



JUL 17 1991

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

Mr. Tom Folden
Director, Product Development
Fresenius USA, Inc.
4090 Pike Lane
Concord, California 94520

Re: K911459/A
Granulyte Powder Dialysate
Concentrate and Mixing System
Dated: April 2, 1991
Received: April 29, 1991
Regulatory Class: II

Dear Mr. Folden:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). General controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device as described. A FDA finding of substantial equivalence for your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in anyway represent your device or its labeling as being approved by FDA. If you desire specific advice on the labeling for your device, please contact the Division of Compliance Operations, Regulatory Guidance Branch (HFZ-323) at (301) 427-1116. Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Memorandum

Date 7/10/91

From REVIEWER(S) - NAME(S) Ruth Hubbard, R.S. Cow

Subject 510(k) NOTIFICATION K911459/A

To THE RECORD

It is my recommendation that the subject 510(k) Notification:

- (A) Is substantially equivalent to marketed devices.
- (B) Requires premarket approval. NOT substantially equivalent to marketed devices.
- (C) Requires more data.
- (D) Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Additional Comments:

Granulex Powder Concentrate - Dialysate Concentrate for HD
Mixing System - Hemodialysis System Accessory
876.5820

The submitter requests under 21 CFR 807.95:

Predicate Product Code w/Panel and class:

- No Confidentiality Concentrate - KPO 78 Class II
- Confidentiality for 90 days Additional Product Code(s) w/Panel (optional):
- Continued Confidentiality exceeding 90 days Mixing System FKQ 78 Class II

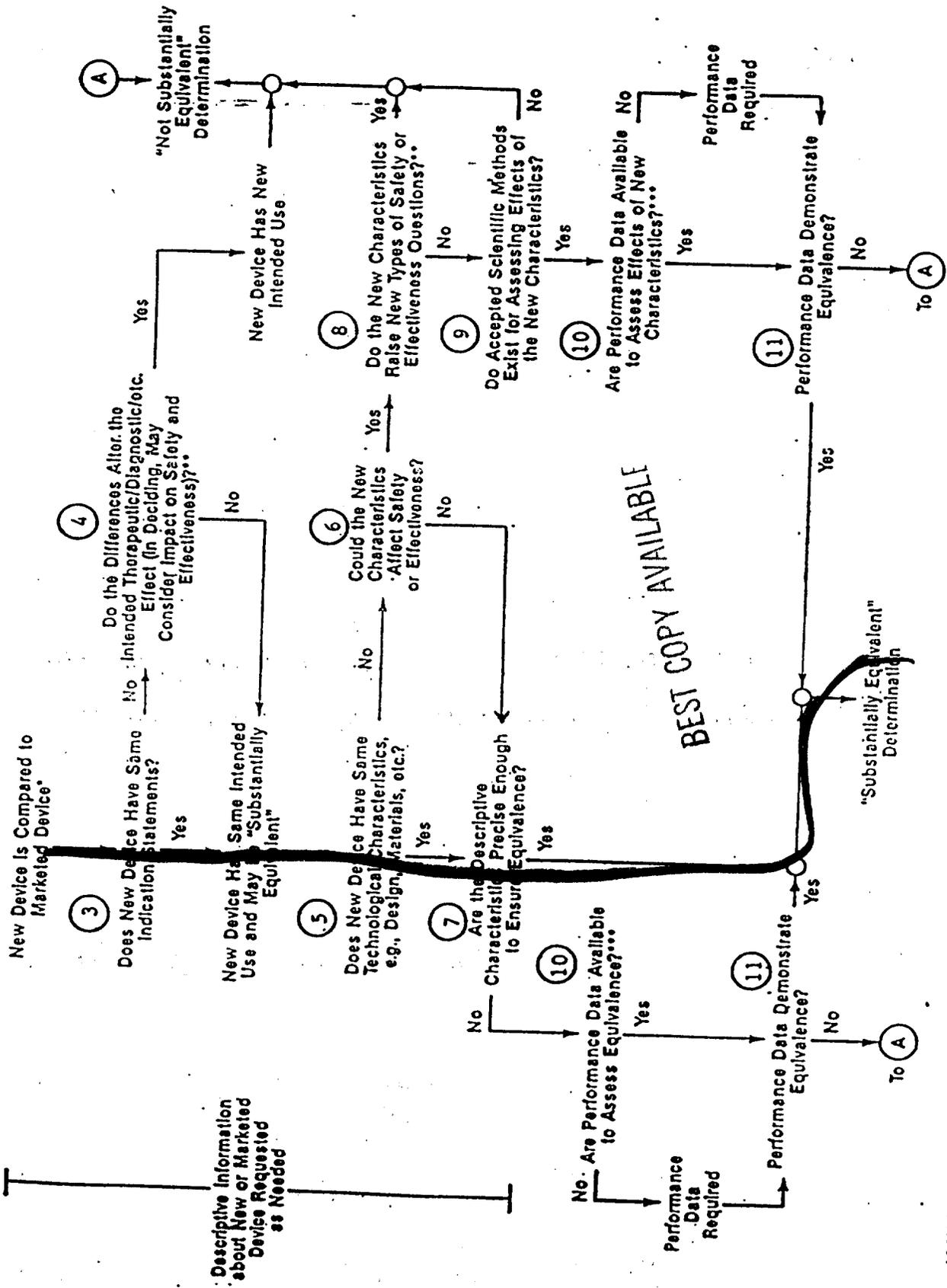
REVIEW:	EC Derru (BRANCH CHIEF)	GROB (BRANCH CODE)	7/12/91 (DATE)
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FINAL REVIEW:	Ruth Hubbard for L. W. (DIVISION DIRECTOR)	7/16/91 (DATE)
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2

510(k) "Substantial Equivalence" Decision-Making Process (Detailed)



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* 510(k) Submissions Compare New Devices to Marketed Devices. FDA Requests Additional Information if the Relationship Between Marketed and "Predicate" (Pre-Amendment or Reclassified Post-Amendment) Devices is Unclear.

** This Decision is Normally Based on Descriptive Information Alone, But Limited Testing Information is Sometimes Required. Data May Be in the 510(k), Other 510(k)s, The Center's Classification Files, or the Literature.

MEMO TO THE RECORD

DATE: 28 JUN 91
FROM: RUTH W. HUBBARD

OFFICE: HFZ-420
DIVISION: DRAERD/GRDB

SUBJECT: K911459/A Fresenius USA, Inc.
Granulyte Powder Dialysate Concentrate and Mixer

CONTACT: Tom Folden

PHONE: 415-676-1600

Additional information has been received and reviewed for these two devices.

The two devices that are the subject of this document are the Fresenius Granulyte Powder Dialysate Concentrates and the Fresenius Mixing System for these concentrates. The powdered concentrates are similar in composition and intended use to other dialysate concentrates that are currently legally marketed, namely that marketed by Renal Systems and the mixer is similar in materials, design and intended use to the Renal Systems Renapak™ Concentrate Mixing System that were both reviewed in K840182.

The Fresenius Granulyte Powder Concentrates are for both acid and bicarbonate concentrates that will be available in a variety of concentrations to suit both patient prescription needs and various proportioning hemodialysis machines. Instructions for use are included on all forms which appear to be accurate and complete. Labeling is included which includes the prescription statement and the final expected dialysate conductivity, [redacted] and the expected pH range of 7.0 - 7.3.

The Mixing System is intended for use in the mixing of powdered dialysate concentrate with AAMI quality water. The system consists of [redacted] mixing and holding tanks, an agitator that is made of [redacted] a control panel and hydraulic circuits, as well as [redacted]. The system has 2 cycles that are pre-programmed, the Rinse/Disinfection Cycle in which the system is prepared for mixing the dialysate concentrate, and the Dissolution Cycle. During this cycle, the powdered concentrate is mixed with AAMI quality water by agitating the solution for a preset period of time in order for the granules to dissolve completely. Once this step has been completed, the entrained air is removed during a deaeration cycle and then the system automatically proceeds to final fill. At this point, AAMI quality water fills the tank to the final level and the unit then homogenizes the solution until it is completely mixed. The concentrate is now ready for transfer and testing. Detailed instructions for use, including a Quality Control Section, will be provided and appear to be accurate and complete.

The labeling stating the name of the device and the manufacturer/distributor name and address that will be affixed to the mixing system has not been provided and the materials for the filter (figure 1) and confirmation that

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page 2 K911459/A

this filter is intended for medical use, must be provided. I have discussed these two items with Mr. Folden today and am waiting for them to arrive in the mail.

Ruth W. Hubbard

RUTH W. HUBBARD, R.N., C.N.N.
Division of Reproductive, Abdominal,
ENT, and Radiological Devices

ADDENDUM: 10 JUL 91

The information concerning the on-line filter has been received, the filter is a [redacted] support structure. The labeling for the mixing device has also been included which states the device name and has the name and address of the firm.

I recommend that this Mixing System and the Granulyte Powder Dialysate Concentrate be found substantially equivalent to the Renal Systems Concentrate Mixing System as reviewed in K840182.

Ruth W. Hubbard

RUTH W. HUBBARD, R.N., C.N.N.
Division of Reproductive, Abdominal,
ENT, and Radiological Devices

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FRESENIUS USA, INC.

1390 Pike Lane
Concord, California 94520
(415) 676-1600

07-01-91

Food and Drug Administration
Center for Devices
Office of Device Evaluation
Document Control Center (HFZ-401)
1390 Piccard Drive
Rockville, Md. 20850

Attention: Ms. Ruth Hubbard

Reference # K911459
Granulyte™ Powder
Dialysate Concentrate
& Mixing System

Dear Ms. Hubbard,

Enclosed is a copy of the proposed label for the Fresenius Granulyte™ Concentrate mixing system for your review. In regards to your question regarding the filter used in the system the filter is specified as a

Care and routine maintenance of the filter system is specified in the manual. The filter specific filter will be indicated in the manual under parts and accessories.

Please contact me if you have any further questions.

Sincerely,



Tom Folden
Director, Product Development
Fresenius USA, Inc.

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**FRESENIUS
GRANULYTE™ CONCENTRATE
MIXING SYSTEM**

CAUTION: Federal U.S.A. Law restricts this device to sale by or on order of a physician.

CAUTION: Electrical shock hazard. Refer servicing to qualified service personnel.

MODEL NO:

SERIAL NO:

VOLTS:

AMPS:

HZ:

Manufactured By
Fresenius USA, Inc.
Concord, Ca. 94520

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, Maryland 20850

MAY 30, 1991

FRESENIUS USA, INC.
ATTN: TOM FOLDEN
4090 PIKE LANE
CONCORD, CA 94520

510(k) Number: K911459
Received: 05-29-91
Product: GRANULYTE POWDER
DIALYSATE
CONCENTRATE AND MIXI

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so within 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 427-1190.

