. IF CONCENTRATE SOLUTION NEEDS TO BE DISPOSED, MAKE SURE TO COMPLY WITH LOCAL, STATE AND FEDERAL REQUIREMENTS. AFTER DRAIN OPERATION, UNPLUG DRY ACID DISSOLUTION UNIT FROM ITS POWER SOURCE. A REACH TOOL IS RECOMMENDED FOR REMOVING FOREIGN OBJECT OUT OF TANK. HOWEVER, SHOULD THE FOREIGN OBJECT BE UNATTAINABLE, CALL TECHNICAL SERVICE FOR FURTHER ASSISTANCE (1-800-227-2572).



WARNING! IF THE DRY ACID DISSOLUTION UNIT IS RELOCATED A SAMPLE MUST BE DRAWN FROM THE FIRST BATCH OF CONCENTRATE MADE, WHICH MUST BE ANALYZED FOR CORRECT SOLUTION MIX BEFORE THE CONCENTRATE CAN BE USED. PRIOR TO RELOCATION, REQUEST TWO (2) EMPTY SAMPLE BOTTLES (P/N G83-535-02) THEN SEE APPENDIX D FOR FURTHER INSTRUCTIONS ON WHEN AND WHERE TO SEND SAMPLE OF THE FIRST BATCH OF CONCENTRATE.



WARNING! THE USE OF EYE PROTECTION, 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.



WARNING! SHOULD THE DRY ACID DISSOLUTION UNIT FAIL TO COMPLETE ANY OPERATION WITHIN ANY CYCLE DO NOT PROCEED THROUGH CYCLE USING STEP MODE. CALL TECHNICAL SERVICE FOR FURTHER ASSISTANCE (1-800-227-2572).



WARNING! FAILURES TO INSTALL, OPERATE, AND MAINTAIN THIS EQUIPMENT ACCORDING TO THE MANUFACTURER'S INSTRUCTIONS MAY CAUSE PATIENT DEATH OR INJURY.



WARNING! THIS DRY ACID DISSOLUTION UNIT MAY BE SUSCEPTIBLE TO ELECTROMAGNETIC INTERFERENCE (EMI). DEVICES EMITTING ELECTROMAGNETIC RADIATION SUCH AS ANALOG PORTABLE PHONES, RADIO EQUIPMENT (WALKIE-TALKIES, ETC.), RADIO TRANSMITTERS, AND LIKE EQUIPMENT, SHOULD NOT BE USED IN THE VICINITY OF THIS EQUIPMENT. THE OPERATOR SHOULD MONITOR THE FUNCTION OF THE MACHINE AND REMOVE UNNECESSARY EQUIPMENT FROM THE TREATMENT AREA SHOULD THESE EVENTS OCCUR.



WARNING! THE ELECTRICAL SOURCE MUST BE SINGLE PHASE, THREE-CONDUCTOR TYPE PROVIDED WITH A GROUND FAULT INTERRUPTER AT 120 VAC, 60 HZ. THE PROPER POLARITY AND GROUND INTEGRITY MUST BE INITIALLY CHECKED AND MAINTAINED. FAILURE TO DO SO MAY RESULT IN ELECTRICAL SHOCK OR BURN TO THE OPERATOR.



WARNING! SHOCK HAZARD. DO NOT REMOVE PANELS. REFER SERVICING TO QUALIFIED PERSONNEL. REPLACE FUSES ONLY WITH THE SAME TYPE AND RATING.



WARNING! FOLLOWING DISINFECTION, TWO (2) COMPLETE RINSE CYCLES MUST BE PERFORMED AND THE UNIT TESTED TO ENSURE THE ABSENCE OF RESIDUAL BLEACH. SEE SECTION 8.3, PAGE 23.



WARNING! USE THE SUPPLIED *HYDROMETER* TO MEASURE THE SPECIFIC GRAVITY OF A SAMPLE OF THE MIXED FRESenius MEDICAL CARE DRY ACID PRODUCT (SEE APPENDIX A FOR GRANUFLO® PRODUCT OR APPENDIX B FOR CITRASATE DRY PRODUCT).



WARNING! CONNECT WATER INLET ACCORDING TO THE SPECIFICATIONS FOR THE DRY ACID DISSOLUTION UNIT. THE WATER USED MUST MEET *ANSI/AAMI* OR *ISO* STANDARDS FOR WATER USED IN HEMODIALYSIS (CURRENTLY *ANSI/AMMI RD62*, OR *ISO 13959*). THE CORRECT IONIC CONCENTRATION AND BACTERIAL QUALITY CAN GENERALLY BE ACHIEVED IN THE DIALYSATE ONLY WITH TREATED WATER. BE SURE THAT ALL SPECIFICATIONS ARE SATISFIED. THE WATER SOURCE MUST BE MONITORED PERIODICALLY TO DETECT FLUCTUATIONS IN WATER COMPOSITION AND QUALITY THAT COULD HAVE AN ADVERSE EFFECT ON THE PATIENT, HEMODIALYSIS MACHINE OR DRY ACID DISSOLUTION UNIT. PARTICULAR ATTENTION MUST BE TAKEN FOR CHEMICALS SUCH AS ALUMINUM, CHLORINE, AND CHLORAMINES, AS THESE CHEMICALS CAN CAUSE COMPLICATIONS IN DIALYSIS PATIENTS. THE CHEMICAL QUALITY OF THE TREATED WATER USED FOR DIALYSIS SHOULD BE ANALYZED A LEAST ONCE A YEAR TO ENSURE IT MEETS THE REQUIREMENTS OF *ANSI/AMMI RD62*, OR *ISO 13959*.



WARNING! THE DIALYSIS PHYSICIAN IS RESPONSIBLE FOR SELECTING THE APPROPRIATE CONCENTRATE MIXING EQUIPMENT FOR DIALYSIS AND THE PRESCRIPTION FOR DIALYSIS.



CAUTION! THE DRY ACID DISSOLUTION UNIT IS COMPUTER CONTROLLED. EXTREME CARE SHOULD BE EXERCISED IN ITS OPERATION. WHEN POWER IS CONNECTED TO THE DRY ACID DISSOLUTION UNIT, A FAILURE OF THE COMPUTER COULD START ANY OF THE OPERATIONS AT ANY TIME.



CAUTION! ASSEMBLY, INSTALLATION, ADJUSTMENT, OR REPAIR IS TO BE PERFORMED ONLY BY PERSONS AUTHORIZED BY THE FACILITY MEDICAL DIRECTOR OR BY FRESENIUS MEDICAL CARE.



CAUTION! DISINFECT DRY ACID DISSOLUTION UNIT TANK IF WATER IN TANK UNIT EXCEEDS 200 CFU/ML AS OUTLINED BY ANSI/AMMI RD62, OR ISO 13959. (REFER TO SECTION 8.3, PAGE 23).



CAUTION! THE DRY ACID DISSOLUTION UNIT IS ONLY INTENDED FOR MIXING FRESENIUS MEDICAL CARE DISTRIBUTED DRY ACID CONCENTRATE. DO NOT MIX BICARBONATE IN THE DRY ACID DISSOLUTION UNIT



CAUTION! AN ANSI/AAMI OR ISO STANDARD PURIFIED WATER ANALYSIS FOR BACTERIA AND ENDOTOXIN IS RECOMMENDED MONTHLY.



CAUTION! A BACK PRESSURE REGULATOR MAY BE REQUIRED ON THE TREATED WATER FEED LINE IF THE DRY ACID DISSOLUTION UNIT IS TO BE USED AT THE SAME TIME AS OTHER DIALYSIS EQUIPMENT. THE MAXIMUM INPUT WATER PRESSURE IS 60 PSI AT A MINIMUM FLOW RATE OF ½ GALLON PER MINUTE FOR THE DRY ACID DISSOLUTION UNIT.



CAUTION! KEEP THE DRY ACID DISSOLUTION UNIT MIXING AREA FREE OF CLUTTER. THE FLOOR NEAR THE UNIT SHOULD BE KEPT FREE OF WATER TO AVOID SLIP-AND-FALL INJURIES.



NOTE: SOME FACILITIES MAY BE REQUIRED TO PURCHASE AND INSTALL A STORAGE TANK FOR CENTRALIZED ACID FEED LOOPS. IF SO, THE STORAGE TANK AND ASSOCIATED PLUMBING INTERCONNECTIONS MUST BE COMPLETED PRIOR TO THE INSTALLATION OF THE DRY ACID DISSOLUTION UNIT.



NOTE: IF THE FINAL FILL SENSOR NEEDS ADJUSTMENT OR REPLACEMENT, THEN A QUALIFIED TECHNICAL PERSONNEL SHALL COMPLETE THIS AND THE FOLLOWING TASKS. SAMPLE MUST BE DRAWN FROM THE FIRST BATCH OF CONCENTRATE MIXED. THIS SAMPLE MUST BE ANALYZED FOR CORRECT SOLUTION MIX BEFORE THE CONCENTRATE CAN BE USED. BEFORE REPLACING THE FINAL FILL SENSOR OR RELOCATING THE DRY ACID DISSOLUTION UNIT CONTACT FRESENIUS MEDICAL CARE TECHNICAL SERVICE AT 1 (800) 227-2572 AND REQUEST TWO (2) EMPTY SAMPLE BOTTLES (P/N G83-535-02). SEE APPENDIX D, PAGE 42, FOR FURTHER INSTRUCTIONS.

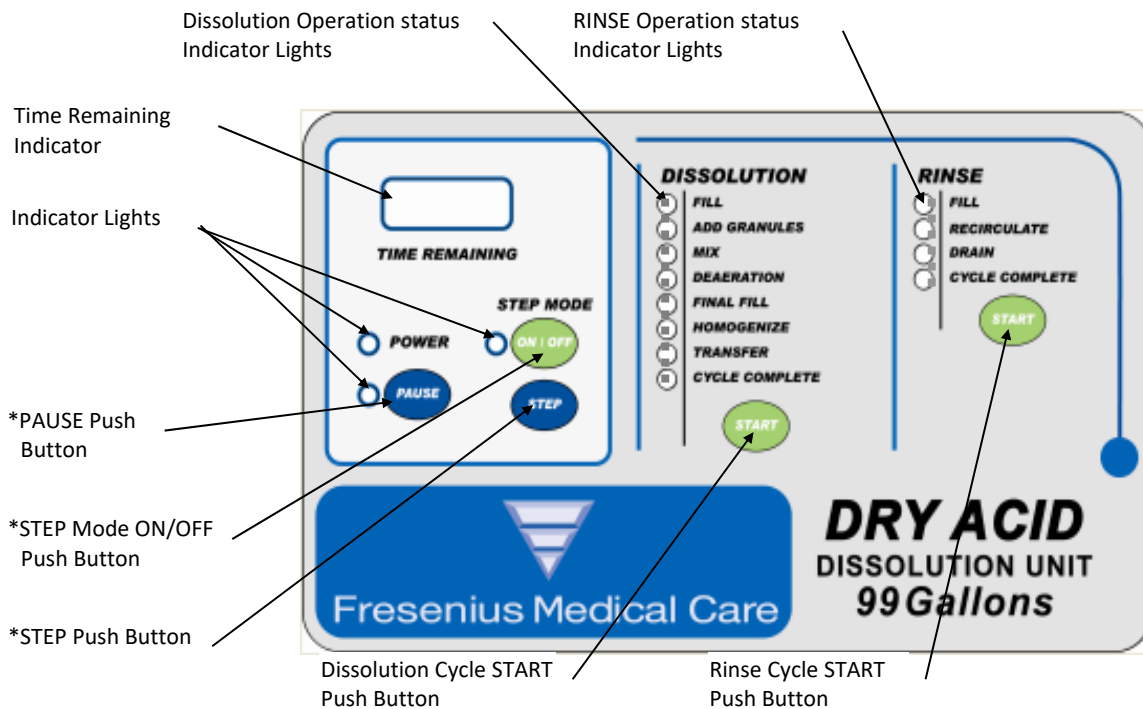
NOTE: THE RECIRCULATION/TRANSFER PUMP IS NOT SELF-PRIMING AND IS INSTALLED WITH A POSITIVE FLOODED SUCTION. THE LIQUID BEING PUMPED SERVES AS THE LUBRICATION FOR THE IMPELLER ASSEMBLY SPINNING ON A POLYPROPYLENE STATIONARY SHAFT. IF THE PUMP IS RUN DRY FOR LONGER THAN 30 SECONDS THIS MAY CAUSE IMPELLER DAMAGE.



RECIRCULATION/TRANSFER PUMP MANUFACTURE RATINGS AND SPECIFICATIONS

ELECTRICAL			GALLONS PER MINUTE AT LIST HEAD					
HP	WATTS	AMPS	3 FT.	10FT.	20 FT.	30FT.	40 FT.	45 FT.
½	620	8.8/4.4	36	34	30	25	16.5	1

DIAGRAM 1: FRONT PANEL BUTTONS AND INDICATOR LIGHTS/CYCLE PROGRAM OVERVIEW



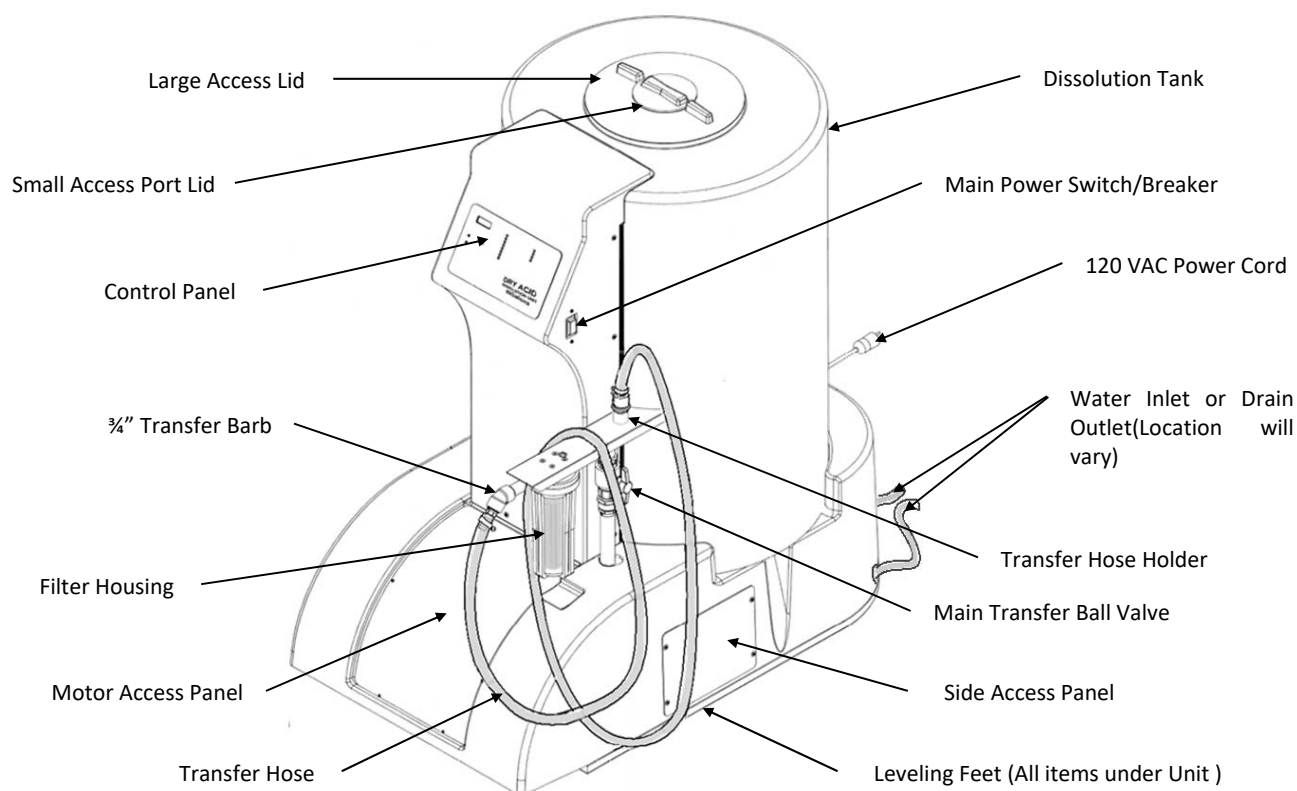
Dissolution Cycle consists of the following Operations:

- **FILL** –Input water Fill Valve Opens and allows water into tank. Once water reaches Mid-Level Sensor the unit switches to ADD GRANULES Operation. *During the FILL Operation a Short Rinse Program is done before the water reaches the Mid-Level Sensor.*
- **ADD GRANULES** – The indicator light is flashing and the unit is waiting for operator interaction. Once Dry Acid Powder is added the operator is to press START Button. The unit proceeds to the MIX Operation.
- **MIX** – The Mixer Motor turns on for 35minutes, and then the unit automatically proceeds to DEAERATION Operation.
- **DEAERATION** – The Unit sits motionless to allow excess bubble to rise out of solution for 2 minutes. The unit automatically proceeds to the FINAL FILL Operation.
- **FINAL FILL** – The Unit opens the Fill Valve and Closes the Fill Valve once the Final FILL Sensor is contacted by the rising level in the tank. The program shall continue on to the HOMOGENIZE Operation.
- **HOMOGENIZE** – The Mixer Motor runs to mix the contents of the tank for 10 minutes and then the program continues to the TRANSFER Operation.
- **TRANSFER** – The indicator light is flashing. Unit is waiting for Operator Interaction. Once Transfer Operation is complete the program continues to the CYCLE COMPLETE Operation.
- **CYCLE COMPLETE** – The Unit will sit motionless until next Operator Interaction is initiated.