Sincerely yours,

Robert I. Chissler
Chief, Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

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8

K _____ "SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

REVIEWER: _____ DIVISION/BRANCH: _____

TRADE NAME: _____ COMMON NAME: _____

PRODUCT TO WHICH COMPARED: _____
(510(k) NUMBER IF KNOWN)

YES	(NO)
-----	------

1. IS PRODUCT A DEVICE?

--	--

- IF NO STOP

2. DEVICE SUBJECT TO 510(k)?

--	--

- IF NO STOP

3. SAME INDICATION STATEMENT?

--	--

- IF YES GO TO 5

4. DO DIFFERENCES ALTER THE EFFECT OR RAISE NEW ISSUES OF SAFETY OR EFFECTIVENESS?

--	--

- IF YES STOP



5. SAME TECHNOLOGICAL CHARACTERISTICS?

--	--

- IF YES GO TO 7

6. COULD THE NEW CHARACTERISTICS AFFECT SAFETY OR EFFECTIVENESS?

--	--

- IF YES GO TO 8

7. DESCRIPTIVE CHARACTERISTICS PRECISE ENOUGH?

--	--

- IF NO GO TO 10
- IF YES STOP



8. NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS?

--	--

- IF YES STOP



9. ACCEPTED SCIENTIFIC METHODS EXIST?

--	--

- IF NO STOP



10. PERFORMANCE DATA AVAILABLE?

--	--

- IF NO REQUEST DAT.

11. DATA DEMONSTRATE EQUIVALENCE?

--	--



NOTE: IN ADDITION TO COMPLETING PAGE TWO, "YES" RESPONSES TO QUESTIONS 4, 6, 8, AND 11, AND EVERY "NO" RESPONSE REQUIRES AN EXPLANATION ON PAGE THREE AND/OR FOUR

NARRATIVE DEVICE DESCRIPTION

1. INTENDED USE: _____

2. DEVICE DESCRIPTION: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. The following should be considered when preparing the summary of the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device for home use or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

SUMMARY: _____

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EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. EXPLAIN WHY NOT A DEVICE: _____

2. EXPLAIN WHY NOT SUBJECT TO 510(k): _____

3. HOW DOES THE NEW INDICATION DIFFER FROM THE PREDICATE DEVICE'S INDICATION: _____

4. EXPLAIN WHY THERE IS OR IS NOT A NEW EFFECT OR SAFETY OR EFFECTIVENESS ISSUE: _____

5. DESCRIBE THE NEW TECHNOLOGICAL CHARACTERISTICS: _____

6. EXPLAIN HOW NEW CHARACTERISTICS COULD OR COULD NOT AFFECT SAFETY OR EFFECTIVENESS: _____

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- 7. EXPLAIN HOW DESCRIPTIVE CHARACTERISTICS ARE NOT PRECISE ENOUGH: _____

- 8. EXPLAIN NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS RAISED OR WHY THE QUESTIONS ARE NOT NEW: _____

- 9. EXPLAIN WHY EXISTING SCIENTIFIC METHODS CAN NOT BE USED: _____

- 10. EXPLAIN WHAT PERFORMANCE DATA IS NEEDED: _____

- 11. EXPLAIN HOW THE PERFORMANCE DATA DEMONSTRATES THAT THE DEVICE IS OR IS NOT SUBSTANTIALLY EQUIVALENT: _____

ATTACH ADDITIONAL SUPPORTING INFORMATION

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FRESENIUS USA, INC.

K911459/A

4090 Pike Lane
Rockville, California 94520
(5) 676-1600

28 MAY 1991
10 35

May 28, 1991

Food and Drug Administration
Center for Devices
Office of Device Evaluation
Document Control Center (HFZ-401)
1390 Piccard Drive
Rockville, Md. 20850

Reference # K911459
Granulyte™ Powder
Dialysate Concentrate
& Mixing System

Attention: Ms. Ruth Hubbard

Dear Ms. Hubbard,

Enclosed please find the documentation to answer the questions you raised concerning our 510 (k) submission for the Fresenius Granulyte™ Powder Dialysate Concentrate and Mixing System. I hope this is all you require. If I can be of further assistance please contact me directly at 1-800-227-2572, extension 233.

Thankyou for your assistance.

Sincerely,



Tom Folden
Director, Product development
Fresenius USA, Inc.

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- 1. Mean and allowable range for solute concentrations in the powder and the analytical method used for each.**

The final diluted solute concentrations found in the Granulyte dialysate are listed on the labels found in the original submission, Appendix A. The range of allowable variation and the analytical method for each solute is enclosed as Addendum 1.

OC

- 2. Add additional references to AAMI water standards where appropriate in the Operator's manual**

In Addendum 2, I have indicated those references where we have modified the operator's manual to indicate that only AAMI quality water or equivalent is to be used. These references are indicated in red and, if you agree, will be included in the final draft of the Granulyte Operator's Manual.

What about
testing for
bicarbonate ions

- 3. For the Bicarbonate mixing procedure add that a clean, calibrated container must be used.**

A statement that clean containers must be used when preparing the bicarbonate solution has been added to the manual and is shown, in red, in Addendum 2. Fresenius supplies only 2.5 gallon containers for use in this procedure which will contain a qs line for 8 liter fill.

OC

- 4. A statement concerning the duration of time the acid concentrate is stable and can be stored**

A statement has been added to the manual indicating that the acid bath should not be stored for longer than 2 weeks once mixed in solution and is found, in red, in section 3.8 found in Addendum 3.

Is there data
to support
14 days
storage.

5. Materials used in the construction of the mixing and holding tanks.

The mixing and holding tanks are made of [redacted]
The agitator is made of [redacted] Pumps and connecting
transfer piping are [redacted]

OK

6, QC section of the manual

The referenced QC section of the manual was inadvertently left out and is enclosed in Addendum 4 for your review.

OK

7. Statement about the design, logic, testing and verification of the software used in the design of the equipment.

The mixing equipment used in the manufacture of the Granulyte solution uses only relay controls for the operation and does not have any software programming involved. However, this relay system has been reviewed through safety design review and failure analysis and by final solution testing procedures detailed above, has been found to be adequate for the functions required.

OK

8. Comparison to Renal Systems Renapak™ Concentrate Mixing Systems

Enclosed in Addendum 5 are copies of literature for the Renal Systems Renapak mixing system. This systems compares in function to the Granulyte system in that:

- a. Both mix acid and bicarb hemodialysate concentrates
- b. The chemical formulations are similar and consistent with standard solutions currently in clinical use.
- c. The material composition and design of both systems are comparable.

- 3 -

The only major difference in the two systems is that the bicarbonate transfer tank of the Renal Systems unit utilizes a UV source for microbiological control for 7 storage while the Fresenius system uses clean containers and use on the day of manufacture.

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ADDENDUM 1

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CHEMICAL (SALT) TESTING

Prior to shipment, the Granulyte salts will be quality control tested by Fresenius to ensure compliance to the stated formulation values on the package when the product is properly dissolved in the Granulyte Concentrate Mixing System as described in the Operator's Manual.

This product will meet or exceed the AAMI (RD5) standards for Hemodialysis Concentrate.

<u>Component</u>	<u>Test Method</u>	<u>AAMI Specification</u>
Sodium	Sodium Analyzer	+/- 2%
Potassium	Atomic Absorption	+/- 5%
Calcium	Atomic Absorption	+/- 5%
Magnesium	Atomic Absorption	+/- 5%
Chloride	Chloridometer	+/- 2%
Dextrose	Ultraviolet/Enzymatic	+/- 5%
Acetate	Liquid Chromatography	+/- 5%

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ADDENDUM 2

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APPENDIX A-5

SODIUM BICARBONATE LABEL

FORMULA 45

Single Treatment Package for USE WITH COBE (45X) EQUIPMENT ONLY.

This solution must be used in conjunction with Fresenius 45X formula Acid Bath Concentrate for Bicarbonate Dialysis. Check pH and conductivity of the dialysate before use.

Chemical Composition: Sodium Bicarbonate, 650 grams

Ionic Composition: Electrolyte concentration in dialysate is determined by Proportioning Ratio used in the Cobe machine.

AAMI STANDARD

When mixed with Purified Water as directed, each liter of concentrate will contain 81.25 g/L of Sodium Bicarbonate.

PREPARATION INSTRUCTIONS:

1. Add 2 liters of purified water (~~AAMI std~~) to a suitable mixing container. *that HAS BEEN CLEANED AND DISINFECTED USING 0.1% BLEACH.**
2. Add contents of this package slowly into the water in the container.
3. Add sufficient quantity of purified water to bring the total volume to 2.1 gallons, 8.0 liters. *(CALIBRATED LINE ON CONTAINER)*
4. Mix solution thoroughly until Bicarbonate is completely dissolved. Avoid vigorous or over agitation.

NOTE: This solution must be used the day in which it is prepared. Storage in a closed container is recommended. Loss of CO₂ may cause precipitation and change in pH.

CAUTION: Federal (USA) Law restricts the use of this product to sale by or on the order of a physician.

DO NOT USE IF SEAL IS BROKEN OR PACKAGE IS DAMAGED.

Not for Parental use.

Lot #
Date of Mfg.
P/N450088

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* AFTER DISINFECTION WITH 0.1% BLEACH THE CONTAINER MUST BE COMPLETELY FILLED AND DRAINED 2 TIMES WITH AAMI STANDARD WATER.

APPENDIX A-6

SODIUM BICARBONATE LABEL

FORMULA 36

847 grams

Single Treatment Package for USE WITH 36.83X EQUIPMENT ONLY.

This solution must be used in conjunction with Fresenius 36X formula Acid Bath Concentrate for Bicarbonate Dialysis. Check pH and conductivity of the dialysate before use.

Chemical Composition: Sodium Bicarbonate, 626 grams
Sodium Chloride, 221 grams

Ionic Composition when mixed: Sodium 59 mEq/L
Bicarbonate 39 mEq/L
Chloride 20 mEq/L

PREPARATION INSTRUCTIONS:

AAMI STANDARD

1. Add 2 liters of purified water (~~AAMI std~~) to a suitable mixing container. *That has been cleaned and disinfected using 0.1% Bleach.* *
2. Add contents of this package slowly into the water in the container.
3. Add sufficient quantity of purified water to bring the total volume to 2.5 gallons, 9.5 liters. *(TOP OF CONTAINER) QS LINE*
4. Mix solution thoroughly until Bicarbonate is completely dissolved. Avoid vigorous or over agitation.

NOTE: This solution must be used the day in which it is prepared. Storage in a closed container is recommended. Loss of CO2 may cause precipitation and change in pH.

CAUTION: Federal (USA) Law restricts the use of this product to sale by or on the order of a physician.

DO NOT USE IF SEAL IS BROKEN OR PACKAGE IS DAMAGED.

Not for Parental use.

Lot #
Date of Mfg.
P/N450089

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** AFTER Disinfection with 0.1% Bleach the container must be completely Filled AND DRAINED 2 times with AAMI STANDARD WATER.*

FRESENIUS USA
GRANULYTE CONCENTRATE MIXING SYSTEM
OPERATOR'S MANUAL

P/N Rev. 1

GRANULYTE CONCENTRATE MIXING SYSTEM

WARNINGS AND PRECAUTIONS

- * Anyone operating this system should read and be thoroughly familiar with the operator's manual.
- * Only AAMI quality water, (RD5), should be used in this system.
- * Use only dry chemicals supplied by Fresenius USA, Inc. and specifically designed for use in this system.
- * Do not use any chemicals if their package is damaged or torn, a portion of the contents have been spilled, or if the contents are wet.
- * CAUTION: Disconnect electrical supply before servicing. Only qualified personnel should remove access panel or attempt repairs.
- * Federal law restricts this device to sale by or on order of a physician.
- * It is the responsibility of the prescribing physician to ensure that this system is properly installed and that personnel are adequately trained in its operation.
- * Subsequent testing and clinical application of concentrates processed in the Granulyte Concentrate Mixing System is the sole responsibility of the attending physician.
- * A floor drain is required for proper operation.
- * Ensure that the floor on which the mixing system will be installed has sufficient load bearing capacity. When filled with water, the system will weigh approximately 1650 lbs.

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Table of Contents

- I. GENERAL
 - 1. Safety
 - 2. Transport and storage conditions
- II. SET UP
 - 1. Receipt of equipment
 - 2. Installation space
 - 3. Drainline connection
 - 4. Water line connection
 - 5. Transfer line connection
 - 6. Connection to the electrical supply
 - 7. Leveling of the mixing system
- III. DEACTIVATING MIXING SYSTEM
 - 1. Deactivation
 - 2. Transport and shipment
- IV. APPLICATIONS
- V. OPERATING INSTRUCTIONS
 - 1. Overview
 - 2. Rinse/Disinfection Cycle
 - 2.1 Rinse cycle
 - 2.2 Disinfection cycle
 - 3. Dissolution/mixing cycle
 - 3.1 Quality Control testing
 - 4. Maintenance
 - 5. Manual Control operations
- VI. TROUBLE SHOOTING
- VII. TECHNICAL CHARACTERISTICS
 - 1. Hydraulic parts
 - 2. Electrical parts
 - 3. Exterior parts

VIII. APPENDICES

- Fig. 1 Top view of dissolution mixing system
- Fig. 2 Top view of the control panel
- Fig. 3 Electrical diagram of the dissolution system
- Fig. 3.1 I/O Address table
- Fig. 4 Hydraulic diagram

Appendix A: Batch Control Record
(Dissolution Document)

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IMPORTANT: Read Operator's Manual completely before operating equipment.

I. GENERAL

1. Safety

The Granulyte Concentrate Mixing System consists of a 500 liter mixing tank, control panel and hydraulic system.

The Granulated salts for use in the system are packed and shipped separately. The standard shipping container for the salts is called a "unit pack". Each unit pack contains 15 bags of salt which will dilute to 500 liters in the mixing tank.

Warranties from the manufacturer will be in effect only if instructions and warnings given in this booklet have been followed, and only if accessories from Fresenius USA, Inc. have been exclusively used.

The measures that have to be taken for the set up, modifications or repairs which involve an opening of the module, must be done by trained technicians with authorization, and only with the manufacturers spare parts.

Highlight → Use only AAMI standard water for hemodialysis (RDS)

2. Transport and Storage Conditions

The equipment must not to be exposed to the elements and should be kept dry during transport and storage.

II. SET UP

The following will describe the steps that are necessary to make your equipment operational.

1. Receipt of Equipment

A complete inventory as well as a verification of the condition of the equipment should be carried out. The system contains:

- the module which includes:
 - a 500 liter tank with a propeller
 - a control panel which contains electric components and removable hydraulic circuits
 - electric wiring and solid state circuitry

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II. SET UP (cont.)

- a transfer filling "pistol"
- a dilution water line
- a concentrate transfer line
- a tank drain line
- a cutter to open the bags
- a spanner to unscrew the filter housing
- 5 ea. 9" 3/4--1 micron filtration cartridges
- a male 3/4" cam connector
- an instruction manual
- a key to unlock "emergency stop" switch
- a male 3/4" threaded quick connector for the water inlet

2. Installation Space

The mixing area must comply with the following requirements:

- be dust-free and easily cleaned
- close to purified water and electric supply
- have a main floor drain
- close to a storage area

3. Drain Line Connection

Connect the drain line hose to:

- the drain line connection under the control panel module
- the main floor drain (n 5 Fig. 4)

4. Water Line Connection

Connect the water line (n 4 Fig. 1) to:

- the water line connector under the control panel module
- the distribution tap of the purified water source

5. Transfer Line Connection

5.1 Connect the transfer line either to a concentrate storage tank, or

5.2 to the filling pistol, if the concentrate is transferred in jerrycans.

NOTE: The transfer line (n 10 fig. 1) is already connected to the filtration cover.

6. Connection to the Electrical Supply

- Check that your electrical supply is 115 AC, grounded outlet.
- Then connect the lead (n 1 fig. 1) to the plug. (16A+ ground).
- Turn the main power disconnect to "Start". (n 7 fig. 1).
- The green indicator (n 4 fig. 2) light is on.

7. Leveling of the Mixing System

- Check that the equipment is horizontal with a level. The legs can be adjusted individually to level the machine.

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III. DEACTIVATING MIXING SYSTEM

1. Deactivation

- Disconnect the water line, drain line and transfer line.
- Turn the main power disconnect switch (n 7 fig. 1) to "stop" position.
- Disconnect the electric lead cord.

2. Transport and Shipment

- Make sure that the module is dry.
- Pack the module in its original packing or if not available, in adequate packing to ensure protection.
- Keep the system dry!

IV. APPLICATIONS

The system allows for the automated mixing/dissolution of the Granulyte products with the appropriate amount of purified water in order to obtain dialysate concentrate in specific formulations.

Water to be used: AAMI quality water for hemodialysis.

NOTE: This system should not be used for the dissolution of sodium bicarbonate.

FRESENIUS
CONCENTRATE MIXING SYSTEM
OPERATOR'S MANUAL

V 1.0 OVERVIEW

The Fresenius concentrate mixing unit is automated and designed to operate with a minimum of operator supervision.

There are two (2) pre-programed cycles built into the Fresenius mixing unit, the "Rinse Cycle" and the "Dissolution Cycle". The control panel will display the machine's status at any given time, making it easy for the operator to follow the progress of these cycles.

The right side of the panel displays the "Rinse Cycle", and the left side displays the "Dissolution Cycle".

CAUTION: Prior to initiating a rinse cycle or dissolution cycle, adequate power and water connections must be made. The Fresenius dissolution unit is designed to operate on a standard 115 V / 60 CYCLE / SINGLE PHASE / AC circuit. The purified water source connection is made with the water hose located inside the access panel, and the drain hose must be routed to a floor drain. (Refer to Figure 1)

AAMI
STANDARD

2.0 RINSE / DISINFECTION CYCLE

2.1 Rinse Cycle

CAUTION: Before initiating the rinse cycle, the fill gun must be attached to the transfer line and placed above a suitable drain with the trigger locked open. Care should be taken to avoid contaminating the fill gun nozzle. The mixer will pump the solution from the tank, through the hose and filter housing, and finally through the fill gun in order to completely clean and rinse the transfer system. In addition, the operator must insure that the tank access port lid is closed. (Refer to Figure 1)

If necessary, the concentrate filter should be removed, and the empty housing reset as described in section 4.

In order to minimize microbial growth, the rinse cycle should only be performed just prior to the dissolution cycle. The 1 micron filter should not be allowed to stand in fresh water, it should only be left completely filled with concentrate.

- 1) The rinse cycle consists of two complete rinsing operations. Pressing the rinse START/HOLD button on the right side of the panel will fill the tank to the LOW WATER level sensor. The # 1 amber light (see figure 2) will turn on indicating the first rinse cycle is in progress.

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- 2) Once the low water level is reached, the recirculation pump will start and the mixer motor will run for a 5 minute period. During the last 2 minutes of the 5 minute period, the dissolution unit will switch to **Transfer** and the rinse water will be pumped through the transfer line and fill gun to drain. Next, the Fresenius dissolution unit will switch to **Drain** and empty any residual rinse water from the process piping to the floor drain.
- 3) Once the **DRAIN** period is completed, the tank will refill to the **LOW WATER** level. The #2 amber indicator will light indicating the second stage of the rinse cycle is in progress. Once the low water level is made, the recirculation pump will start and the mixer motor will run for a 5 minute period. During the last two minutes of the 5 minute period the unit will switch to **Transfer** and the rinse water will be pumped through the transfer line and fill gun to drain. Next, the Fresenius dissolution unit will switch to **Drain** and empty any residual rinse water from the process piping to the floor drain.
- 4) The rinse **CYCLE COMPLETE** indicator will light. The unit is now ready to mix concentrate.

2.2 Disinfection Cycle

- 1) Remove the filter housing and discard the filter element. Replace the filter housing, but do not insert a replacement filter at this time.
- 2) Follow the Rinse Cycle procedures in 2.1. When the water reaches the low water level during the second rinse step (#2 amber indicator will light), add 1 liter (.26 gallons) of bleach (sodium hypochlorite, 5.25%) to the rinse water in the tank and allow to recirculate for the duration of the rinse cycle.
- 3) At the completion of the last rinse step (to which the bleach has been added), initiate another complete Rinse Cycle by following the steps in 2.1.
- 4) When completed, test for residual bleach in system at the fill gun nozzle and inside the filter housing. Follow your facility protocol for testing for residual quantities of bleach.

If residual bleach levels are higher than what your facility protocol allows, initiate another complete rinse cycle, after which you must again test for residual bleach. Continue this rinse and test procedure until bleach residuals are within your facility's acceptable limits.
- 5) Remove filter housing, then drain all residual water out and install a new filter element. Replace filter housing.

NOTE: Do not let tank sit with residual water in it or in any of the lines. A new batch of concentrate should be prepared following the Rinse and/or Disinfection Cycle.

This system should be periodically checked for contamination and bacterial growth.

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3.0 DISSOLUTION CYCLE

NOTE: Just prior to initiating a dissolution cycle, the operator must insure a rinse cycle has been completed and that the 1 micron filter has been properly installed in the concentrate filter housing. (See section 4.3 for installation instructions.)

Mixing, documentation, and subsequent testing of each hemo concentrate batch should be completed in accordance with the applicable MIX DOCUMENT.

1. Pressing the dissolution **START/HOLD** button opens the water inlet valve and fills the tank to mid level.
2. Once mid level is reached, the water supply valve will turn off and the **ADD GRANULES** light will begin to flash. This flashing indicates that the Fresenius dissolution unit is in a hold state waiting for the operator to add the concentrate granules in accordance with the mix document. After the granules have been added, the operator presses the **CONTINUE / STEP** button and the machine will proceed to the **MIXING** operation.