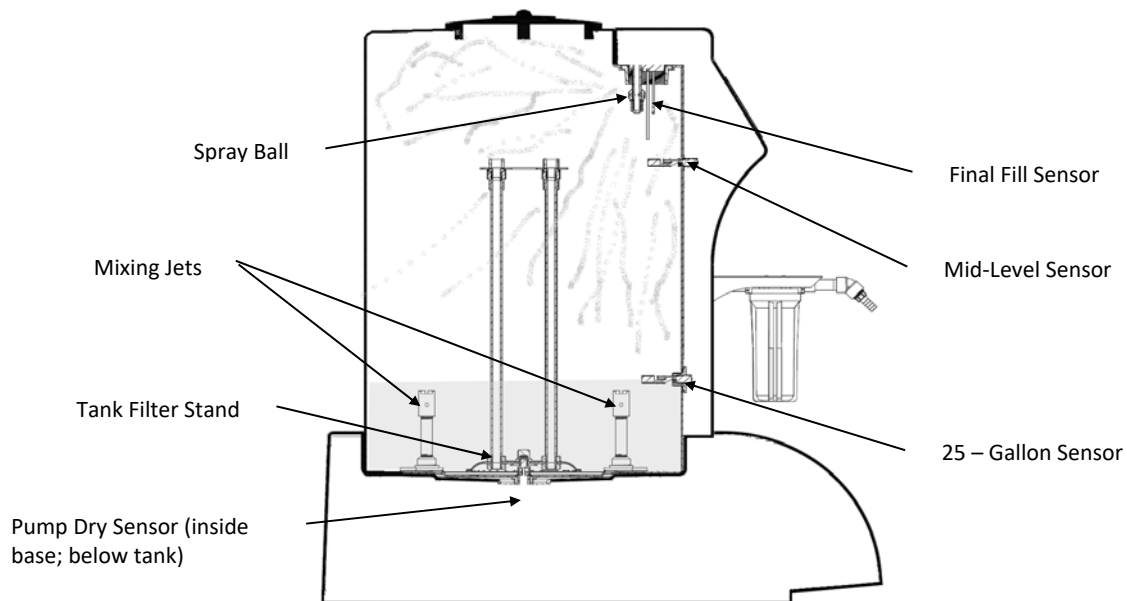
Rinse Cycle consists of the following Operations:

- **1st FILL** –Input water Fill Valve Opens and allows water into tank. Once water reaches 25-gallon sensor the unit switches to RECIRCULATE Operation.
- **1st RECIRCULATE** – The RECIRCULATE Operation runs for a 12 minute period. The spray ball and mixer motor runs for duration of the time. Then, the program continues to DRAIN Operation.
- **1st DRAIN** –the DRAIN Operation drains the contents of the tank. Then, the program continues to the 2nd FILL Operation.
- **2nd FILL** – Input Water Fill Valve Opens and allows water into tank. Once water reaches 25-gallon sensor the unit switches to RECIRCULATE Operation.
- **2nd RECIRCULATE** – The RECIRCULATE Operation runs for 12 minute period. The spray ball and mixer motor runs for duration of the time. Then, the program continues to DRAIN Operation.
- **2nd DRAIN** – The DRAIN Operation drains the contents of the tank. Then, the program continues to CYCLE COMPLETE Operation.
- **CYCLE COMPLETE** – The Unit shall sit motionless until Operator Interaction is initiated.

***PAUSE State and STEP Mode:** For information on the use of PAUSE State and STEP Mode refer to Section 9: “Manual Control Operations.”



External Parts



Internal Parts

SECTION 5: DRY ACID DISSOLUTION UNIT PREPARATION

1. Power Cord is connected to 115 Volt, 60 Cycle, Single Phase, 15 Amp, GFI protected circuit.
2. Be certain the Drain Hose is over a floor drain
3. Transfer Hose is connected to the Transfer Hose Holder of the Dry Acid Dissolution Unit.
4. Make sure input water source is turned ON.
5. Power Switch is in the ON position.



NOTE: INPUT WATER PRESSURE DIRECTLY AFFECTS HOW FAST THE DRY ACID DISSOLUTION UNIT WILL FILL. THE MAXIMUM INPUT WATER PRESSURE IS 60 PSI.



CAUTION! BEFORE INITIATING THE RINSE CYCLE, THE DRAIN HOSE MUST BE PLACED ABOVE A SUITABLE DRAIN. ALWAYS LEAVE ACCESS PORT LID IN PLACE UNLESS MANUAL INSTRUCT OTHERWISE.



CAUTION! IMMEDIATELY AFTER A COMPLETED RINSE CYCLE, MAKE A BATCH OF DRY ACID PRODUCT. DO NOT LEAVE THE DRY ACID DISSOLUTION UNIT WITH ONLY TREATED WATER OR WETTED WITH ONLY TREATED WATER FOR 4 OR MORE HOURS SINCE THE DRY ACID DISSOLUTION UNIT IS SUSCEPTIBLE TO BACTERIAL GROWTH. IF A DRY ACID DISSOLUTION UNIT IS FOUND TO BE STANDING FOR 4 OR MORE HOURS WITH TREATED WATER OR WETTED WITH TREATED WATER, THEN A DISINFECTION CYCLE (SEE SECTION 8.3 SODIUM HYPOCHLORITE (BLEACH) DISINFECTION, PAGE 23), MUST BE COMPLETED BEFORE THE DISSOLUTION CYCLE IS STARTED.

1. Before initiating the RINSE CYCLE, the operator must ensure that the Dry Acid Dissolution Unit Access Port Lid in place (do not fully secure) and the Main Transfer Ball Valve is in the CLOSED position. Make sure input water supply valve is OPEN (Figure 1).

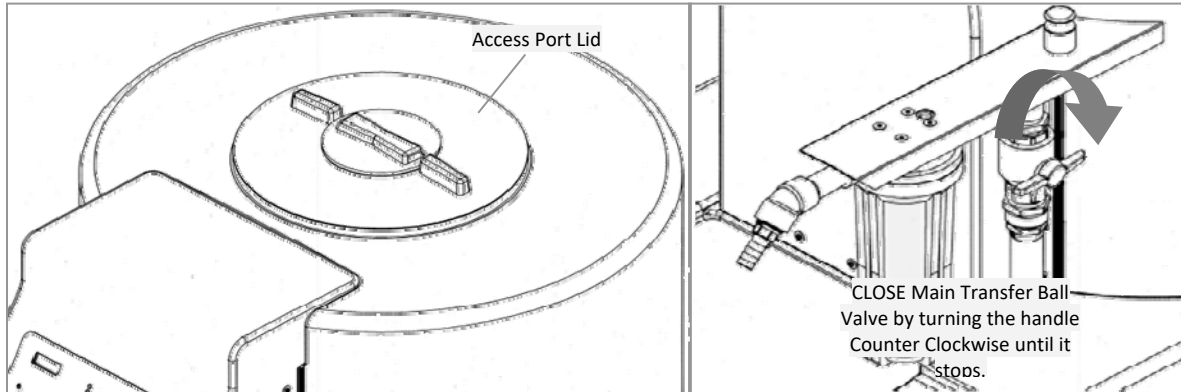


Figure 1

2. The RINSE CYCLE consists of two RINSE Operations. Press the Rinse START button. The Fill Indicator Light will illuminate indicating the RINSE CYCLE has started and the Dry Acid Dissolution Unit is in FILL Operation (Figure 2). Lift the Access Lid and look into the tank to verify that the tank is filling.

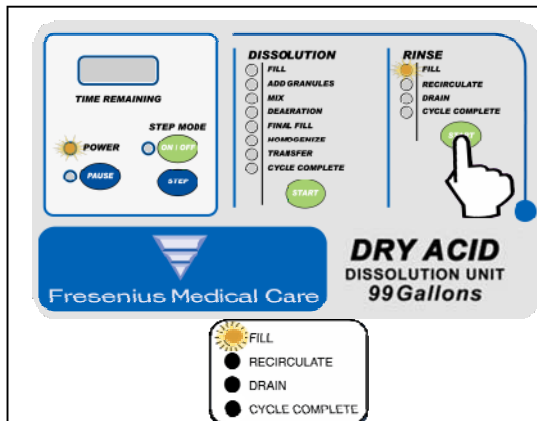


Figure 2

The Dry Acid Dissolution Unit will fill to the 25 GALLON LEVEL SENSOR.

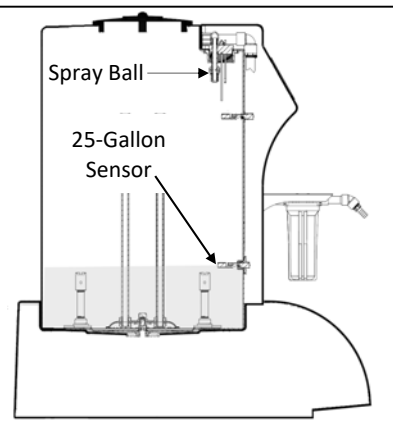
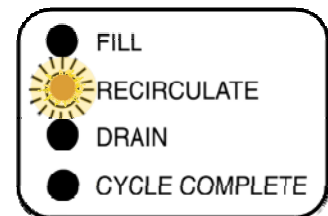


Figure 3

3. Once the 25 Gallon Level Sensor is reached, the process automatically steps to RECIRCULATE Operation (Figure 3). The operation will run for a twelve (12) minute period. During this operation, the Spray Ball and jets shall operate in 3 minute intervals. With your safety glasses on, lift the lid after the Spray Ball has stopped operating and ensure that the water is level with 25 Gallon Level Sensor. Since the water will be swirling in the tank it is okay for the level to be a little above the 25 Gallon Sensor, but you should ensure that the level is not rising. During this time period, follow the procedure outlined on the following page to inspect and clean the Spray Ball Ring if needed see Figure: Spray Ball Ring Inspection / Cleaning Instructions



4. Inspect Spray Ball for correct operation:

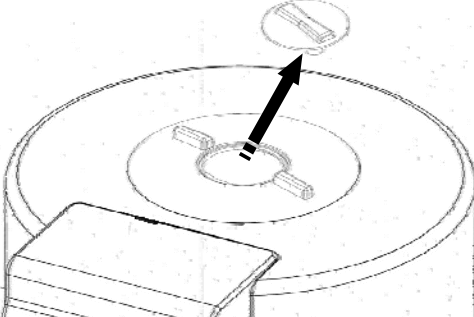
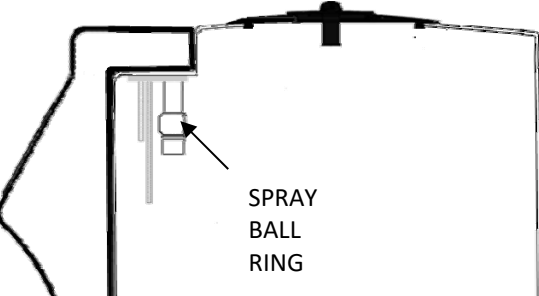
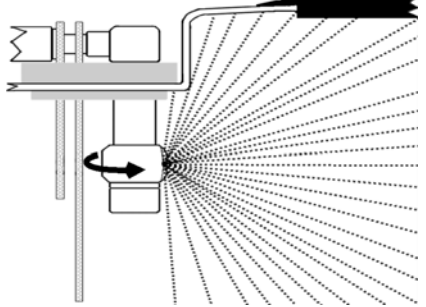
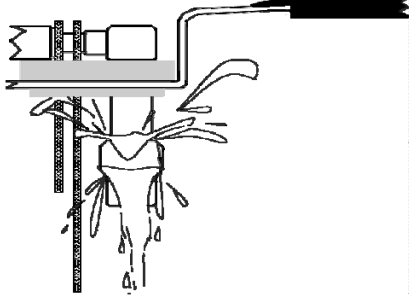
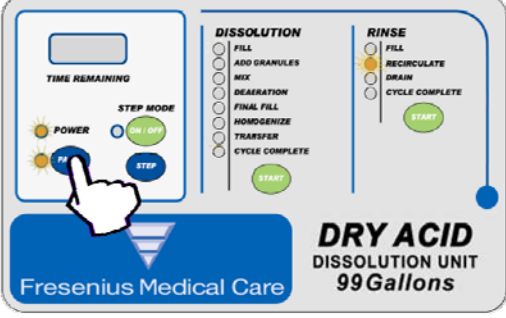
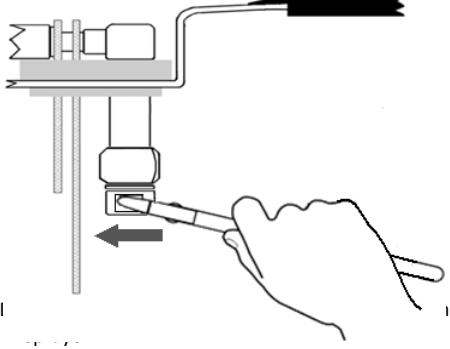
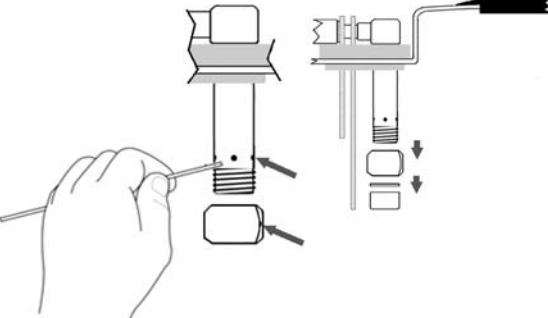
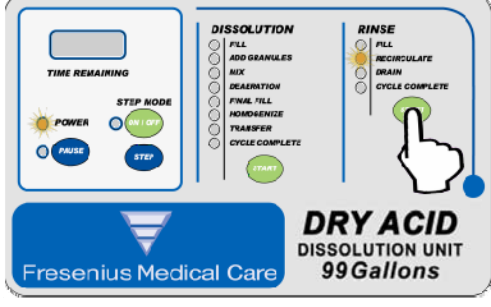
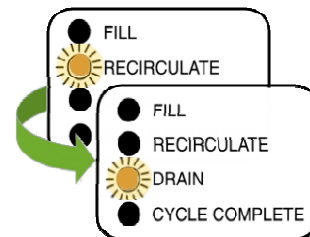
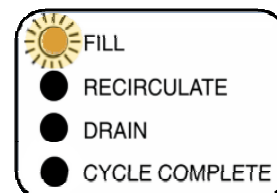
 <p>A. Remove the Small Access Port and look inside to check for the Spray Ball Ring proper rotation.</p>	 <p>B. Check the Spray Ball Ring for rotation.</p>
 <p>♦ If Correct Spray and rotation of the Spray Ball Ring, then proceed to step 4, pg 12.</p>	 <p>♦ If Spray Ball Ring is clogged the water flow looks like this, then call TECHNICAL SUPPORT (1-800-227-2572)</p>
<p align="center">Below Instructions is for Technical Service Use Only:</p>	
 <p>C. If the Spray Ball is stationary, push the PAUSE button. RECIRCULATE Light will flash. Turn Main Power Switch OFF.</p>	
 <p>Sprayer of debris and reassemble.</p>	 <p>F. Turn main Power Switch ON. Press RINSE CYCLE START button. PAUSE LED will turn off and RECIRCULATE LED will not flash. Check for proper Spray Ring rotation before continuing to pg. 12.</p>