NOTE: Add the entire contents of each bag in the "unit pack" to the mixer through the port cover on the top of the mixing tank. As each bag is emptied into the mixer, remove the peel-off label from the bag and place it on the Batch Control Record. When you have completed emptying all bags into the tank, you should have one peel-off label in each of the 15 spaces on the Batch Control Record.

3. During **MIXING** the solution is agitated for a preset time period allowing the granules to completely dissolve. After which, the Fresenius dissolution unit will automatically step to the **DEAERATION** phase of the cycle.
4. The **DEAERATION** portion of the cycle is a preset time period during which the entrained air is allowed to separate out of the solution. Upon completion, the Fresenius dissolution unit will automatically proceed to **FINAL FILL**.
5. In **FINAL FILL**, ^{AAMI STANDARD} the supply water valve will open and fill the tank to the final level.
6. When the final water level is reached, the unit will step to **HOMOGENIZATION**. During **HOMOGENIZATION**, the mixer will stir the solution until it is completely mixed. After the homogenization phase, the indicator will flash. The flashing indicates the unit is holding its status, waiting for the operator to press the **CONTINUE / STEP** button once the **TRANSFER** operation is ready.

4.0 MAINTENANCE

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

The recommended program for proper care of the Fresenius Dissolution Unit consists of three basic steps. They are: 1) **REGULAR VISUAL INSPECTION**, 2) **CLEANING**, and 3) **FILTER MAINTENANCE**.

4.1 VISUAL INSPECTION

The Fresenius Dissolution Unit should be visually inspected prior to each use. The operator should look for any defects which may inhibit the safe or proper operation of the unit. Items such as damaged hydraulic hoses or fittings, damaged electrical cables or connections, loose - missing - or damaged hardware, or process contamination should be corrected prior to the use of the Fresenius Dissolution Unit.

4.2 CLEANING

The exterior surface of the Fresenius Dissolution Unit should be thoroughly cleaned 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.

NOTE: Do not use chemical cleaning agents that may damage the materials used in the dissolution unit. Agents which contain **ALCOHOL, BENZENE, TOLUENE, XYLENE, ACETONE** or any other **AROMATIC** or **KETONE** solvents should be avoided.

4.3 FILTER MAINTENANCE

The 1 micron filter (refer to figure 1) should be changed under the following conditions:

1. The type of concentrate to be mixed has changed from the previous batch. (The system rinse procedure, described in section 2, must be followed prior to filter installation.)
2. A significant reduction occurs in the flow from the transfer line.
3. The system has been contaminated.

4.3.1 FILTER REMOVAL

1. Ensure the mixing tank is empty and that the dissolution unit power has been turned off.
2. Remove the lower filter housing with the housing wrench. Empty the housing.
3. Discard the used filter and reset the empty filter housing. Lightly lock the housing in place using the wrench.

4.3.2 FILTER REPLACEMENT

Note: When required, filter replacement should occur just prior to the dissolution cycle.

1. Ensure the mixing tank is empty and that the dissolution unit power has been turned off.
2. Remove the lower filter housing with the housing wrench. Empty the housing.
3. Insert a new 1 micron filter inside the lower housing.
4. Reset the filter and housing. Lightly lock the housing in place using the housing wrench.

5.0 MANUAL CONTROL OPERATIONS

5.1 HOLDING STATES

To allow for special occurrences, and allow some latitude in the operation of the Fresenius dissolution unit, a **STEP / HOLD** sequence has been included in the control system.

If at any time the operator needs to "hold" a timed state during the cycle, the **START / HOLD** button may be pressed.

This will cause the indicating light for the current step of the process to flash. Any equipment in operation when the hold button was depressed, such as the agitator or the pump, will continue operating. In "HOLD", only the timers are stopped.

To continue the cycle, press the **CONTINUE / STEP** button and the timers will resume.

NOTE: To prevent over filling, the fill states can not be placed on "HOLD".

CAUTION: DO NOT LEAVE THE UNIT ON "HOLD" IN THE TRANSFER STATE AFTER THE TANK IS EMPTY. THIS WILL CAUSE EXCESSIVE WEAR AND MAY CAUSE THE PUMP'S SANITARY SEAL TO FAIL.

5.2 STEPPING STATES

In the operation of the Fresenius dissolution unit it may become necessary to "STEP" from the current state to another state, skipping one or several steps in between.

This is possible by pressing and holding down the **START / HOLD** button. After three seconds the system will enter the "STEPPING" mode, and all of the equipment will be shut down. By continuing to hold down the **START / HOLD** button and pressing the **STEP / CONTINUE** button, the states may be stepped sequentially. When the desired step is illuminated, the **STEP / HOLD** button is then released, the **STEP / CONTINUE** button is pressed and the operation is continued.

CAUTION: WHEN THE STEP / HOLD BUTTON IS RELEASED THE Fresenius dissolution unit WILL RESUME OPERATION.

5.3 STOPPING STATES

The **STOP** button has been provided to allow the operator to stop the process without having to re-initiate. When the stop button is pressed, the red indicator light will turn on and the current status light will flash, indicating a "HOLD" state. All operations will stop (ie. pumps, agitators, drains, fill valve etc.). The cycle may be resumed by pressing the **CONTINUE / STEP** button.

5.4 EMERGENCY STOP

The **EMERGENCY STOP** switch is provided in order to allow the operator to completely shut down the Fresenius dissolution unit in case of an emergency. Pressing the **EMERGENCY STOP** shuts off the main power to the Fresenius dissolution unit.

The **EMERGENCY STOP** switch requires a key to release it back to normal operation.

NOTE: When power is restored to the Fresenius dissolution unit, such as after use of the EMERGENCY STOP, the MAIN DISCONNECT switch, or a power failure, the Fresenius dissolution unit will resume operation where it was interrupted.

Operating the **STOP** button or placing the control into the **STEP** mode (**START / HOLD** button depressed for more than 3 seconds) will disable the working parts of the machine (ie. pump, agitator or water fill valve).

CAUTION: The Fresenius dissolution unit is computer controlled, extreme care should be exercised in its operation. When power is connected to the Fresenius dissolution unit, a failure of the computer could start any of the operations at any time. (Refer to Figure 3)

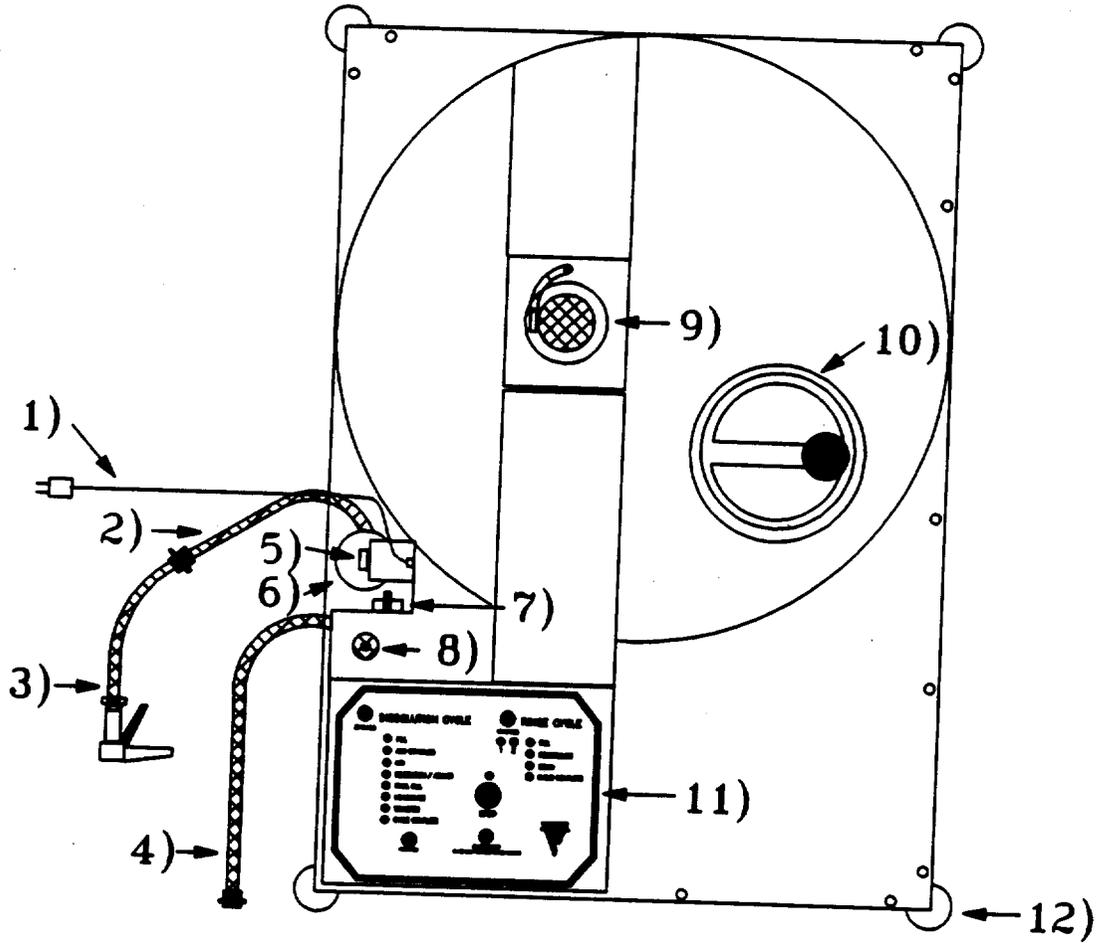
VI
TROUBLE SHOOTING

PROBLEM	POSSIBLE CAUSE	SOLUTION
1 No sign of working and the on/off light (6) is not lit	<ul style="list-style-type: none"> - No power on the network - The wire (7) is not or not correctly connected - The cutout switch (13) is "off" - The FU2 fuse is faulty - The indicator light (6) is faulty - The transformer 220/4V TR1 is faulty 	<ul style="list-style-type: none"> - Call the maintenance department - Connect it correctly - Turn it on "I" - Change it - Change it - Change it
2 No sign of working but the indicator light is on	<ul style="list-style-type: none"> - Emergency stop (1) on - Water inlet shut. - FU3 fuse is faulty - The water inlet electrovalve (Y1) is faulty. 	<ul style="list-style-type: none"> - Unlock (1) with wrench Nr 455. - Open it. - Change it. - Change The (Y1) electrovalve coil
3 Green light Nr 17A off	<ul style="list-style-type: none"> - The green light Nr 17A is faulty - The RK2 relay is faulty - There is already some liquid in the dissolution tank 	<ul style="list-style-type: none"> - Change light Nr 17A - Change RK2 - Empty the tank
4 Green light Nr 17B off	<ul style="list-style-type: none"> - The green light Nr 17B is faulty - The RK3 relay is faulty - The level probe is covered with powder 	<ul style="list-style-type: none"> - Change it - Change RK3 relay - Clean the level probe
5 Green light Nr 17C off	<ul style="list-style-type: none"> - It is faulty - The RK1 relay is faulty - There is already some liquid in the dissolution tank 	<ul style="list-style-type: none"> - Change it - Change it - Empty the tank
6 Filling does not stop	<ul style="list-style-type: none"> - The optical probe N1 is faulty - The probe relay K1 is faulty 	<ul style="list-style-type: none"> - Change probe N1 - Change K1