Figure 4: Spray Ball Ring Inspection/Cleaning Instructions

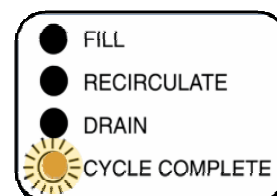
4. When the RECIRCULATE Operation is complete, the Dry Acid Dissolution Unit will switch to DRAIN Operation and empty rinse water from the Dry Acid Dissolution Unit to the floor drain.



5. At the completion of the DRAIN Operation, the Dry Acid Dissolution Unit will refill to the 25 Gallon Sensor. The Fill Indicator Light will turn ON and the second RINSE Operation will start.



6. When the second RINSE CYCLE is finished, the Dry Acid 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.





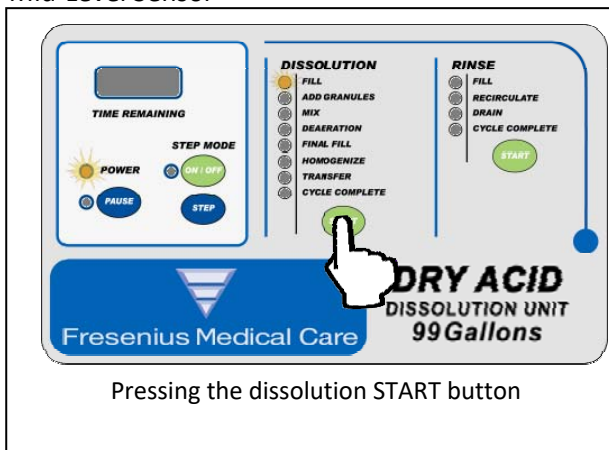
CAUTION! A COMPLETE FULL RINSE CYCLE IS REQUIRED BEFORE MAKING BATCH OF CONCENTRATE.

1. Before initiation of Dissolution Cycle, ensure the tank is empty and the 1 micron filter is installed in the Filter Housing (Diagram 2, pg 8) by ensuring that there is a filter present. Ensure you have the appropriate personal protective equipment donned. If the filter is not present in the filter housing, refer to Section 8.4.1, Filter Removal and Replacement.



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

2. Ensure the power switch is ON and water supply valve is in the OPEN position, then place Dry Acid Dissolution Unit in Dissolution FILL Operation by pressing the Dissolution START button (Figure 5).
3. Gather six dry acid cases and process documentation accordingly. Succeeding testing of each hemodialysis concentrate batch should be completed in accordance with the applicable Dry Acid Batch Production Record Form (GranuFlo® Form 1, pg 31, or Citrasate Dry Form 2, pg 32). Identification should be attached to the Dry Acid Dissolution Unit.
4. Verify the tank is actually filling. The Dry Acid Dissolution Unit will do a short Recirculation Operation with only the Fill Indicator Light illuminated and once complete the Dry Acid Dissolution Unit shall fill to the Mid-Level Sensor



Pressing the dissolution START button

Figure 5

The Dry Acid Dissolution Unit will fill to the Mid Water Level Sensor

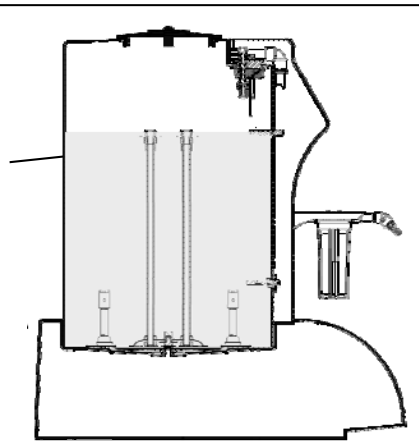
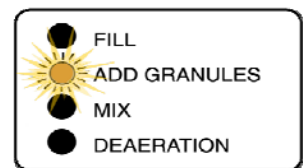


Figure 6

5. When the Mid-Level Sensor is reached (Figure 6), the Fill Valve will CLOSE and the Add Granules Light will begin to flash.

This flashing light indicates that the Dry Acid Dissolution Unit is in a hold state waiting for the operator to add the dry acid product in accordance with the Dry Acid Batch Production Record Form.



WARNING! IF WATER LEVEL EXCEEDS MID WATER LEVEL DO NOT ADD GRANULES. CALL FRESenius MEDICAL CARE TECHNICAL SUPPORT AT 1-800- 227-2572.

6. Before adding Dry Acid Granules make sure to check the following:
 - ◆ Ensure water is not leaking from underneath or any external connections to and from Dry Acid Dissolution Unit. In addition, ensure there is no leak at the end of the drain hose.
 - ◆ Remove the large access lid and ensure water has stopped at the Mid-Level Sensor (See Figure 6, pg. 13). Then place large access lid back on the tank loosely.
 - ◆ Ensure you have the appropriate personal protective equipment donned.

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. Fill in the Dry Acid Batch Production Record Form (GranuFlo® Form 1, pg 31, or Citrasate Dry Form 2, pg 32).



CAUTION! BE CERTAIN THE SAME CATALOG NUMBER IS ON ALL CASES.



CAUTION! USING EYE PROTECTION, AND GLOVES IS RECOMMENDED. IF CONTACT WITH EYES, RINSE IMMEDIATELY FOR 15 MINUTES. IF CONTACT WITH SKIN, FLUSH WITH PLENTY OF SOAP AND WATER. SEE MATERIAL SAFETY DATA SHEET (MSDS) FOR FURTHER PERSONAL PROTECTIVE EQUIPMENT OR EMERGENCY INSTRUCTIONS FOR THE DRY ACID PRODUCT BEING USED.



WARNING! DO NOT USE CASE OF DRY ACID CONCENTRATE THAT HAS BEEN OPENED OR TAMPERED WITH. IT IS IMPORTANT THAT THE ENTIRE CONTENTS OF EACH CASE OF DRY ACID CONCENTRATE IS EMPTIED INTO THE DRY ACID DISSOLUTION UNIT. BE CERTAIN ALL BAGS PER CASE HAVE BEEN ADDED.

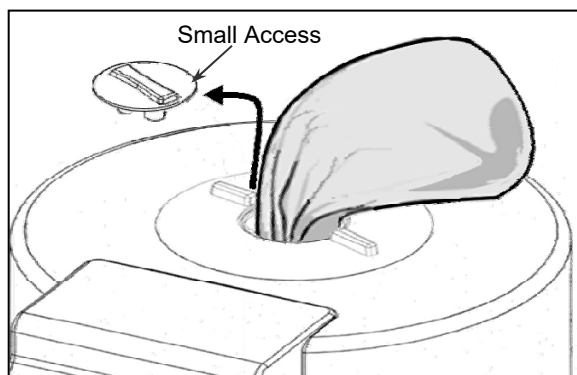


NOTE: GRANUFLO® DRY ACID PRODUCT CONTAINS 3 BAGS PER BOX AND CITRASATE DRY WITH ACETATE DRY ACID PRODUCT CONTAINS 4 BAGS PER BOX. CONTENTS OF ALL SIX BOXES MUST BE POURED INTO THE TANK DURING THE ADD GRANULES OPERATION.

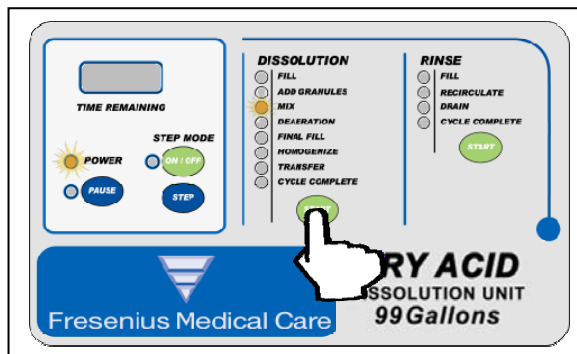


NOTE: INPUT WATER PRESSURE DIRECTLY AFFECTS HOW FAST THE DRY ACID DISSOLUTION UNIT WILL FILL. THE MAXIMUM INPUT WATER PRESSURE IS 60 PSI AND A MINIMUM ½ GALLON PER MINUTE FLOWRATE.

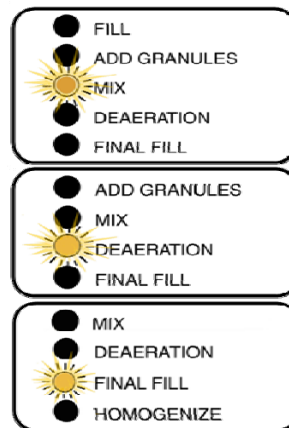
7. Remove the Dry Acid Dissolution Unit Small Access Lid and add granules as seen in the adjacent picture. This minimizes the amount of particulates launched into the air while adding granules to the tank. If clumping in Dry Acid Product is present, then the Large Access Lid can be used to load the Tank. However, If you have large sized clumps, then it would be best to break the clumps into a smaller size before adding granules into the tank. Large clumps have the ability to break the Mid-Level Sensor. (See Appendix C for Dry Acid Mixing information, page 40).



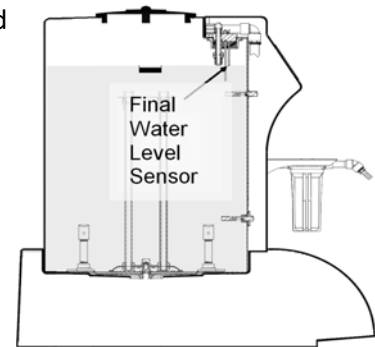
8. After adding all bags of Dry Acid, reinstall Large and Small Access Lids, then press the Dissolution START button. The Dry Acid Dissolution Unit will proceed to the MIX Operation.



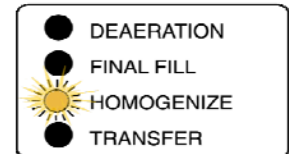
9. During the MIX Operation, the solution is mixed for a period of thirty-five (35) minutes allowing the granules to dissolve. The Dry Acid Dissolution Unit will then automatically step to the DEAERATION Operation.
10. The DEAERATION Operation is two (2) minutes during which the entrapped air is allowed to separate out of the solution. Upon completion, the Dry Acid Dissolution Unit will automatically step into the FINAL FILL Operation and the Final Fill Light will illuminate.



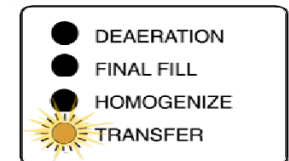
11. In the FINAL FILL Operation, the Fill Valve will OPEN and the Dry Acid Dissolution Unit will fill to the FINAL WATER LEVEL.



12. 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 Dry Acid Dissolution Unit. Then, CLOSE the water supply valve to the Dry Acid Dissolution Unit.



13. During HOMOGENIZE Operation, the Mixer will mix the solution for ten (10) minutes. When the HOMOGENIZE Operation is complete, the Transfer Indicator LED will flash. Remove Large Access Lid and look into the tank to make sure the granules have dissolved and the solution is colorless.



14. Once you have verified the granules are dissolved and the solution is colorless, the solution is ready for Specific Gravity Testing. If the granules have not dissolved and/or the solution is not colorless, call Technical Service (1-800-227-2572) for further instructions.



NOTE: DO NOT PLACE THE *HYDROMETER* INTO THE DRY ACID DISSOLUTION UNIT AT ANY TIME.



WARNING: SPECIFIC GRAVITY TEST MUST BE PERFORMED AFTER EVERY BATCH OF CONCENTRATE THAT IS MADE. IN ADDITION, CONCENTRATE SAMPLES SHOULD BE TAKEN FROM THE TRANSFER HOSE ONLY.

7.1 SPECIFIC GRAVITY TEST:

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.

To determine a Specific Gravity Reading:

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 specific gravity. 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.

2. Remove Transfer Hose from the Transfer Hose Holder (Figure 7, A) and connect the Transfer Hose to the Transfer Nozzle (Figure 7, B).

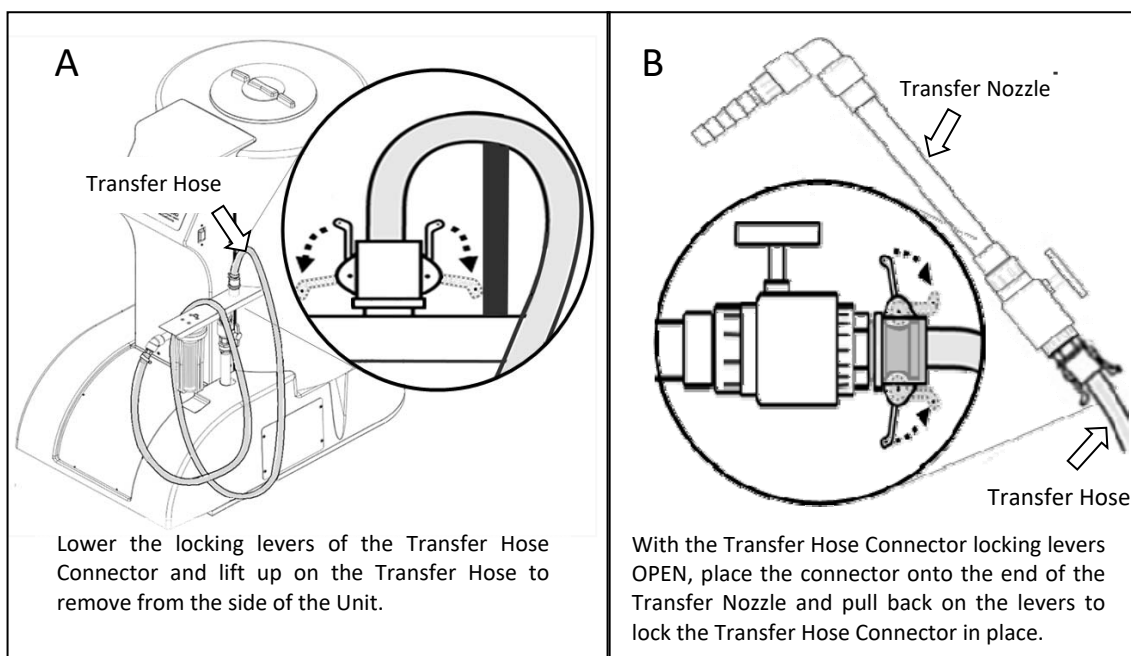


Figure 7

3. Hold the Transfer Nozzle and make sure the Ball Valve on the Transfer Nozzle is CLOSED (Figure 8).

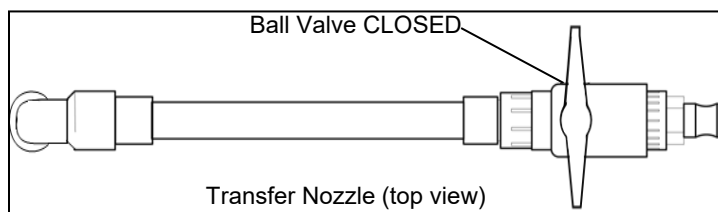


Figure 8

4. Slightly OPEN the Main Transfer Ball Valve next to the Filter Housing (Figure 9, item B).
5. Press Dissolution START button, slightly open Transfer Nozzle Valve and flush approximately 3.5 gallons of solution to the *Residual Solution Bucket* (the solution bucket should be equal to or greater than 5 gallons).
 - This removes any solution left in the Transfer Hose from a prior batch.
 - Once the 3.5 gallons of solution have been flushed out of the Transfer Hose, CLOSE the Transfer Nozzle Valve.
 - Dispose of the transferred solution In accordance with local, state, and federal requirements. If you have questions regarding the disposal of concentrate solution, then See Section 13: Concentrate Solution Disposal, page 37.

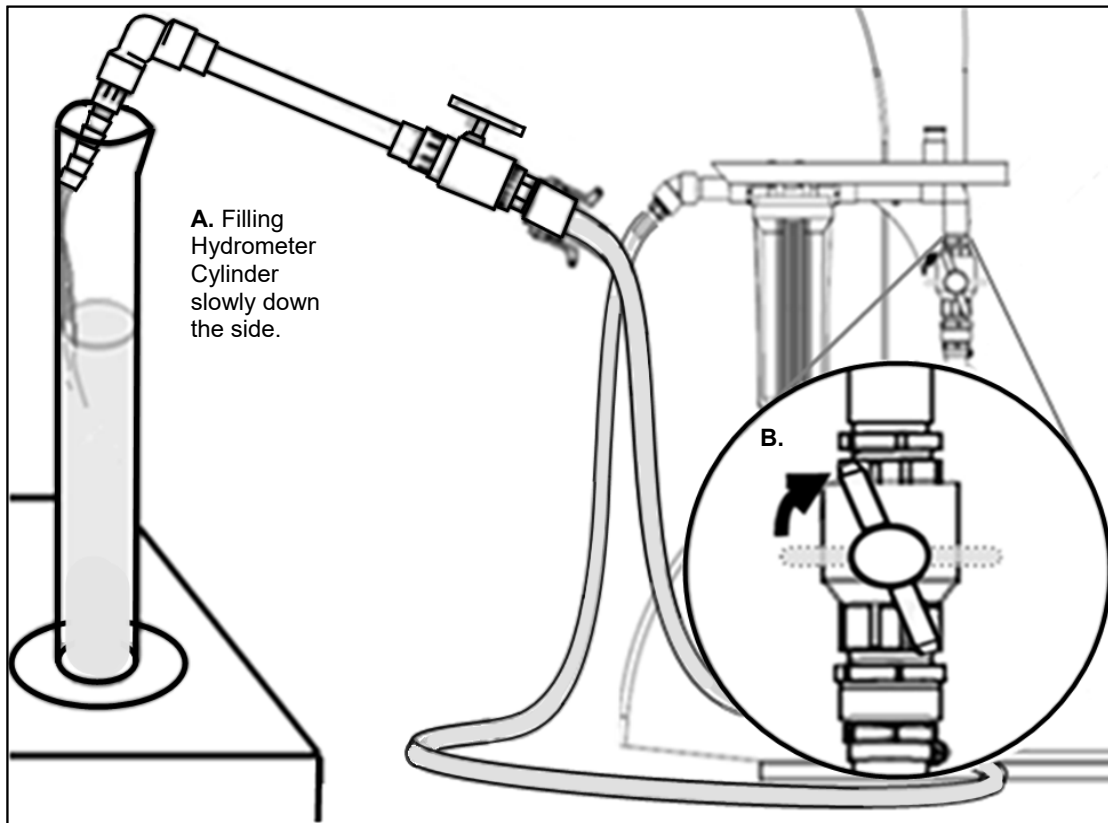


Figure 9: Item A, Filling Hydrometer and Item B, Slightly OPEN Main Transfer Ball Valve

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 (Figure 9, item A).
 - Fill the Hydrometer Cylinder approximately 2/3rd full.
 - CLOSE Transfer Nozzle and then press PAUSE on the Display Panel.
 - Place Transfer Nozzle onto a clean surface.
7. Make sure the solution you gathered does not have excessive amount of bubbles. To release excess amount of bubbles from the solution gently tap the Hydrometer Cylinder and/or gently swirl the entire Hydrometer Cylinder until a majority amount bubbles have been released from the solution (Figure 10).

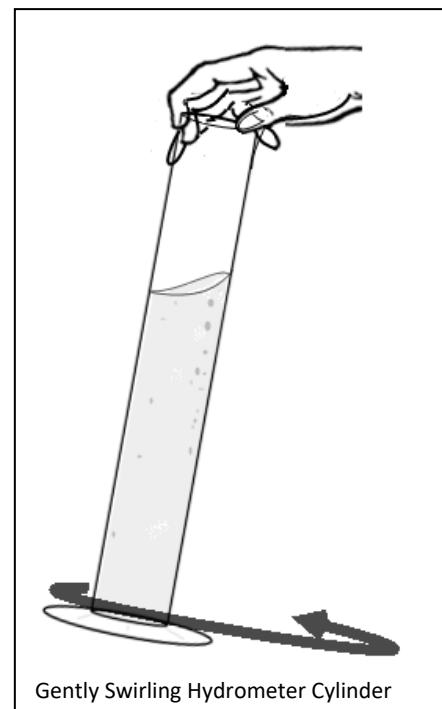


Figure 10



NOTE: TO ENSURE THAT THE SPECIFIC GRAVITY READING IS CORRECT, THE OPERATOR MUST MEASURE THE TEMPERATURE OF THE SOLUTION IN THE HYDROMETER CYLINDER FOR EVERY BATCH.

8. Place Hydrometer Cylinder on a level table and using a Thermometer measure the temperature of the solution in the Hydrometer Cylinder immediately (Figure 11A). For Thermometer requirements refer to Appendix A or B. The measurement of the temperature collected during this step will be known as the *measured temperature* of the solution and will be required on the next step.

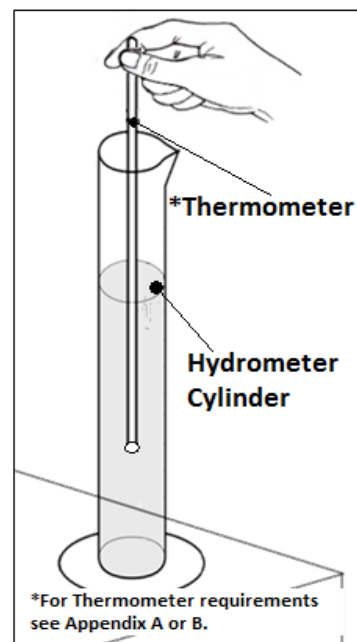
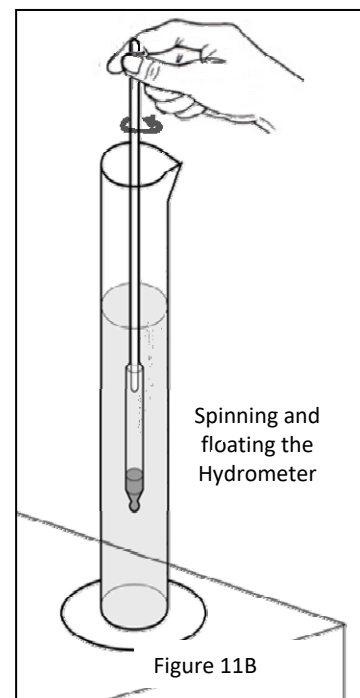


Figure 11A

9. Depending on what Dry Acid Product is being used go to Appendix A: GranuFlo® Dry Acid Specific Gravities Table, page 38, or Appendix B: Citrasate DRY Specific Gravities Table, page 39.

On the chart:

- Locate the catalog number of the dry acid product being used.
 - Using the *measured temperature* from step 8, locate the value of the *measured temperature* of the solution on the chart.
 - 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 (GranuFlo® Form 1, pg 31 or Citrasate DRY Form 2, pg 32).
 - Record the *measured temperature* in the appropriate box in the Batch Production Record Form as well.
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 (Figure 11B).
- 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*.
12. The *hydrometer* will move up and down.
- While the hydrometer is moving up and down pay attention to the movement of the surface of the solution around the hydrometer.
 - If the meniscus is crinkled or dragged out of shape by the motion of the hydrometer, then this indicates either the hydrometer or the surface of the solution is not clean (Figure 12).
 - *Discard contents of Hydrometer Cylinder into the Residual Solution Bucket.* Clean the hydrometer and the hydrometer cylinder and restart from Section 7.1, #1, page 15.



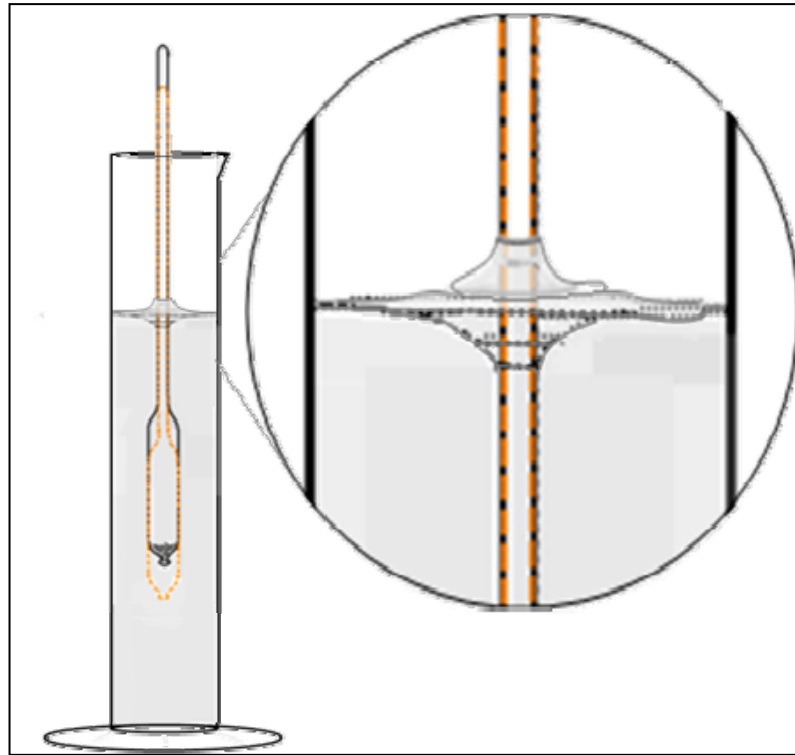


Figure 12: Meniscus crinkled and dragged out

13. 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 (Figure 13).

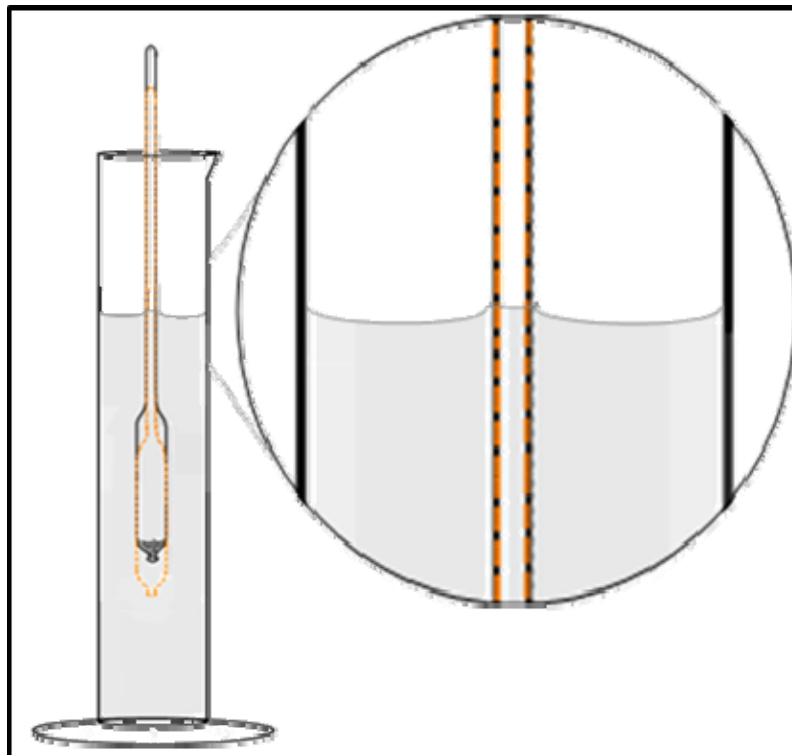


Figure 13: Correct movement of Hydrometer

14. 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 Figure 14.
- Read the specific gravity value at the point where the bottom of the *meniscus* crosses the *hydrometer*.
 - Do not take a reading if the *hydrometer* is touching the side of the hydrometer cylinder.