TROUBLE SHOOTING

<p>7 No stop on step 5 : ADJUSTMENT/ Dissolution</p>	<ul style="list-style-type: none"> - The optical probe N2 is faulty - The probe relay K2 is faulty 	<ul style="list-style-type: none"> - Change probe N2 - Change K2
<p>8 No stop on step 1 : FILLING/Rinsing</p>	<ul style="list-style-type: none"> - The resistive probe N3 is faulty - The probe relay K3 is faulty 	<ul style="list-style-type: none"> - Change probe N3 - Change K3
<p>9 Mixing fault</p>	<ul style="list-style-type: none"> - Propeller timer switch not set - Wrong gauging of DM1 - Propeller timer switch is faulty - Mixing device locked 	<ul style="list-style-type: none"> - Set the timer on - Gauge DM1 - Change it - Check it
<p>10 Faulty transfer or circulation</p>	<ul style="list-style-type: none"> - The filter is full up - The concentrate storage tank inlet is shut - The pump timer switch is off - Wrong gauging of DM2 - Pump timer switch is faulty - Motorized valve Y2 is locked - The pump is locked 	<ul style="list-style-type: none"> - Change the filter - Open it - Set the timer on - Gauge DM2 - Change it - Clean it - Check it

Figure 1 FRESINIUS DISSOLUTION UNIT

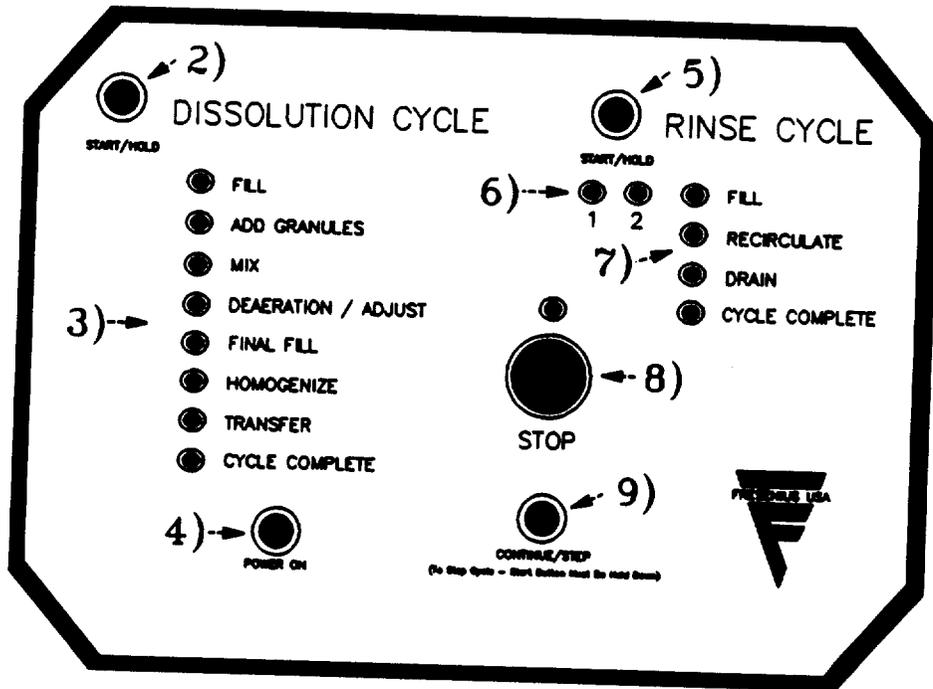


TOP VIEW

- 1.) 115 VAC POWER CORD
- 2.) SOLUTION TRANSFER LINE
- 3.) FILL GUN (OPTIONAL)
- 4.) WATER INLET LINE
- 5.) FILTER BACK PRESSURE GAUGE
- 6.) FILTER HOUSING
- 7.) MAIN POWER DISCONNECT
- 8.) EMERGENCY STOP
- 9.) MIXER MOTOR
- 10.) TANK ACCESS PORT
- 11.) CONTROL PANEL
- 12.) LEVELING FOOT

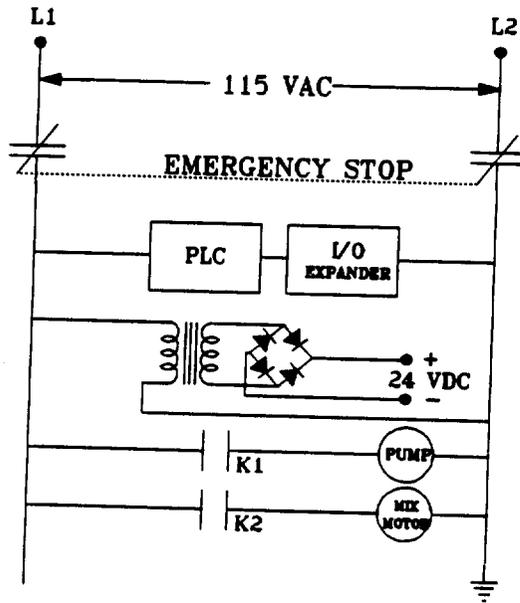
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Figure 2 CONTROL PANEL

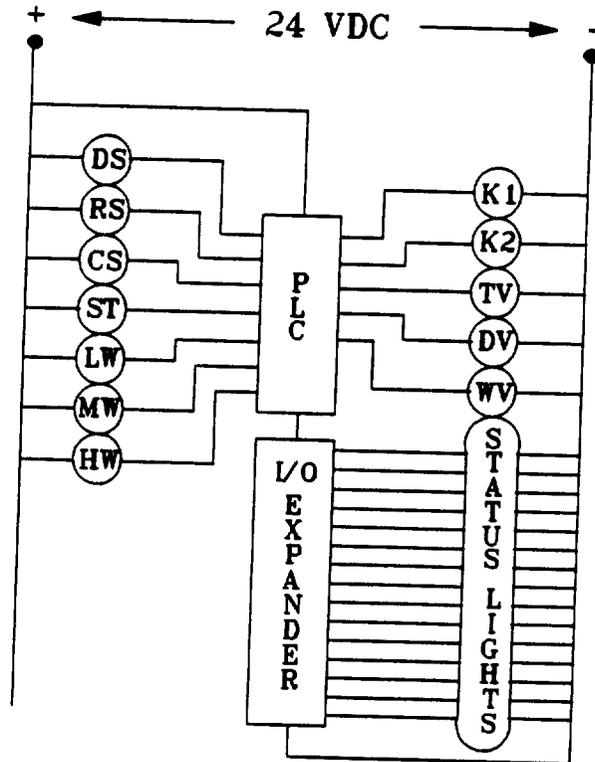


- 1.) **EMERGENCY STOP**
- 2.) **DISSOLUTION CYCLE START/HOLD PUSH BUTTON**
- 3.) **DISSOLUTION CYCLE STATUS INDICATORS (BLUE)**
- 4.) **POWER ON INDICATOR (GREEN)**
- 5.) **RINSE CYCLE START/HOLD PUSH BUTTON**
- 6.) **RINSE CYCLE STEP INDICATORS (AMBER)**
- 7.) **RINSE CYCLE STATUS INDICATORS (BLUE)**
- 8.) **CYCLE STOP PUSH BUTTON**
- 9.) **CYCLE CONTINUE/STEP PUSH BUTTON**

FIGURE 3 ELECTRICAL SCHEMATIC



115 VOLT POWER DISTRIBUTION



24 VOLT DC POWER DISTRIBUTION

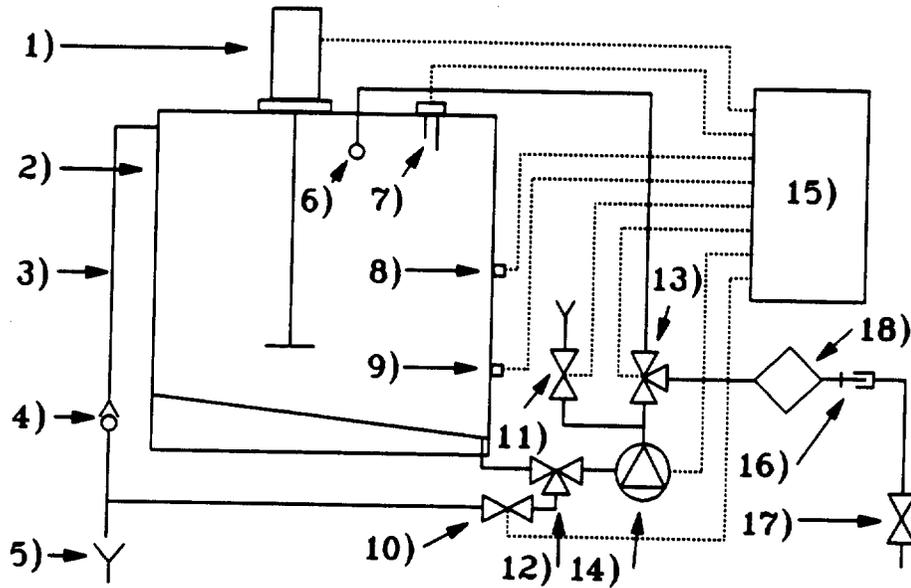
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FIGURE 3.1

I/O ADDRESS TABLE

INPUTS		OUTPUTS	
001	Dissolution Start/Hold	011	Mixer Motor
002	Rinse Start/Hold	012	Pump Motor
003	Continue / Step	013	Transfer Valve
004	Stop Button	014	Drain Valve
005	Low Water Level	015	Fill Valve
006	Mid Water Level	314	Disso. Fill Light
007	High Water Level	111	Add Granules Light
		112	Mix Light
		113	Deaeration Light
		114	Final Fill Light
		115	Homogenize Light
		116	Transfer Light
		211	Cycle Complete Light
		212	Rinse Fill Light
		213	Recirculation Light
		214	Drain Light
		215	Cycle Complete Light
		216	Stop Indicator
		311	First Rinse Light
		312	Second Rinse Light

Figure 4 HYDRAULIC DIAGRAM



- 1.) MIXER
- 2.) DISSOLUTION TANK
- 3.) OVERFILL PIPE
- 4.) BACKFLOW VALVE
- 5.) MAIN DRAIN
- 6.) RINSING SPRAY BALL
- 7.) HIGH LEVEL SENSOR
- 8.) MID LEVEL SENSOR
- 9.) LOW LEVEL SENSOR
- 10.) DRAIN VALVE
- 11.) FILL VALVE
- 12.) MANUAL DRAIN VALVE
- 13.) TRANSFER / RINSE VALVE
- 14.) TRANSFER / RINSE PUMP
- 15.) CONTROL ENCLOSURE
- 16.) TRANSFER LINE COUPLER
- 17.) FILL GUN
- 18.) FILTER HOUSING

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	GRANULYTE	
DATE	BATCH CONTROL RECORD (DISSOLUTION DOCUMENT)	OPERATOR

Formulation:

Batch No:

Mfg. Date:

Quality Control Testing:

Conductivity of Dialysate:

pH of Dialysate:

Empty Bag Count:

Other Tests:

Lot #:

Exp. Date

Note : The entire contents of each bag in the Granulyte "Unit Pack" must be emptied into the mixing tank to ensure proper electrolyte concentration.