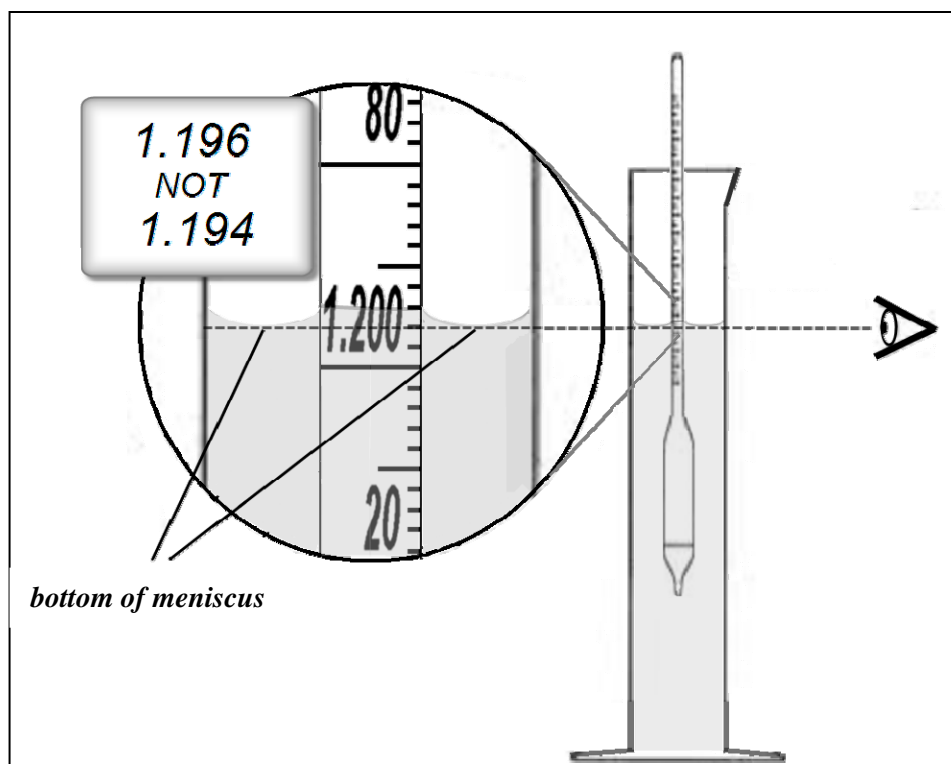


Figure 14: Reading the Hydrometer

15. Document the Specific Gravity in the Batch Production Record Form in the “Measured Specific Gravity Value” box.
16. If the actual *Specific Gravity* value that you measured falls within the ‘low’ and ‘high’ range on the Batch Record Production Form, then the value is acceptable, the solution can be used and its ready for TRANSFER Operation. Prior to Transferring the finished batch, the Batch Record Form must be checked for completeness and signed off by qualified verifier. Place the solution in the Hydrometer Cylinder into the *Residual Solution Bucket*. Rinse the hydrometer cylinder and the hydrometer before storing equipment. To dispose the solution in the Residual Solution Bucket, See section 13.1: *Residual Solution Bucket Disposal*, page 37.
17. If the actual *Specific Gravity* value does not fall within the ‘low’ and ‘high’ range, then the entire batch must be disposed, See Section 13.2: Tank Disposal, page 37.



WARNING! DO NOT USE THE CONCENTRATE IF THE *SPECIFIC GRAVITY* IS NOT WITHIN THE EXPECTED RANGE. IF CONCENTRATE IS NOT WITHIN EXPECTED RANGE DISCARD THE ENTIRE BATCH. ONCE THE SOLUTION IS REMOVED, RESTART FROM SECTION 7, PAGE 13.



NOTE: CONCENTRATE SOLUTION MUST BE DISPOSED OF IN ACCORDANCE WITH LOCAL, STATE, AND FEDERAL REQUIREMENTS. IF YOU HAVE QUESTIONS REGARDING THE DISPOSAL OF CONCENTRATE SOLUTION, PLEASE SEE SECTION 13: DISPOSAL OF CONCENTRATE SOLUTION, PAGE 37.



WARNING! NEVER ADD WATER OR ADDITIONAL DRY ACID PRODUCT TO OBTAIN THE CORRECT SOLUTION SPECIFIC DENSITY.

7.2 TRANSFER TO STORAGE TANK:



CAUTION! COMPARE THE CATALOG NUMBER ON THE STORAGE TANK WITH THE CATALOG NUMBER ON THE DRY ACID CASE TO BE CERTAIN THEY ARE THE SAME.

1. After you have obtained a valid *specific gravity* reading, remove the Transfer Hose from the Transfer Nozzle.
2. Connect Transfer Hose to the storage tank and OPEN Main Transfer Ball Valve at the side of the Filter Housing. Press the Dissolution START button to transfer concentrate into the storage tank (Figure 15).

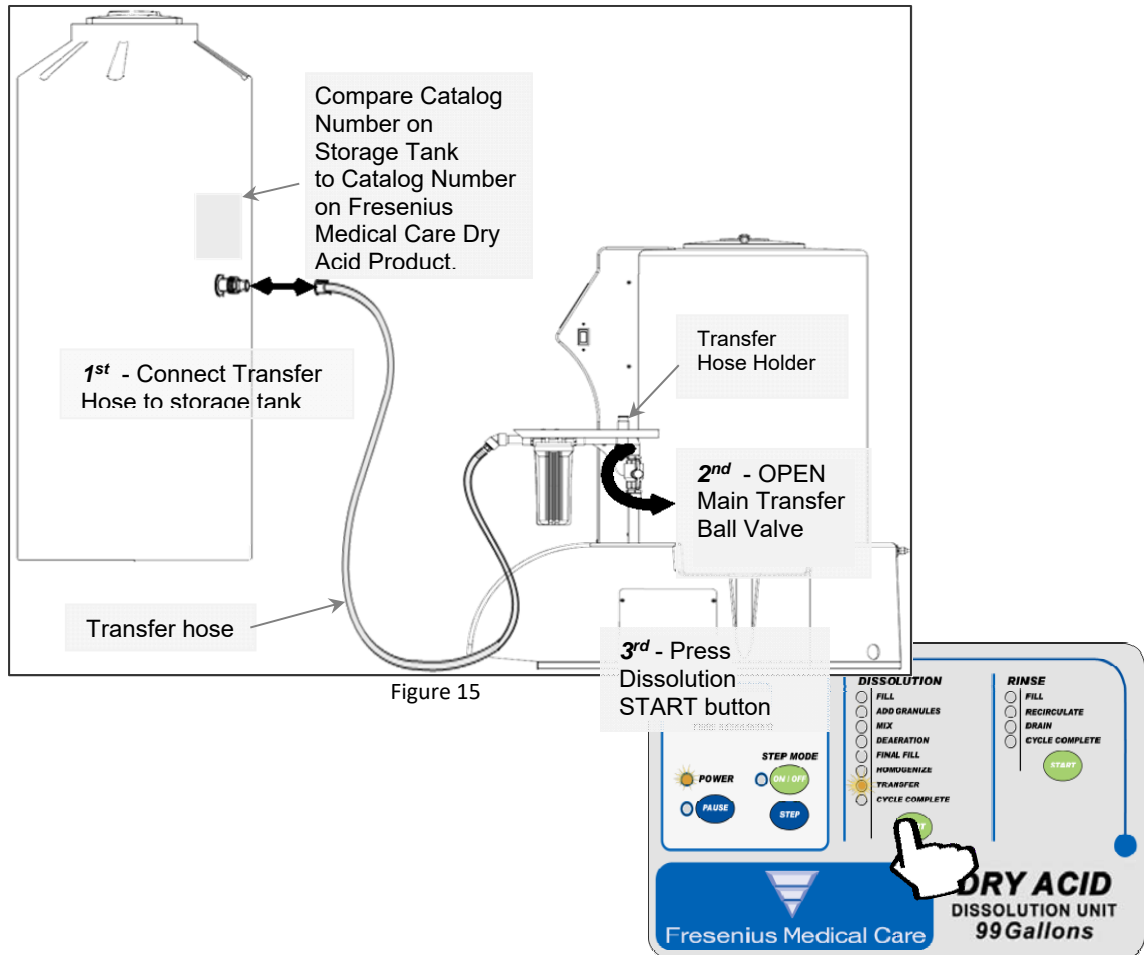


Figure 15

3. Once Transfer of solution is complete, CLOSE the Main Transfer Valve, and place Transfer Hose on to the Dry Acid Dissolution Unit Transfer Hose Holder (see Figure 15). Do not leave Transfer Hose attached to the Storage Tank.

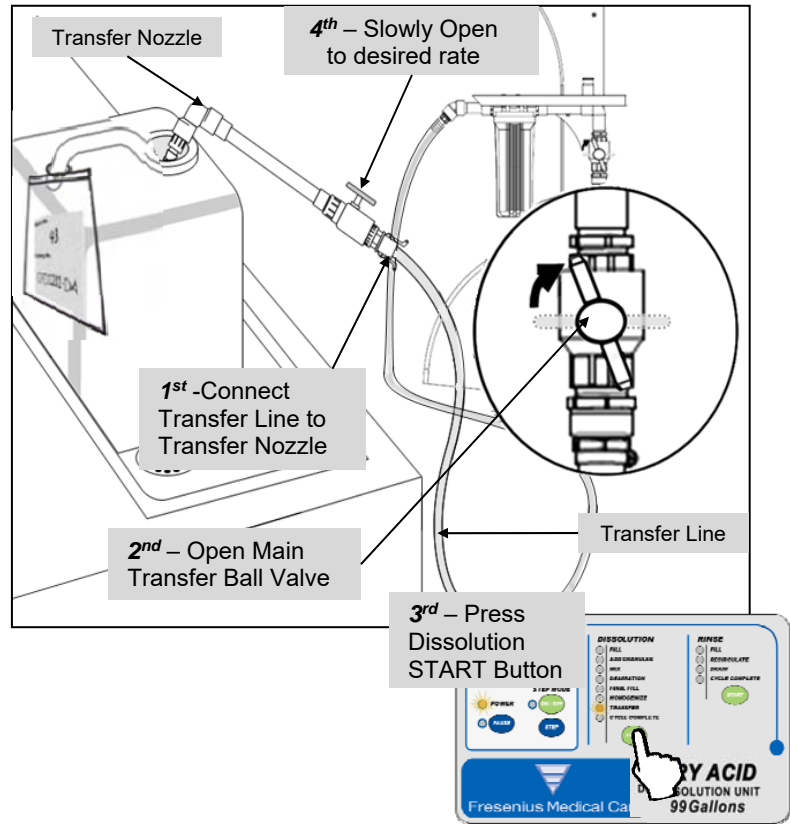


CAUTION! IF THE PUMP IS RUN DRY FOR LONGER THAN 30 SECONDS IT MAY CAUSE PUMP FAILURE.

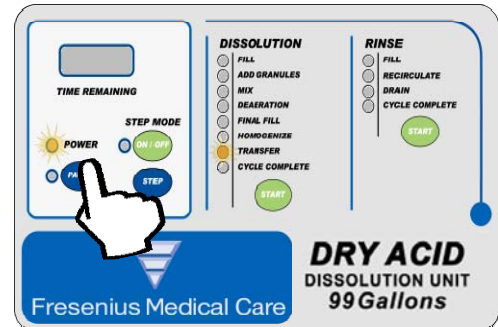
7.3 TRANSFER TO INDIVIDUAL CONTAINERS:

1. To transfer product into individual containers (containers must be properly labeled):

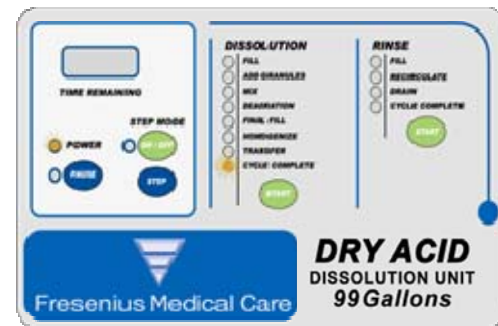
- a. Connect the Transfer Hose to the Transfer Nozzle.
- b. Place the Transfer Nozzle into the opening of an individual container
- c. Slightly OPEN the Main Transfer Ball Valve next to the Filter Housing.
- d. With the Transfer Light flashing, Press Dissolution START button. The Transfer Pump will start.
- e. Slowly OPEN Ball Valve on the Transfer Nozzle until the desired rate of flow through the nozzle is achieved.



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



3. When the Dry Acid Dissolution Unit is empty, the Dry Acid Dissolution Unit will step to the CYCLE COMPLETE Operation. CLOSE the Dry Acid Dissolution Unit's Main Transfer Ball Valve. Then Remove Transfer Nozzle and place Transfer Hose onto the Transfer Hose Holder of the Tank. Ensure you place the Transfer Nozzle in appropriate area free from dirt and other contaminates.



NOTE: IF THE PUMP IS RUN DRY FOR LONGER THAN 30 SECONDS IT MAY CAUSE PUMP FAILURE.



NOTE: ACID CONCENTRATE SHOULD NOT BE STORED IN MIX TANK LONGER THAN 14 DAYS FROM THE DATE OF MIXING. ACID CONCENTRATE MAY BE STORED FOR LONGER PERIODS IN APPROVED CONTAINERS UNDER PROPER STORAGE CONDITIONS.



WARNING! TO PREVENT ACCIDENTAL SHOCK HAZARD, THIS DEVICE MUST BE PLUGGED INTO A PROPERLY GROUNDED *GFI* PROTECTED THREE WIRE RECEPTACLE AC CIRCUIT. DO NOT EMPLOY EXTENSION CORDS OF ANY KIND. WHEN THE POWER CORD IS NOT LONG ENOUGH TO BE SERVICEABLE, A LICENSED ELECTRICIAN MUST INSTALL A NEW THREE WIRE GROUNDED RECEPTACLE IN ACCORDANCE WITH THE NATIONAL ELECTRICAL CODE. DO NOT USE A THREE TO TWO PRONG PLUG ADAPTER WITH THIS DEVICE.

The Dry Acid Dissolution Unit has been designed for ease of use and trouble free operation. However, a minimal amount of preventive maintenance is required in order to maintain the Dry Acid Dissolution Unit in good working condition and minimize the possibility of a system malfunction.

The recommended program for proper care of the Dry Acid Dissolution Unit consists of four basic steps. They are: (8.1) Visual inspection, (8.2) Cleaning, (8.3) Sodium Hypochlorite (Bleach) Disinfection and (8.4) Filter Maintenance.

8.1 VISUAL INSPECTION

Visually inspect the Dry Acid Dissolution Unit prior to mixing a batch. 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 or process contamination should be corrected prior to the use of the Dry Acid Dissolution Unit.

Should the power cord or plug become cracked, frayed or otherwise damaged, it should be replaced immediately. Tag unit "OUT of SERVICE" until the repair is made. Always remove the power cord from the power source before attempting to service this device. Never unplug the unit by pulling on the power cord.

8.2 CLEANING

Clean the exterior surface of the Fresenius Medical Care Dry Acid 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.

8.2.1. PREVENTIVE MAINTENANCE (SEE TABLE 1 ON PAGE 30)



CAUTION! DO NOT USE CHEMICAL CLEANING AGENTS THAT MAY DAMAGE THE MATERIAL USED IN THE DRY ACID DISSOLUTION UNIT. AGENTS WHICH CONTAIN *BENZENE*, *TOLUENE*, *XYLENE*, *ACETONE* OR ANY OTHER AROMATIC OR KETONE SOLVENTS MUST BE AVOIDED.

8.3 SODIUM HYPOCHLORITE (REGULAR BLEACH) DISINFECTION



NOTE: USE ONLY 5% TO 10% SODIUM HYPOCHLORITE (REGULAR BLEACH) TO DISINFECT THE DRY ACID DISSOLUTION UNIT.



WARNING! ENSURE THE TRANSFER HOSE IS NOT CONNECTED TO A CONCENTRATE STORAGE CONTAINER/TANK.

1. To start the disinfection process, power OFF the Dry Acid Dissolution Unit, remove the Filter Housing and discard the Filter Element. Place the residual fluid from the Filter housing in the *Residual Solution Bucket*. Reinstall Filter Housing, but do not insert a Filter at this time. Connect the Transfer Nozzle to the end of the Dissolution Unit's Transfer Hose and make sure the valve on the Transfer Nozzle is in the CLOSED position. In addition, loosen the top Access Lid, but leave it in place. Ensure you have the appropriate personal protective equipment donned.



NOTE: A RINSE CYCLE CONTAINS TWO RINSE OPERATIONS THAT RUN IN SEQUENCE WITHIN ONE COMPLETE RINSE CYCLE. THE 1ST RINSE OPERATION CONSISTS OF FILL, RECIRCULATION, AND DRAIN. 2ND RINSE OPERATION CONSISTS OF FILL, RECIRCULATION, DRAIN, AND CYCLE COMPLETE.

2. Turn the power switch ON and ensure that the water supply valve is OPEN then press the Rinse START button. The Fill Indicator Light will illuminate indicating the RINSE CYCLE has started and the Dry Acid Dissolution Unit is in FILL Operation (Figure 16).

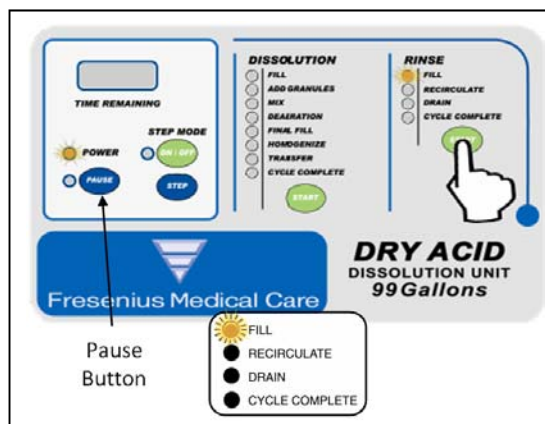


Figure 16

The Dry Acid Dissolution Unit will fill to the 25 GALLON LEVEL SENSOR.

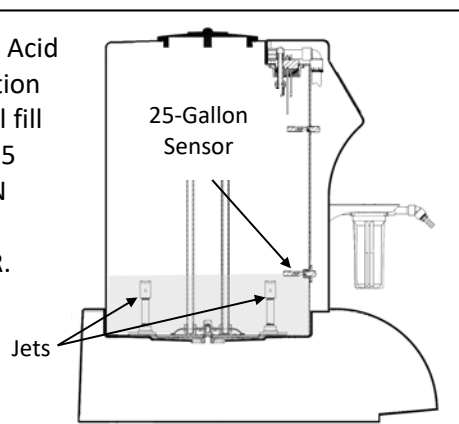


Figure 17

3. Once the 25-Gallon Sensor is reached, the control panel will automatically step to the first RECIRCULATE Operation (figure 17). With your safety glasses on, lift the Access lid and check for correct spray ball operation. See figure 4, page 11, for the illustration of correct or incorrect spray ball operation.
4. When the Fill Indicator Light switches to the RECIRCULATE Indicator Light during the second RINSE Operation, pause the RINSE CYCLE by pressing the PAUSE button (the PAUSE Light will turn ON), then add 0.5 gallons (1.9 liters) of Regular Bleach (sodium hypochlorite 5% to 10%) to the rinse water in the tank. Once the 0.5 gallons of Regular Bleach is added, press the RINSE CYCLE START button (the PAUSE Light will turn off) and the RINSE Operation will continue for the duration of the 2nd RINSE Operation.
5. Once the Dissolution Unit is in the RINSE CYCLE's CYCLE COMPLETE Operation mode, initiate and complete two RINSE CYCLES consecutively by following the steps in Section 6, pg 10.
 - While you are waiting for the RINSE CYCLE to complete, acquire and clean the hydrometer cylinder with purified water before using in the following step. The purified water source must meet ANSI/AAMI or ISO standards for dialysis currently ANSI/AAMI RD62, or ISO 13959.
6. When the two RINSE CYCLES are complete, the unit should be in the RINSE CYCLE, CYCLE COMPLETE Operation. Use the appropriate chlorine test strips to check for the proper chlorine level at the two outputs of the Dry Acid Unit (Transfer Hose and drain hose).
7. Checking bleach residuals from the Transfer Hose.
 - Press DISSOLUTION CYCLE side START button.
 - When water has reached the 25 Gallon Sensor, press STEP MODE ON/OFF button until the STEP MODE Indicator Light turns ON.
 - Use STEP button to step to TRANSFER Operation, the TRANSFER Indicator Light will be flashing.
 - Have chlorine test strip ready for use
 - Press the DISSOLUTION CYCLE side START button. The TRANSFER Indicator Light will stop flashing, the Transfer Valve will OPEN and the Pump will turn ON.
 - OPEN the Main Transfer Ball Valve on the Dry Acid Dissolution Unit.
 - With the end of the Transfer Nozzle placed over a drain, slowly OPEN the valve on the Transfer Nozzle. Allow water to flow to the drain for 15 seconds.
 - Adjust the output of the Transfer Nozzle to a slow output flow.
 - Place test strip under the flow for 30 seconds or the time interval recommended by the manufacture of the test strip being used.
 - CLOSE Transfer Nozzle Valve and press the PAUSE button (the PAUSE Indicator Light will illuminate)

- Ensure that you check the results of the test strip immediately. If the results are higher than 0.1 ppm (ANSI/AAMI RD61: 2006) go to step 9
 - Before proceeding to step 8, ensure the Drain Hose is secure to prevent the hose from flailing around during the DRAIN Operation.
8. Checking bleach residuals during DRAIN Operation from the Drain Hose.
 - Have chlorine test strip and hydrometer cylinder ready for use
 - Using STEP button step to the DRAIN Operation.
 - Press the RINSE CYCLE side START button.
 - PAUSE Indicator Light will turn OFF, the Drain Valve will OPEN and the Motor will turn ON. Allow water to drain for 15 seconds.
 - Press PAUSE button, then quickly collect sample into hydrometer cylinder.
 - Once you have collected a sample, pour sample slowly over the chlorine test strip for 30 seconds.
 - Ensure that you check the results of the test strip immediately. If the results are higher than 0.1 ppm (ANSI/AAMI RD61: 2006) go to step 9
 9. If residual bleach levels are higher than ANSI/AAMI Standard limit of 0.1 ppm (RD61: 2006), in any of the two testing regions initiate another complete RINSE CYCLE. After the RINSE CYCLE is complete, start from section 8.3, #5, to check for residual bleach. Continue the RINSE CYCLE and test procedure until bleach residuals are within ANSI/AAMI Standard limit of less than 0.1 ppm (RD61:2006) at the end of the Transfer and Drain Hose.
 10. Once you have attained an acceptable bleach residual reading, replace the drain hose, and press the RINSE CYCLE START button. Press the STEP MODE ON/OFF button until the STEP MODE Indicator Light turns off. Allow the contents of the Dry Acid Dissolution Unit to drain and wait for the Rinse Cycle to complete. At this point the indicator light should be at the RINSE CYCLE side CYCLE COMPLETE Operation.
 11. Turn OFF the power to the Dry Acid Dissolution Unit Tank and CLOSE the Main Transfer Ball Valve near the filter housing. Then, connect the Transfer Hose to the Dissolution Unit Transfer Hose Holder.
 12. Remove Filter Housing and drain all residual water from the Housing. Install new Filter and tighten Filter Housing into place. See Figure 18.

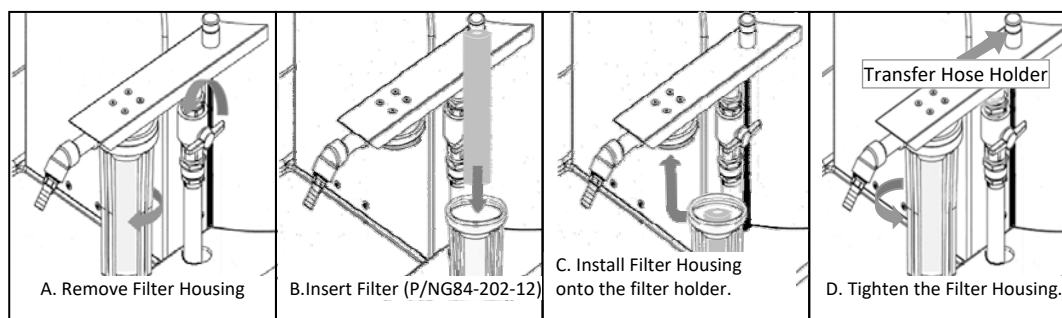


Figure 18

13. Immediately after a successful DISSINFECTION CYCLE, make a batch of Dry Acid Product using Section 7, pg 13. Leaving the Dry Acid Dissolution 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.

8.4 UNIT FILTER AND BASE STAND PIPE FILTER MAINTENANCE

The 1 micron filter (FMCNA, P/N G84-202-12) should be changed under the following conditions:

1. The filter should be changed after mixing 6 batches.
2. When the Dry Acid Dissolution Unit requires disinfection.

8.4.1. FILTER REMOVAL AND REPLACEMENT

Ensure the Mixing Tank is empty and that power to the Dry Acid Dissolution Unit is OFF and the Main Transfer Ball Valve is CLOSED. Follow the Figure A, B, C, and D for removal and replacement of the filter (Figure 19). If the residual fluid in the Filter housing is concentrate, then place the solution in the *Residual Solution Bucket*.

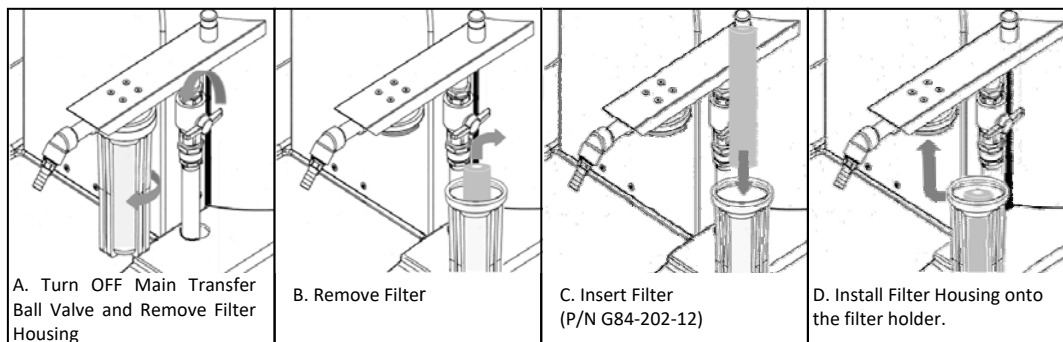


Figure 19



NOTE: THE FILTER USED MUST BE COMPATIBLE WITH FRESenius MEDICAL CARE DRY ACID PRODUCT AND RATED AT 1 MICRON. FRESenius MEDICAL CARE, PN G84-202-12, IS A POLYPROPYLENE FIBER WOUND ON A POLYPROPYLENE MESH CORE MEETS THESE REQUIREMENTS. CELLULOSE FILTERS ARE NOT COMPATIBLE WITH THE FRESenius MEDICAL CARE DRY ACID PRODUCT.



NOTE: IT IS RECOMMENDED TO REPLACE THE FILTER AFTER MIXING 6 BATCHES OR IF THE TANK REQUIRES DISINFECTION.

8.4.2. BASE STAND PIPE FILTER REMOVAL

Using Base Filter Rod, P/N 260025 (Figure 20A), reach into the tank and connect the small end of the shaft into the Screw Nut of Base Filter (Figure 20B). 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. Thoroughly clean off the top of the Pie Plate Filter holes by running purified water over the filter holes until all debris is removed. Once the Pie Plate Filter is clean reinstall the Base Stand Pipe Filter.

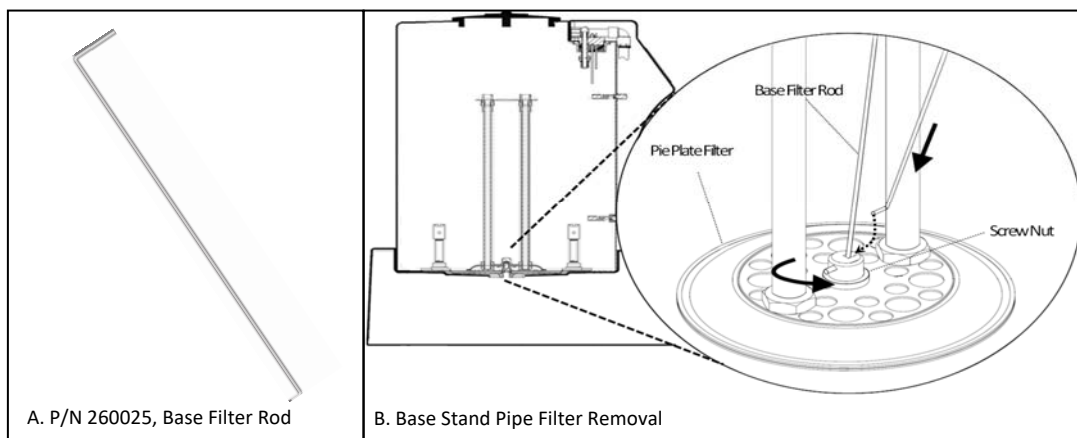


FIGURE 20

8.5 SENSOR REPLACEMENT

An authorized Fresenius Medical Care Service Technician will replace the existing Sensor with a calibrated Sensor. Assure proper concentrate composition after replacement.



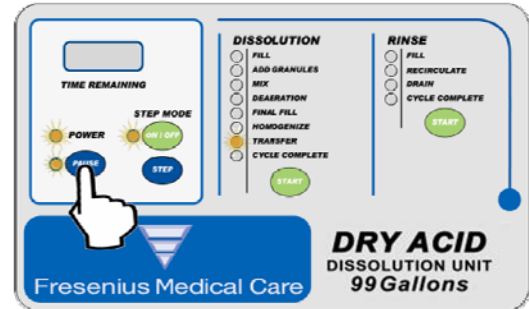
NOTE: IF THE FINAL FILL SENSOR NEEDS ADJUSTMENT OR REPLACEMENT, THEN A QUALIFIED TECHNICAL PERSONNEL SHALL COMPLETE THIS AND THE FOLLOWING TASKS. SAMPLE MUST BE DRAWN FROM THE FIRST BATCH OF CONCENTRATE MIXED. THIS SAMPLE MUST BE ANALYZED FOR CORRECT SOLUTION MIX BEFORE THE CONCENTRATE CAN BE USED. BEFORE REPLACING THE FINAL FILL SENSOR OR RELOCATING THE DRY ACID DISSOLUTION UNIT CONTACT FRESenius MEDICAL CARE TECHNICAL SERVICE AT 1 (800) 227-2572 AND REQUEST TWO (2) EMPTY SAMPLE BOTTLES (P/N G83-535-02). SEE APPENDIX D, PAGE 42, FOR FURTHER INSTRUCTIONS.

9.1 PAUSE STATE

The PAUSE State function is to allow for special occurrences in the operation of the Dry Acid Dissolution Unit. For example; if the unit is not working properly or the operator needs to PAUSE any operation, then the PAUSE button may be pressed.

This will cause the Indicating Light for the current step of the operation to flash. Pressing the PAUSE button will disable the pump, drain valve, fill valve, etc. To continue the cycle, press the START button and the timers will resume.

The FILL Operation cannot be paused.



CAUTION! DO NOT ALLOW THE UNIT TO REMAIN FULL OF WATER WITHOUT THE ADDITION OF DRY ACID PRODUCT. BACTERIAL GROWTH MAY OCCUR.