Ionic Concentrations of Dialysate When Properly Diluted:

Sodium:

Potassium:

Calcium:

Magnesium:

Chloride:

Acid/Acetate:

Dextrose:

Sodium Diacetate		
	P L A C E	
	P E E L - O F F	
	L A B E L S	
	H E R E	

ADDENDUM 3

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Appendix A-1

Granulyte "Unit Pack"
Container Label

GRANULYTE

380001 Acid Concentrate 36.83
for Bicarbonate Dialysis
Part A - 15 Bags (one containing Sodium Diacetate)

For use only with Granulyte Concentrate Mixing System for dissolution.
 Contents of this container dilute to 500 liters (132.1 gallons)
 Caution: Federal (USA) law restricts sale of this device by, or on order of a physician.
Not for Parenteral Use

Final Dialysate Concentration		Dialysate Concentrate (1:35.83)	
Part A/Part B/Water 1 : 1.83 : 34 Total mEq/Liter	Part A Chemical Concentration	Gm/L	Gm/L
Sodium.....139.0 mEq/L	Sodium Chloride.....NaCl	167.9	4.58
Calcium.....3.5 mEq/L	Calcium Chloride.....CaCl ₂ • 2H ₂ O	9.5	.26
Potassium.....2.0 mEq/L	Potassium Chloride.....KCl	5.5	.15
Magnesium....1.0 mEq/L	Magnesium Chloride.....MgCl ₂ • 6H ₂ O	3.7	.10
Chloride.....104.5 mEq/L	Sodium Diacetate.....CH ₃ COONa • n(CH ₃ COOH)	10.4	.28
Acid.....4.0 mEq/L	Dextrose.....C ₆ H ₁₂ O ₆	73.7	2.0
Bicarbonate...35.0 mEq/L	Final Dialysate		
Dextrose.....200 mg/dL	Conductivity: 14.1 (± .2), pH Range: 7.0 - 7.3		

DIRECTIONS: This concentrate is formulated to be used in conjunction with Fresenius Formula 36 Sodium Bicarbonate Concentrate (Part B) in a compatible 36.83X dilution, three stream artificial kidney machine. Please refer to instructions of the kidney machine manufacturer before use.

MIXING INSTRUCTIONS: Contents are to be mixed only in the Fresenius "Granulyte Concentrate Mixing System". **EMPTY ENTIRE CONTENTS OF OF ALL 15 BAGS INTO MIXING TANK.** Read and follow directions in the mixing system Operator's Manual. Upon completion of the dissolution cycle, follow quality control guidelines in the Operator's Manual, verifying conductivity and pH, and reviewing the quality control "Dissolution Document" for accuracy.

CAUTION: This concentrate is designed to be used in conjunction with Fresenius Formula 36 Bicarbonate Concentrate. Mix bicarbonate in a separate container, **NOT** in the Granulyte Mixing Tank. Completed product (liquid concentrate) should be stored between 40° F to 90° F. Avoid freezing. Keep storage containers tightly sealed.

PN: 000121

Fresenius USA
Concord, CA. 94520



Lot #:
Formula #:
Exp. Date:

Do NOT store
FOR MORE THAN
2 weeks

Section 3.8 of manual.

7. Normally during **TRANSFER**, the solution is automatically pumped through the transfer hose to a concentrate holding tank. This is a timed operation. Alternately, the fill gun attachment may be connected to the transfer line, for filling of individual containers. When using the fill gun attachment, the transfer step is placed in the hold state by pressing the **START / HOLD** button. This holds the transfer pump timer and allows the operator time to empty the tank manually.

Upon completion of the **TRANSFER** operation the **CYCLE COMPLETE** indicator will light and the floor drain valve will open to drain any residual solution from the unit.

NOTE: Quality Control testing should be conducted at this time. Refer to the Quality Control section 3.1 for instructions on carrying out this mandatory process. Label concentrate in tank "HOLD" or "QUARANTINE" until QC tests are complete.

8. *ACID BATH concentrate should be stored NOT longer than 2 weeks (14 DAYS) FROM the date of mixing.*

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ADDENDUM 4

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3.1 QUALITY CONTROL

1. Equipment needed

For Conductivity and pH Measurements:

Calibrated beaker, 500ml

Volumetric pipette, 10ml

Conductivity Meter, range to 15 millimhos

Standard Solution, for calibration

2. Sampling, Conductivity

With the sampling pipette, collect 10ml of concentrate solution from the mixing tank and transfer to beaker.

Add 340ml of AAMI quality water to the beaker, mix well.

From the dialysate mixture in the beaker, take a sufficient size sample to test in your conductivity meter.

TEMPERATURE
COMPENSATED

Compare results to the expected values on the Granulyte package and control document.

NOTE: If conductivity is low, check control document to ensure that all bags have been entirely emptied into the mixer. Also, visually check the bottom of the mixer to see if there are any undissolved granules. If so, continue mix cycle for 10 minutes, or until all granules are in solution, and retest.

3. Sampling, pH

Using dialysate mixture described above, take a sufficient size sample to test in your pH meter.

Compare results to the expected values on the Granulyte package and control document.

NOTE: If pH is low, check control document to see if the bag of sodium diacetate has been added to the concentrate in the mixer. Additionally, verify that there is one empty bag of sodium diacetate. Once this verification is made, mix batch for an additional 10 minutes and retest for pH.

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ADDENDUM 5

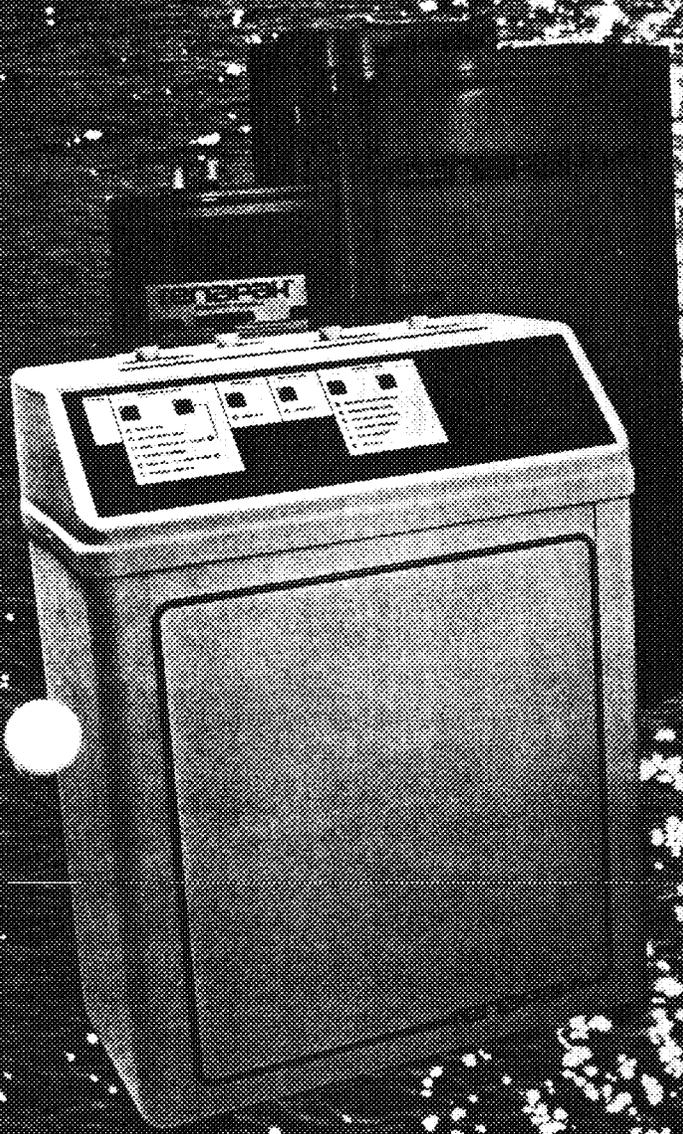
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renapak

CONCENTRATE MANUFACTURING SYSTEM

QUALITY
ECONOMY
CONVENIENCE

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ESSENTIAL

Concentrate Manufacturing System

COMPLETE LINE OF CONCENTRATES

Renapak™ manufactures both acetate and bicarbonate concentrates to meet all your patient needs.

Acetate

Concentrate plays a critical role in the hemodialysis procedure. In order to ensure exact concentrate composition, Renal Systems scientifically blends each formulation. Many Renapak™ Powdered Concentrate formulas are available from stock for both batch and proportioning systems. Custom formulations are prepared upon request to meet your patients' individual needs.

Bicarbonate

Bicarbonate dialysis, the original method of treating patients has become the preferred alternative therapy for many patients. Studies indicate that bicarbonate dialysis improves patient comfort by reducing such symptoms as post dialysis nausea, vascular instability, fatigue, and headache. With Renapak™, prescribing bicarbonate dialysate doesn't have to be limited to a select group of patients. It is affordable and available for everyone. Renal Systems stocks a variety of stable, additive-free, bacteriostatic bicarbonate concentrate formulas for proportioning machines.

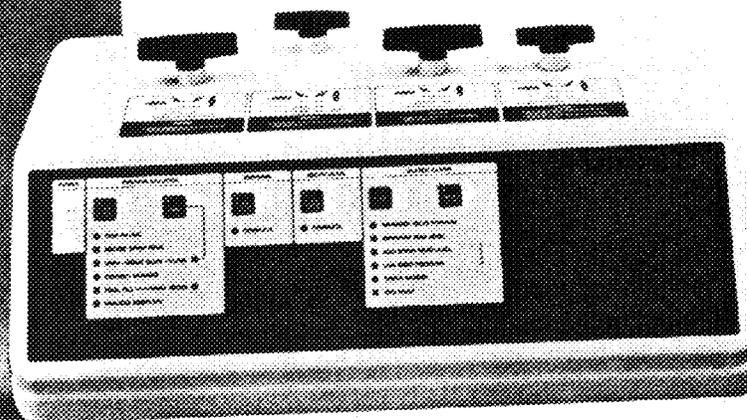
Control Valves
Control dispensing, machine draining, recirculation and mixing, chemical addition and dilution.