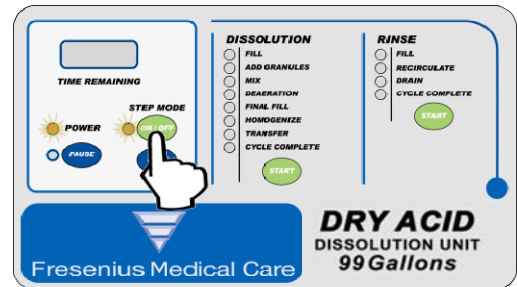
9.2 STEP MODE



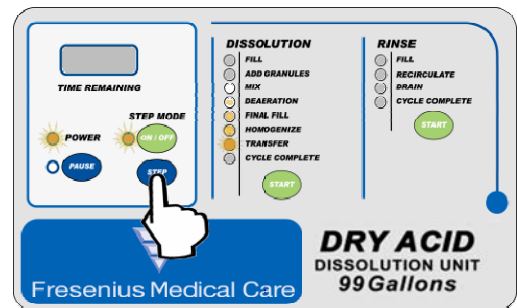
CAUTION! STEP MODE FUNCTION IS NOT TO BE USED TO SPEED UP THE DISSOLUTION OR RINSE OPERATIONS.

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. The STEP MODE function has the ability to skip critical steps in the Dissolution and Rinse cycles, using this mode during these cycles can cause unintended operation of the Dry Acid Dissolution Unit resulting in incorrectly mixed solution.

To enter the STEP MODE press the STEP MODE ON/OFF button until the Step Mode Indicator Light illuminates. The system will enter the STEP MODE and all operations will be suspended.



Press the STEP button to step to the desired operation. When the desired operation light becomes illuminated, press the ON/OFF button and the operation is continued.



CAUTION! WHEN THE STEP LIGHT IS OFF, THE DRY ACID DISSOLUTION UNIT WILL RESUME OPERATION.

9.3 MAIN POWER DISCONNECT

The MAIN POWER Switch is provided to allow the operator to completely shut down the power to the Dry Acid Dissolution Unit. The Main Power Disconnect Switch should be switched to the OFF position when the Dry Acid 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 (Figure 21).

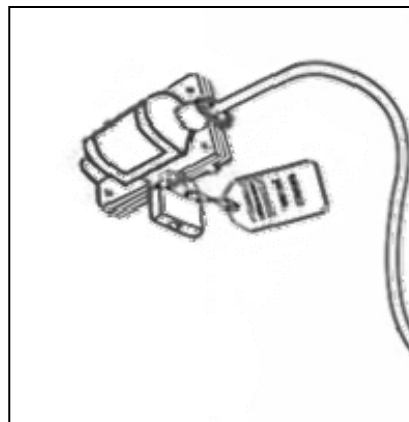


Figure 21



NOTE: WHEN POWER IS RESTORED TO THE DRY ACID DISSOLUTION UNIT, SUCH AS AFTER USE OF THE MAIN POWER SWITCH, OR A POWER FAILURE, THE DRY ACID DISSOLUTION UNIT WILL RESUME THE OPERATION THAT WAS IN OPERATION AT THE TIME OF THE INTERRUPTION, AFTER THE OPERATOR HAS PRESSED THE START BUTTON.

PRESSING THE PAUSE BUTTON OR PLACING THE CONTROL INTO THE STEP MODE WILL DISABLE THE PUMP, AGITATORS, DRAIN, FILL VALVES, ETC.

DIAGRAM 3: TOP VIEW OF VALVE ASSEMBLY

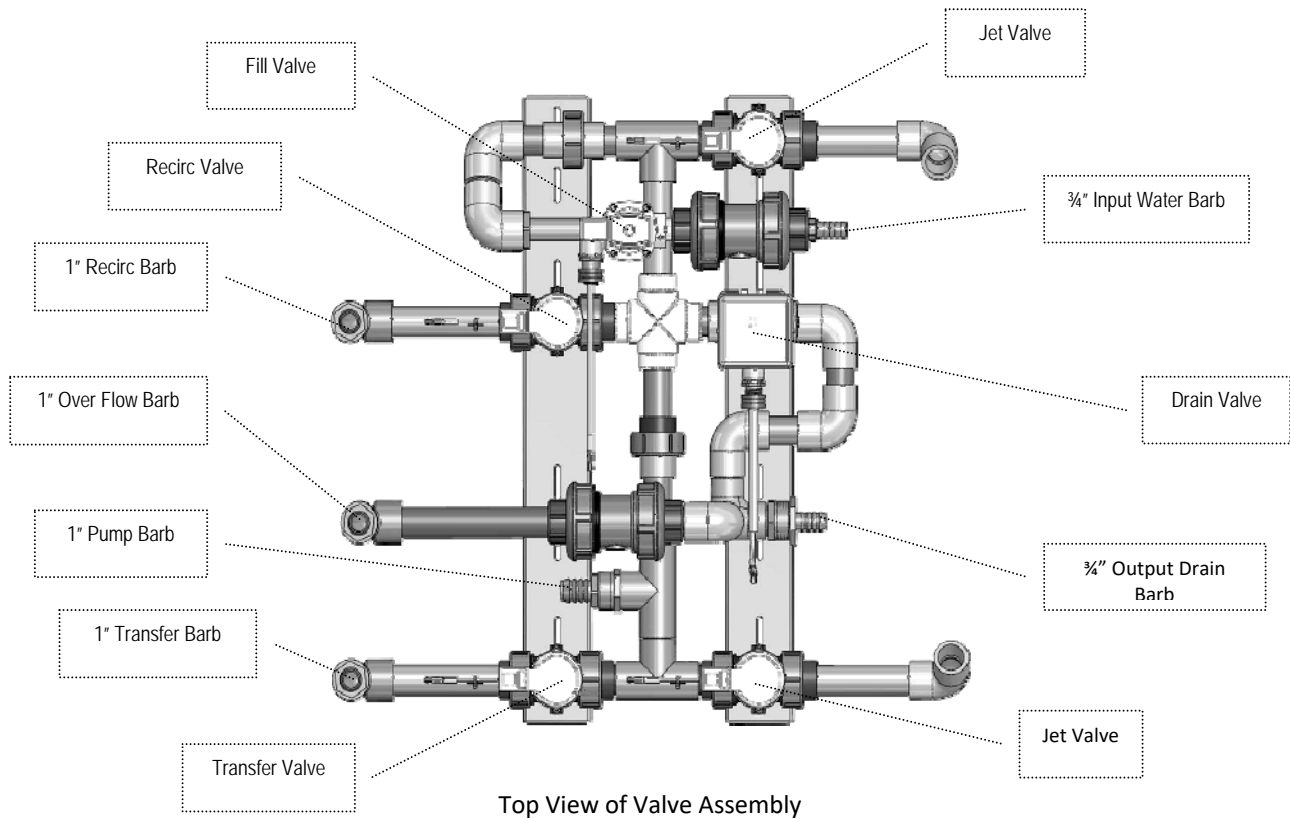


TABLE 1: MAINTENANCE SCHEDULE

PROCEDURE	PER BATCH	MONTH	AS NEEDED	REF. SECTION
RINSE CYCLE	X			6
VISUAL INSPECTION	X			8.1
CLEANING SURFACES	X			8.2
DISINFECTANT			X	8.3
FILTER			X*	8.6
STAND PIPE FILTER			X	8.4.2
CORROSION		X**		N/A
SPRAY BALL			X	SECTION 6 STEP 3

* It is recommended to change the Filter after mixing 6 batches or when the Dry Acid 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 the final fill sensor, connectors at every valve, and the unit's tank be checked for corrosion and salt deposits. Any excessively corroded part should be cleaned or replaced as needed.

FORM 1: GRANUFLO® BATCH PRODUCTION RECORD

Dialysis Unit Name & Location #:		Dry Acid Dissolution Unit Serial #:	
DRY ACID PRODUCT CASE INFORMATION			
OPERATOR (<i>print name</i>):		DATE:	TIME:
CASE 1: Dry Acid Catalog # (label on box)		Batch #:	
CASE 2: Dry Acid Catalog #		Potassium # (1K, 2K, 3K)	
CASE 3: Dry Acid Catalog #		Potassium #	
CASE 4: Dry Acid Catalog #		Potassium #	
CASE 5: Dry Acid Catalog #		Potassium #	
CASE 6: Dry Acid Catalog #		Potassium #	
1. After Final Fill Level has been reached, CLOSE water supply valve to the Unit. Once this is done check the box. <input type="checkbox"/>			
SPECIFIC GRAVITY			
Measured Temp	Print Catalog # -Specific Gravity Value for the Measured Temp listed in Appendix A:		Measured Specific Gravity Value:
TEMP:	LOW:	HIGH:	Check one <input type="checkbox"/> -Pass <input type="checkbox"/> -Fail (void section)
OPERATOR SIGNATURE:		VERIFIER SIGNATURE:	
DRY ACID PRODUCT CASE INFORMATION			
OPERATOR (<i>print name</i>):		DATE:	TIME:
CASE 1: Dry Acid Catalog # (label on box)		Batch #:	
CASE 2: Dry Acid Catalog #		Potassium # (1k, 2k, 3k)	
CASE 3: Dry Acid Catalog #		Potassium #	
CASE 4: Dry Acid Catalog #		Potassium #	
CASE 5: Dry Acid Catalog #		Potassium #	
CASE 6: Dry Acid Catalog #		Potassium #	
1. After Final Fill Level has been reached, CLOSE water supply valve to the Unit. Once this is done check the box. <input type="checkbox"/>			
SPECIFIC GRAVITY			
Measured Temp	Print Catalog # -Specific Gravity Value for the Measured Temp listed in Appendix A:		Measured Specific Gravity Value:
TEMP:	LOW:	HIGH:	Check one <input type="checkbox"/> -Pass <input type="checkbox"/> -Fail (void section)
OPERATOR SIGNATURE:		VERIFIER SIGNATURE:	
DRY ACID PRODUCT CASE INFORMATION			
OPERATOR (<i>print name</i>):		DATE:	TIME:
CASE 1: Dry Acid Catalog # (label on box)		Batch #:	
CASE 2: Dry Acid Catalog #		Potassium # (1k, 2k, 3k)	
CASE 3: Dry Acid Catalog #		Potassium #	
CASE 4: Dry Acid Catalog #		Potassium #	
CASE 5: Dry Acid Catalog #		Potassium #	
CASE 6: Dry Acid Catalog #		Potassium #	
1. After Final Fill Level has been reached, CLOSE water supply valve to the Unit. Once this is done check the box. <input type="checkbox"/>			
SPECIFIC GRAVITY			
Measured Temp	Print Catalog # -Specific Gravity Value for the Measured Temp listed in Appendix A:		Measured Specific Gravity Value:
TEMP:	LOW:	HIGH:	Check one <input type="checkbox"/> -Pass <input type="checkbox"/> -Fail (void section)
OPERATOR SIGNATURE:		VERIFIER SIGNATURE:	

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FORM 2: CITRASATE DRY BATCH PRODUCTION RECORD

Dialysis Unit Name & Location #:		Dry Acid Dissolution Unit Serial #:	
DRY ACID PRODUCT CASE INFORMATION			
OPERATOR (<i>print name</i>):	DATE:	TIME:	Batch #:
CASE 1: Dry Acid Catalog # (label on box)	BOX Lot #	4 TH bag used ✓ box Yes <input type="checkbox"/>	Potassium # (1K, 2K, 3K)
CASE 2: Dry Acid Catalog #	BOX Lot #	4 TH bag used ✓ box Yes <input type="checkbox"/>	Potassium #
CASE 3: Dry Acid Catalog #	BOX Lot #	4 TH bag used ✓ box Yes <input type="checkbox"/>	Potassium #
CASE 4: Dry Acid Catalog #	BOX Lot #	4 TH bag used ✓ box Yes <input type="checkbox"/>	Potassium #
CASE 5: Dry Acid Catalog #	BOX Lot #	4 TH bag used ✓ box Yes <input type="checkbox"/>	Potassium #
CASE 6: Dry Acid Catalog #	BOX Lot #	4 TH bag used ✓ box Yes <input type="checkbox"/>	Potassium #
1. After Final Fill Level has been reached, CLOSE water supply valve to the Unit. Once this is done check the box. <input type="checkbox"/>			
SPECIFIC GRAVITY			
Measured Temp	Print Catalog # -Specific Gravity Value for the Measured Temp listed in Appendix B:		Measured Specific Gravity Value:
TEMP:	LOW:	HIGH:	Check one <input type="checkbox"/> Pass <input type="checkbox"/> Fail (void section)
OPERATOR SIGNATURE:		VERIFIER SIGNATURE:	
DRY ACID PRODUCT CASE INFORMATION			
OPERATOR (<i>print name</i>):	DATE:	TIME:	Batch #:
CASE 1: Dry Acid Catalog # (label on box)	BOX Lot #	4 TH bag used ✓ box Yes <input type="checkbox"/>	Potassium #
CASE 2: Dry Acid Catalog #	BOX Lot #	4 TH bag used ✓ box Yes <input type="checkbox"/>	Potassium #
CASE 3: Dry Acid Catalog #	BOX Lot #	4 TH bag used ✓ box Yes <input type="checkbox"/>	Potassium #
CASE 4: Dry Acid Catalog #	BOX Lot #	4 TH bag used ✓ box Yes <input type="checkbox"/>	Potassium #
CASE 5: Dry Acid Catalog #	BOX Lot #	4 TH bag used ✓ box Yes <input type="checkbox"/>	Potassium #
CASE 6: Dry Acid Catalog #	BOX Lot #	4 TH bag used ✓ box Yes <input type="checkbox"/>	Potassium #
1. After Final Fill Level has been reached, CLOSE water supply valve to the Unit. Once this is done check the box. <input type="checkbox"/>			
SPECIFIC GRAVITY			
Measured Temp	Print Catalog # -Specific Gravity Value for the Measured Temp listed in Appendix B:		Measured Specific Gravity Value:
TEMP:	LOW:	HIGH:	Check one <input type="checkbox"/> Pass <input type="checkbox"/> Fail (void section)
OPERATOR SIGNATURE:		VERIFIER SIGNATURE:	
DRY ACID PRODUCT CASE INFORMATION			
OPERATOR (<i>print name</i>):	DATE:	TIME:	Batch #:
CASE 1: Dry Acid Catalog # (label on box)	BOX Lot #	4 TH bag used ✓ box Yes <input type="checkbox"/>	Potassium #
CASE 2: Dry Acid Catalog #	BOX Lot #	4 TH bag used ✓ box Yes <input type="checkbox"/>	Potassium #
CASE 3: Dry Acid Catalog #	BOX Lot #	4 TH bag used ✓ box Yes <input type="checkbox"/>	Potassium #
CASE 4: Dry Acid Catalog #	BOX Lot #	4 TH bag used ✓ box Yes <input type="checkbox"/>	Potassium #
CASE 5: Dry Acid Catalog #	BOX Lot #	4 TH bag used ✓ box Yes <input type="checkbox"/>	Potassium #
CASE 6: Dry Acid Catalog #	BOX Lot #	4 TH bag used ✓ box Yes <input type="checkbox"/>	Potassium #
1. After Final Fill Level has been reached, CLOSE water supply valve to the Unit. Once this is done check the box. <input type="checkbox"/>			
SPECIFIC GRAVITY			
Measured Temp	Print Catalog # -Specific Gravity Value for the Measured Temp listed in Appendix B:		Measured Specific Gravity Value:
TEMP:	LOW:	HIGH:	Check one <input type="checkbox"/> Pass <input type="checkbox"/> Fail (void section)
OPERATOR SIGNATURE:		VERIFIER SIGNATURE:	

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Fresenius USA, Inc. (the Company) warrants to the purchaser that the equipment delivered is free from defects in material and workmanship for the period specified below, provided that the equipment is used and maintained in accordance with the Company's Operating Instructions.