Water Proof, Touch Sensitive Control Panel
Organized in separate, well defined sectors, with touch activated switches and light emitting diodes for efficient, sequential operator prompting.

Hydraulic Control Console
Contains filling, priming and venting, that are reliable and easy to operate.

EASY TOUCH CONTROL

Renapak's Hydraulic Control Console automatically guides the operator through solution preparation and dispensing procedures. The step-by-step instructions are prompted by the panel's audible and visible indicators, making Renapak™ easy to operate.



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renapak™

Now you can manufacture your own acetate or bicarbonate hemodialysis concentrate, reduce costs and maintain complete quality control. The RS-8400 Renapak™ Concentrate Manufacturing System is an easy-to-use, professional concentrate manufacturing system. It allows dialysis center personnel to prepare all your hemodialysis concentrate on site. Costly delivery charges of premixed concentrate in drums are eliminated. Renapak™ was developed by Renal Systems, a leader in concentrate manufacturing. It features state-of-the-art manufacturing equipment, documented quality control processes, detailed instructions, USP (or equivalent) grade chemicals and reliable quality control instruments.

COST EFFECTIVE

Renapak™ Concentrate Manufacturing System significantly reduces the cost of acetate and bicarbonate concentrate for your dialysis patients. Preparation is done on-site. You provide your own water instead of paying expensive freight delivery charges. Handling and storage of large volumes of premixed concentrate is eliminated. Bulky container inventory is obsolete. Storage space is available for other functions.

QUALITY CONTROL

For more than ten years, Renal Systems has manufactured and supplied quality acetate and bicarbonate hemodialysis bath concentrate to dialysis centers, hospitals and home patients. Now you can prepare these same quality concentrates in your center. Renal Systems provides prescription acetate and bicarbonate concentrate "dry" chemicals that are precisely prepared for use with Renapak™. These dry chemicals are pretested, premeasured and are available in numerous formulations. Renapak™ dissolves the pretested dry chemical powder and thoroughly mixes, filters and dispenses the liquid concentrate into storage containers.

Renal Systems also provides support instruments, training, and instruction manuals necessary to perform your own in-house quality control. The RS-2120 and RS-2130 Concentrate and Bicarbonate Conductivity Meters are factory calibrated to test for correct mixture prior to filtering. Solution conductivity specifications are indicated on the formulation label attached to each drum of Renapak™ Powdered Concentrate.

SAFE, SIMPLE OPERATION

Renapak™'s microcomputer controlled Hydraulic Control Console combines precision with simplicity for reliable performance. The control panel is organized with touch activated switches and message lights prompting the user step-by-step through the process. Renapak™ Concentrate Manufacturing System automatically fills the tank to predetermined computer controlled water levels. The console also controls a unique, proprietary chemical pick-up system that loads the dry chemicals into the mixing tank. Audible and visible indicators diagnose procedural or machine related problems.

Mixing Tank
130 gallon (492 liter) capacity for final liquid concentrate dilution and mixing. Includes cover with attached level sensors, skimmer, recirculation, suction and spray head lines.

Chemical Suction Wand
Conveniently transfers chemicals from shipping container to tank; eliminates lifting of powder.

Spray Head Cover/Attachment
Helps control solution flow for diluting powder to a chemical slurry.

Precisely Premeasured Dry Chemicals
No measuring or weighing required.
No unnecessary shipping of water.



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57

FIRST IN BICARBONATE CONCENTRATE

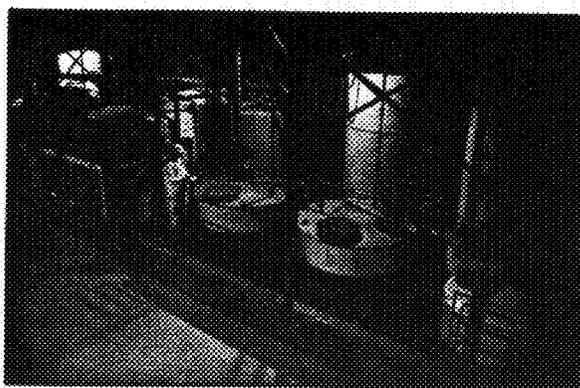
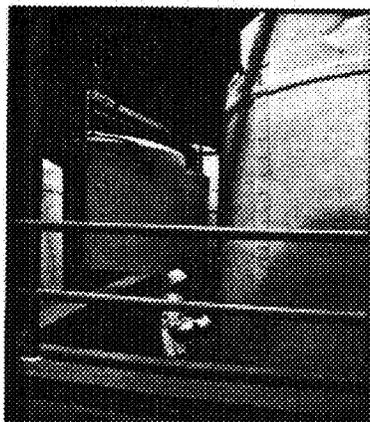
In 1978, Renal Systems was the first company to offer acid and bicarbonate concentrates for three-stream proportioning delivery systems. With this innovation, we helped you provide superior hemodialysis treatment for your patients.

THE LEADING SUPPLIER — THE MOST COMPLETE LINE

We are still the leading supplier of high quality concentrates for bicarbonate-type kidney machines. Only Renal Systems provides a complete line of concentrates with special Short Dialysis (SD™) formulas, Citrate Dialysis (CD™) formulas, low calcium formulas, and of course, standard formulas. We offer RENASOL™ liquid bicarbonate solutions for use with industry-norm 36.83 X machines. We also offer CENTRISOL™ solutions for use with 45 X machines.

STATE-OF-THE-ART MANUFACTURING FACILITY

Renal Systems' years of experience, combined with the most technologically advanced concentrate manufacturing facility, enable us to provide the finest hemodialysis concentrates. And although our multi-million dollar manufacturing plant is recognized for its unmatched superiority, we continue to invest substantially in future technological innovations that make us the "reference standard" for the industry. All Renal Systems concentrates are prepared in our custom designed plant using computer automated batch preparation. Only Renal Systems utilizes the exclusive Renapure™ process to manufacture the highest quality hemodialysis concentrates. Renal Systems concentrates are made using our sophisticated multistage water treatment facility. All bottles are filled aseptically in an HEPA filtered environment. Final product is meticulously checked by our Quality Control laboratory using the latest analytical equipment to guarantee correct chemical concentrations.



LABOR SAVING AND COST-EFFECTIVE

Renal Systems' liquid bicarbonate solutions save staff time by eliminating the need to mix and test powders. Since the solutions are thoroughly blended and filtered at our factory, conductivity readings are always consistent. There are no residues to clog the fluid path of your kidney machines and cause machine malfunctions.

STABLE, NON-PYROGENIC AND BACTERIA FREE

Our solutions are stable for eighteen months. They are provided to you pyrogen free and bacteria free, for use in high flux dialysis. For your added protection, all concentrate is packaged in tamper-proof containers.

ACCURATE PRODUCT IDENTIFICATION — COLOR-CODED PACKAGING

To ensure that the proper solution is used with the proper machine, Renal Systems' labels and bottle caps are color-coded. RENASOL is red, and CENTRISOL is purple. Each container is clearly labeled to ensure rapid, positive identification of formula numbers, concentrate type, ingredients (USP or better quality) and expiration date. Our labeling complies with AAMI standards.

DEPENDABLE QUALITY AND SERVICE NATIONWIDE

Renal Systems has a well-earned reputation for high quality products and reliable service. Our commitment and performance remain unequalled by any of the "newcomers" to this field who may be low budget but high risk. Renal Systems provides the right concentrate for the right machine at the right time. We supply concentrates to all 50 states and a number of foreign countries. Whatever you need and wherever you need it, you can count on us.

ORDERING INFORMATION

RENASOL™ LIQUID BICARBONATE CONCENTRATE

Product Code: BC-1-L

4 bottles, each containing 1 US gallon (3.78 liters), are packaged in each case. Used with 36.83 X machines such as the Baxter (Travenol/Extracorporeal) SPS*, CD Medical/Drake Willock*, Hospal Monitral*, Gambro AK-10*, and Fresenius* dialysis delivery systems.

CENTRISOL™ LIQUID BICARBONATE CONCENTRATE

Product Code: MB-330-L

4 bottles, each containing 1 US gallon (3.78 liters), are packaged in each case. Used with 45 X machines such as the Cobe Centry* delivery systems.

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RENAPAK™ CONCENTRATE MANUFACTURING SYSTEM PRICE LIST

Concentrate Manufacturing System Price
 Model RS-8400 Concentrate Manufacturing System \$13,495.00
 includes the following:

- RS8400-01 CONTROL MODULE
- RS8400-RP2 MIXING TANK — 130 GAL. CAPACITY
- 78234-002 ACID-BICARD SPRAY HEAD
- 75142-001 STORAGE TANK — 130 GAL. CAPACITY
- RS-2120 ACID/ACETATE CONCENTRATE CONDUCTIVITY METER
- RS-2130 BICARBONATE CONCENTRATE CONDUCTIVITY METER
- RS-8420 SODIUM BICARBONATE CONCENTRATE STORAGE SYSTEM

Components and optional Renapak accessories sold separately:

RS8400-01	CONTROL MODULE	\$7,995.00
RS8400-RP2	MIXING TANK — 130 GAL. CAPACITY	\$2,995.00
RS-8420	SODIUM BICARBONATE CONCENTRATE STORAGE SYSTEM	\$2,900.00
78234-001	ACETATE SPRAY HEAD	\$245.00
78234-002	ACID/BICARBONATE SPRAY HEAD	\$245.00
75142-001	STORAGE TANK — 130 GAL. CAPACITY	\$875.00
43048-001	FILTER CARTRIDGE (1.0 μ)	\$10.95
43049-001	FINAL FILTER CARTRIDGE (0.1 μ)	\$94.00
43056-000	SURFACE SKIMMER FILTER	\$5.95
RS-2100A	DIALYSATE METER	\$495.00
CS134	CONCENTRATE CONDUCTIVITY STANDARD (FOR USE WITH RS-2100A METER ABOVE) (8) 225 ml. Bottles/Case	\$24.00/case
RS-2120	ACETATE/ACID CONCENTRATE CONDUCTIVITY METER	\$495.00
CS1540	CONCENTRATE CONDUCTIVITY STANDARD (FOR USE WITH RS-2120 METER ABOVE) (8) 225 ml. Bottles/Case	\$24.00/case
RS-2130	NaHCO ₃ CONDUCTIVITY METER	\$495.00
CS750	NaHCO ₃ CONDUCTIVITY STANDARD (FOR USE WITH RS-2130 METER ABOVE) (8) 225 ml. Bottles/Case	\$24.00/case
RS-2140	COBE (26.14X) BICARBONATE CONCENTRATE CONDUCTIVITY METER	\$495.00
CS440	NaHCO ₃ CONDUCTIVITY STANDARD (FOR USE WITH RS-2140 METER ABOVE) (8) 225 ml. Bottles/Case	\$24.00/case

Terms are Net, 30 days with approved credit. F.O.B. Minneapolis, Minnesota.
 Effective January 1, 1989.