- A. Mainframe chassis and electronic components, lamps, etc. shall be warranted for ninety (90) days from the date of initial installation or one hundred and eighty (180) days from the date of shipment, whichever comes first.
- B. Consumables shall not be warranted.

The Company will repair or replace, at the company's option, using new or reconditioned parts and/or assemblies, any parts subject to this warranty which are proven defective in materials or workmanship. Such repair and replacement will be made without cost to the purchaser. The Company reserves the right to determine the location at which the repair or replacement shall be accomplished.

This Warranty does not apply to any equipment which is misused, abused, neglected, tampered with, damaged by accident, flood, fire, corrosion, or other hazard, subjected to abnormal or unusual electrical or fluid stress, improperly installed or operated, not maintained in accordance with the routine maintenance schedule set forth in this Operators Manual.

The foregoing Warranty shall be in lieu of any other warranties, expressed, implied or statutory, respecting the equipment or any parts or components thereof. The Company makes no implied warranty of merchantability or fitness for a particular purpose. The purchaser's sole and exclusive remedy in contract, tort or under any other theory against the Company respecting the equipment and its use shall be the replacement or repair of the equipment and its parts as described above, and no other remedy (including, without limitation, consequential damages) shall be available to the purchaser. The Company shall have no further obligation of liability with respect to the equipment or its sale, operation and use, and the Company neither assumes, nor authorizes the assumption of, any obligation or liability in connection with such equipment.

TERMS: Net 30 Days, FOB Shipping Points plus sales and similar taxes. The Company's prices do not include sales, use, excise or similar taxes. Consequently, in addition to the prices specified herein, the amount of any present or future sales, use, excise or similar tax applicable to the sale or use of the equipment hereunder shall be paid by the purchaser, or in lieu thereof, the purchaser shall provide the Company with a tax exemption certificate acceptable to the taxing authorities.

INSTALLATION: purchase prices will include installation and operation training for purchaser's personnel when a complete system is purchased. Installation for replacement parts will be charged to the purchaser on a time, material and expense basis unless covered under the limited warranty or a service contract.

SHIPPING: The Company will use its own judgement in determining the most effective method of shipping unless otherwise specified by the purchaser.

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Refer all servicing and information requests to:

Fresenius USA, Inc.
4040 Nelson Avenue.
Concord, CA. 94520.

TEL: 1-800-227-2572

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IDENTIFYING INDICATORS:

- **Rinse Cycle** - The RINSE cycle has four Operations- FILL, RECIRCULATE, DRAIN and CYCLE COMPLETE. An indicator LED will illuminate on the control panel to highlight which operation is currently in process during the cycle.
- **Dissolution Cycle** - The DISSOLUTION cycle has eight Operations- FILL, ADD GRANULES, MIX, DEAERATION, FINAL FILL, HOMOGENIZE, Transfer and CYCLE COMPLETE. An indicator light will illuminate on the control panel to highlight which operation is currently in process during the cycle.
- **Time Remaining**- Once the Dissolution cycle or Rinse cycle is initiated, the time remaining will be displayed until the entire cycle is completed.
- **Power On**- An indicator light will illuminate to alert the operator that the Dissolution Unit is powered on.

CONTROL PANEL BUTTONS:

- **Step Mode On/Off**- If at any time the operator needs to step from the current operation to another, the STEP mode On/OFF button may be pressed. When the On/Off button is pressed, all operations will be suspended. STEP MODE function is NOT to be used to speed up the dissolution or rinse operations.
- **Step** - Press the STEP button to step to the desired operation.
- **Pause**- If at any time the operator needs to pause a timed process during a cycle, the PAUSE button may be pressed.
- **Dissolution Cycle START**- Press the dissolution START button to initiate the Dissolution Cycle.
- **Rinse Cycle START**- Press the rinse START button to initiate the Rinse Cycle.

OTHER COMMON TERMS:

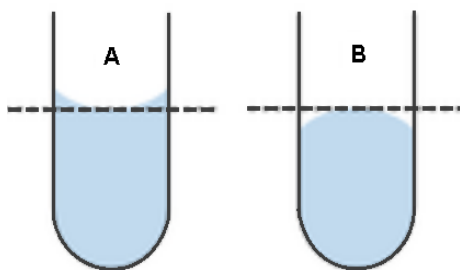
- **Acetic Acid**- It is a colorless liquid that when undiluted is also called *glacial acetic acid*, which is classified as a weak acid. As the main component of vinegar, it has a distinctive sour taste and pungent smell.
- **ANSI/AAMI**- Association for the Advancement of Medical Instrumentation and American National Standards Institute.
ANSI/AAMI RD61: 2006 Concentrates for hemodialysis
ANSI/AAMI RD62: 2006 Water treatment equipment for hemodialysis applications
- **CFU/mL**- In microbiology, **colony-forming unit (CFU or cfu)** is a measure of viable bacterial or fungal numbers. Unlike direct microscopic counts where all cells, dead and living, are counted, CFU measures viable cells. For convenience the results are given as CFU/mL (colony-forming units per milliliter) for liquids, and CFU/g (colony-forming units per gram) for solids
- **GFI (Ground Fault Indicator)**- is an electrical wiring device that disconnects a circuit whenever it detects that the electric current is not balanced between the energized conductor and the return neutral conductor.
- **Hydrometer**- an instrument used to measure the specific gravity (or relative density) of liquids; that is, the ratio of the density of the liquid to the density of water.
- **IEC** - International Electrotechnical Commission is An organization that sets international electrical and electronics standards founded in 1906. It is made up of national committees from over 60 countries.
IEC 60601-1 General safety requirements for Medical Devices

- **ISO**- International Organization for Standardization is an international standard-setting body composed of representatives from various national standards organizations. Founded on February 23, 1947, the organization promulgates worldwide proprietary industrial and commercial standards. It has its headquarters in Geneva, Switzerland.^[2] While ISO defines itself as a non-governmental organization, its ability to set standards that often become law, either through treaties or national standards, makes it more powerful than most non-governmental organizations. In practice, ISO acts as a consortium with strong links to governments.

ISO 13958:2009 Concentrates for haemodialysis and related therapies

ISO 13959:2009 Water for haemodialysis and related therapies

- **LED**-Light Emitting Diode
- **Meniscus** - A meniscus is phase boundary that has been curved because of surface tension. *Also Known As:* menisci, meniscuses.



Measure the meniscus at eye level from the center of the meniscus. In the case of water and most liquids, the meniscus is concave (A). Mercury produces a convex (B) meniscus.

- **NEC- National Electrical Code** is a United States standard for the safe installation of electrical wiring and equipment.
- **OEM** - Original Equipment Manufacturer
Parts used in the manufacturing of the Dry Acid Dissolution Unit have been specified, qualified, and tested as per the guidelines set by FMCNA in accordance with the requirements of *Systems for Mixing Concentrate at a Dialysis Facility* listed in Section 5.3 of the American National Standards Institute (ANSI) / Advancing Safety in Medical Technology (AAMI) RD61:2006 and Section 5.4 of the International Organization for Standardization (ISO) 13958:2009 Regulations.
- **Residual Solution Bucket** – This bucket can be purchased at any hardware store and should be made of plastic since a metal bucket corrodes quickly. Any 5 or more gallon plastic bucket can be used. The use of a bottleneck type container should be avoided.



- **Specific Gravity** - is the ratio of the density (mass of a unit volume) of a substance to the density (mass of the same unit volume) of a reference substance. *Apparent* specific gravity is the ratio of the weight of a volume of the substance to the weight of an equal volume of the reference substance.

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 solution. 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 tank after the dry acid product has been added.
- **Incorrect Catalog:** 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 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 FURTHER 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 GRANUFLO® DRY ACID PRODUCT. BACTERIAL GROWTH MAY OCCUR.

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Specific Gravity Ranges

1:44 PROPORTIONING

		17°C to 21°C		22°C to 26°C		27°C to 31°C	
Catalog Number		Low	High	Low	High	Low	High
1K	0FD1251-3B	1.191	1.203	1.188	1.200	1.186	1.198
	0FD2201-3B	1.191	1.203	1.189	1.201	1.187	1.199
2K	0FD2231-3B	1.192	1.204	1.190	1.202	1.187	1.199
	0FD2251-3B	1.192	1.204	1.190	1.202	1.188	1.200
	0FD2301-3B	1.193	1.205	1.191	1.203	1.189	1.201
3K	0FD3201-3B	1.193	1.205	1.191	1.203	1.188	1.200
	0FD3231-3B	1.194	1.206	1.191	1.203	1.189	1.201
	0FD3251-3B	1.194	1.206	1.192	1.204	1.189	1.201
	0FD3301-3B	1.195	1.207	1.193	1.205	1.190	1.202

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

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APPENDIX B: CITRASATE DRY SPECIFIC GRAVITIES TABLE

Specific Gravity Ranges

1:44 PROPORTIONING

		17°C to 21°C		22°C to 26°C		27°C to 31°C	
Catalog Number		Low	High	Low	High	Low	High
1K	0FD1231-DA	1.191	1.203	1.189	1.201	1.187	1.199
	0FD1251-DA	1.192	1.204	1.189	1.201	1.187	1.199
2K	0FD2231-DA	1.193	1.205	1.191	1.203	1.189	1.201
	0FD2251-DA	1.193	1.205	1.191	1.203	1.189	1.201
	0FD2301-DA	1.194	1.206	1.192	1.204	1.190	1.202
3K	0FD3231-DA	1.195	1.207	1.193	1.205	1.190	1.202
	0FD3251-DA	1.195	1.207	1.193	1.205	1.191	1.203
	0FD3301-DA	1.196	1.208	1.194	1.206	1.192	1.204

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

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GranuFlo®**Citrasate Dry****FMCNA DRY Acid Mixing Procedure Card**

This card is intended to be a supplement to the FMCNA Dry Acid Dissolution Unit Operators Manual and the Citrasate Dry /GranuFlo® product labels. Refer to the FMCNA Dry Acid Dissolution Unit Operators Manual and the Citrasate Dry/GranuFlo product labels for a complete description of mixing instructions, hazards, contraindications and precautions.

Preparation for Dissolution Cycle

Note: FMCNA Dry Acid Dissolution Units are designed for use with Citrasate Dry or GranuFlo Acid products only
Note: Do not use GranuFlo or Citrasate Dry cases if package is opened or damaged

Step 1

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

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

Table 1: Citrasate Dry /GranuFlo Case Requirements

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/AAMI RD62 or ISO 13959 hemodialysis water quality standards. Water temperature should be 20C – 30C (68F – 86F) 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 Fill Cycle on the FMCNA Dry Acid Dissolution Unit by pressing the DISSOLUTION START button.

Step 4

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

Step 5

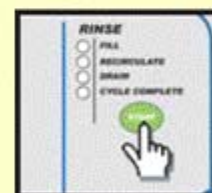
Put on PPE.

Step 6

Remove small access lid on FMCNA 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.



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Instructions for Dissolution (Continued)

Step 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.



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 FMCNA 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 FMCNA 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 FMCNA Dry Acid Dissolution Unit Operator 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 FMCNA Dry Acid Dissolution Unit Operators 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

Fresenius Medical Care North America, 920 Winter Street, Waltham, MA 02451, web: www.fmcna-concentrator.com

FMCNA Customer Service: 800-323-5188, Technical Support: 800-227-2572

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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 Dry Acid Dissolution Unit). Verify the power light activates.
2. As per the Operators Manual P/N 460017 section 6.0, secure the tank lid and initiate the RINSE CYCLE.
3. As per the Operators Manual P/N 460017 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 six (6) 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, 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 P/N 460017 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. 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 the 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 (972) 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 13: DISPOSAL OF CONCENTRATE SOLUTION, PAGE 37).

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FRESENIUS MEDICAL CARE

BATCH ANALYSIS FORM

Customer Information Form



NOTE: TO PREVENT BATCH ANALYSIS DELAYS, THIS FORM MUST BE COMPLETE AND ACCURATE.

Clinic Name: _____

Contact Name: _____ Contact Phone Number: _____

Clinic Fax Number: _____ OR Email: _____ @ _____

Dissolution Tank Serial Number: _____

Product Catalog Number: _____

Important: Incorrect catalog number **will** affect the test results.

Lot Number: _____

Date Sample Taken: _____ Sample By: _____

Ship To:

Fresenius Medical Care
Irving Manufacturing
5201 Regent Blvd., Suite 100
Irving, TX 75063
Attention: Laboratory
Ship: **Overnight**

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MANUFACTURER'S EMC DECLARATION

Guidance and manufacturer's declaration – electromagnetic emissions		
The 99 Gallon Dry Acid Dissolution Unit is intended for use in the electromagnetic environment specified below. The customer or user of the 99 Gallon Dry Acid Dissolution Unit should ensure it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF Emissions CISPR 11	Group 1	The 99 Gallon Dry Acid Dissolution Unit uses RF energy only for its internal functions. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. The 99 Gallon Dry Acid Dissolution Unit is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
RF Emissions CISPR 11	Class A	
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration – electromagnetic immunity


The 99 Gallon Dry Acid Dissolution Unit is intended for use in the electromagnetic environment specified below. The customer or the user of the 99 Gallon Dry Acid Dissolution Unit should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air (Level 3)	±6 kV contact ±8 kV air (Level 3)	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial and/or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips, short interruptions, and voltage variation on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycles 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 seconds	<5 % U_T (>95 % dip in U_T) for 0.5 cycles 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the 99 Gallon Dry Acid Dissolution Unit requires continued operation during power mains interruptions, it is recommended that the 99 Gallon Dry Acid Dissolution Unit be powered from an uninterruptible power supply or a battery.
Power-Frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE U_T is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration – electromagnetic immunity

The 99 Gallon Dry Acid Dissolution Unit is intended for use in the electromagnetic environment specified below. The customer or the user of the 99 Gallon Dry Acid Dissolution Unit should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
<p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>3 Vrms 150 kHz to 80 MHz</p> <p>3 V/m 80 MHz to 2.5 GHz</p>	<p>3 Vrms 150 kHz to 80 MHz</p> <p>3 V/m 80 MHz to 2.5 GHz</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of 99 Gallon Dry Acid Dissolution Unit, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>If abnormal performance is observed such as loss of power, LEDs on control panel turn off unexpectedly or the countdown timer stops prematurely, additional measures may be necessary, such as re-orienting or relocating the equipment.</p> <p>Recommended separation distance</p> $1.2 \sqrt{P}$ <p>1.2 \sqrt{P} 80 MHz to 800 MHz</p> <p>2.3 \sqrt{P} 800 MHz to 2.5 GHz</p> <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the 99 Gallon Dry Acid Dissolution Unit is used exceeds the applicable RF compliance level above, the 99 Gallon Dry Acid Dissolution Unit should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the 99 Gallon Dry Acid Dissolution Unit.

^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

**Recommended separation distances between
portable and mobile RF communications equipment and the 99 Gallon Dry Acid Dissolution Unit.**

The 99 Gallon Dry Acid Dissolution Unit is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the 99 Gallon Dry Acid Dissolution Unit can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the 99 Gallon Dry Acid Dissolution Unit as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

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