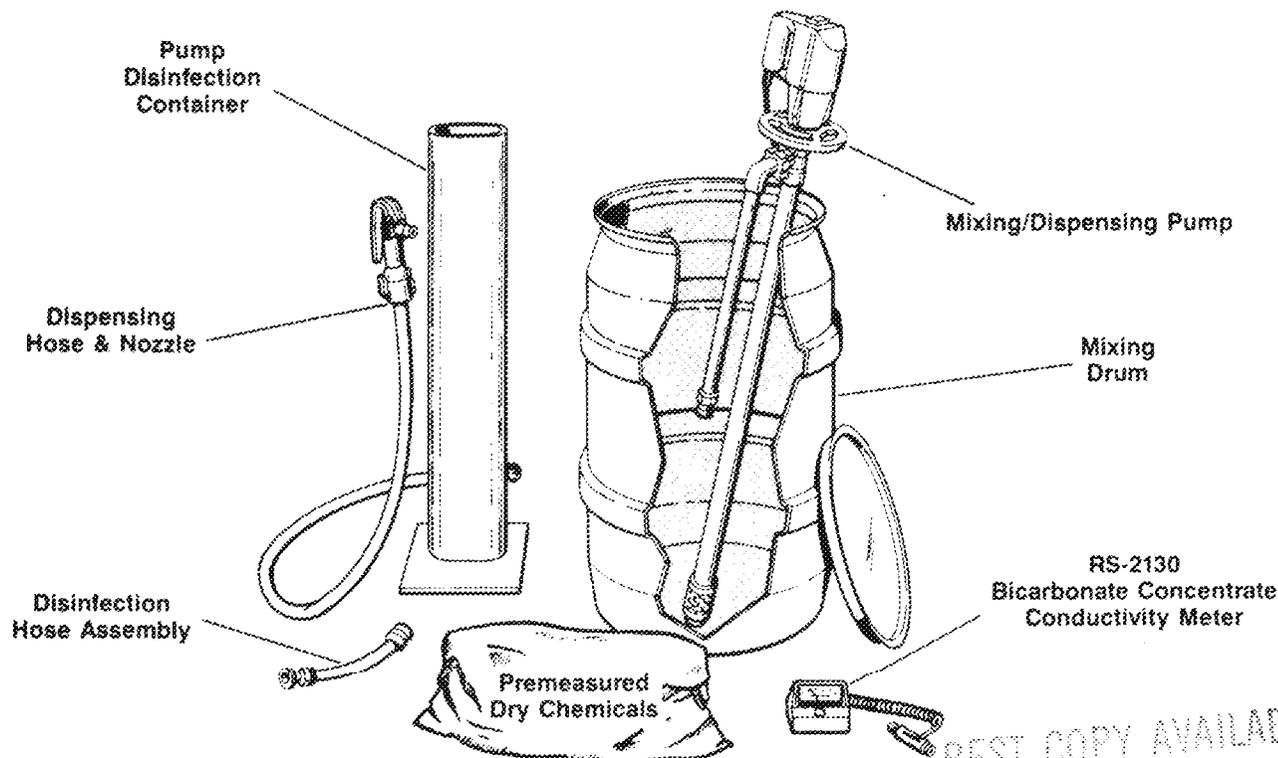
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RS-2500 Mixing System for Sodium Bicarbonate Hemodialysis Concentrate

The RS-2500 Mixing System allows rapid, on-site preparation of large volumes of sodium bicarbonate hemodialysis concentrate from pre-measured dry chemicals and water. The system both mixes and dispenses the concentrate. Mixing is accomplished by recirculating water and chemicals with the high volume, high velocity pump.



1. Add one bag of premeasured chemicals to the plastic drum.	2. Add water to fill line.	3. Operate pump until chemicals are dissolved.	4. Confirm correct conductivity.	
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For centers practicing fast dialysis or performing large numbers of bicarbonate treatments, the RS-2500 Mixing System offers the following benefits:

- **Saves Labor** — The system mixes large quantities of concentrate faster than manual mixing.
- **Cost Effective** — Dry chemicals save shipping costs when compared to liquid concentrate.
- **Saves Time** — 50 gallons (189 liters) of concentrate can be mixed in less than 30 minutes.
- **Flexible** — The mixing pump can also be used as a drum pump.
- **Easy Dispensing** — The mixing pump dispenses the concentrate to storage tanks or individual bottles or jugs.
- **Quality Control** — The RS-2130 Bicarbonate Concentrate Conductivity Meter confirms proper dilution and mixing.
- **Easy Disinfection** — The system includes a pump disinfection container and a hose disinfection assembly.
- **Portable** — Lightweight, easy to move and store.

See instructions for complete details.
Federal (U.S.A.) law prohibits dispensing without prescription.

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RS-JR-12-86-1

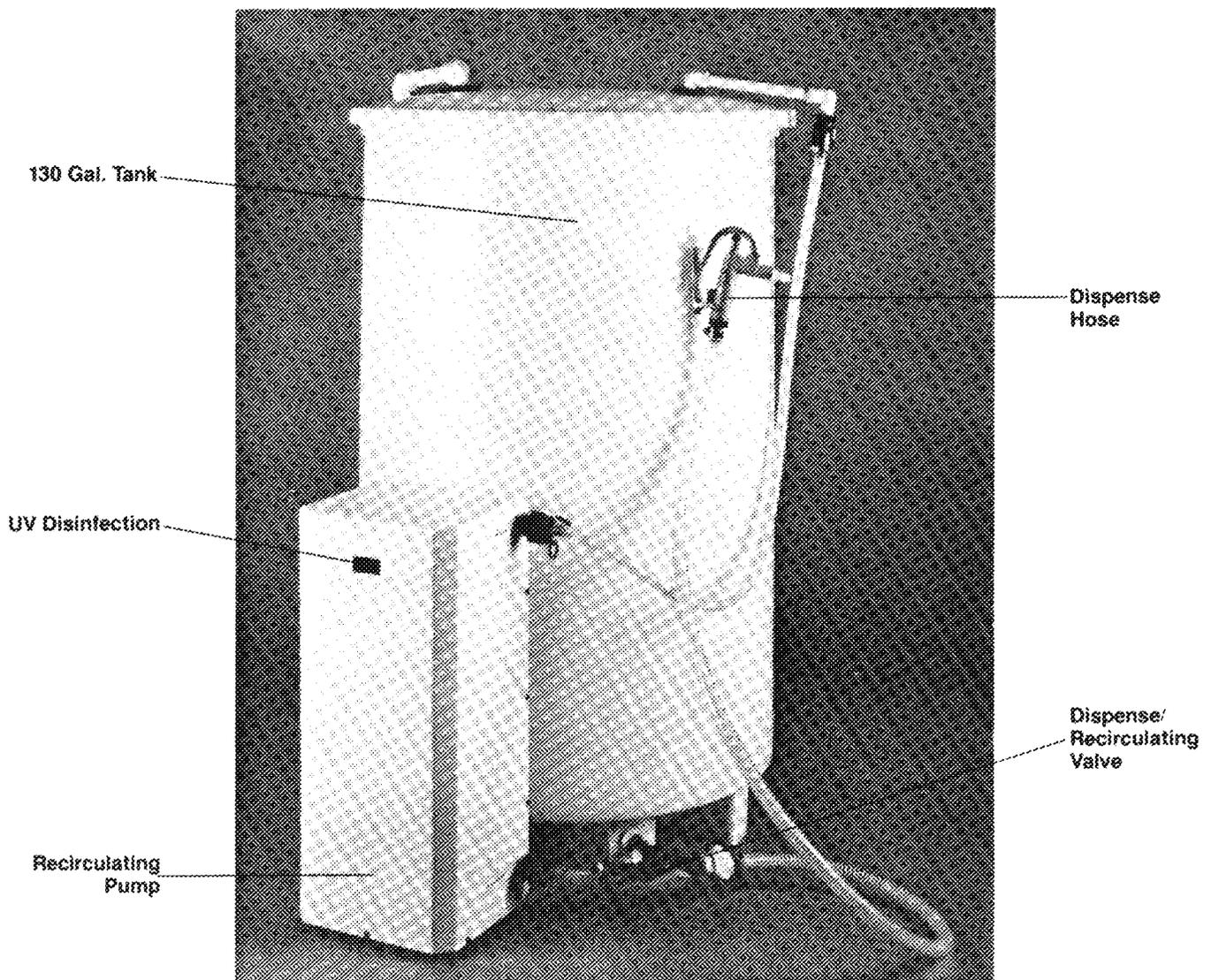
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RS-8420

Sodium Bicarbonate Concentrate Storage System

- Safety store bicarbonate concentrate for up to 7 days
- Proven UV disinfection
- Mix larger batches of solution, saving time & labor
- Compatible with RS-2500 mixing system solution and Renapak® concentrate manufacturing system



For more information contact:

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RENAPAK™ CONCENTRATE MANUFACTURING SYSTEM PRICE LIST

Concentrate Manufacturing System Price
 Model RS-8400 Concentrate Manufacturing System \$13,495.00
 includes the following:

- RS8400-01 CONTROL MODULE
- RS8400-RP2 MIXING TANK — 130 GAL. CAPACITY
- 78234-002 ACID-BICARD SPRAY HEAD
- 75142-001 STORAGE TANK — 130 GAL. CAPACITY
- RS-2120 ACID/ACETATE CONCENTRATE CONDUCTIVITY METER
- RS-2130 BICARBONATE CONCENTRATE CONDUCTIVITY METER
- RS-8420 SODIUM BICARBONATE CONCENTRATE STORAGE SYSTEM

Components and optional Renapak accessories sold separately:

RS8400-01	CONTROL MODULE	\$7,995.00
RS8400-RP2	MIXING TANK — 130 GAL. CAPACITY	\$2,995.00
RS-8420	SODIUM BICARBONATE CONCENTRATE STORAGE SYSTEM	\$2,900.00
78234-001	ACETATE SPRAY HEAD	\$245.00
78234-002	ACID/BICARBONATE SPRAY HEAD	\$245.00
75142-001	STORAGE TANK — 130 GAL. CAPACITY	\$875.00
43048-001	FILTER CARTRIDGE (1.0 μ)	\$10.95
43049-001	FINAL FILTER CARTRIDGE (0.1 μ)	\$94.00
43056-000	SURFACE SKIMMER FILTER	\$5.95
RS-2100A	DIALYSATE METER	\$495.00
CS134	CONCENTRATE CONDUCTIVITY STANDARD (FOR USE WITH RS-2100A METER ABOVE) (8) 225 ml. Bottles/Case	\$24.00/case
RS-2120	ACETATE/ACID CONCENTRATE CONDUCTIVITY METER	\$495.00
CS1540	CONCENTRATE CONDUCTIVITY STANDARD (FOR USE WITH RS-2120 METER ABOVE) (8) 225 ml. Bottles/Case	\$24.00/case
RS-2130	NaHCO ₃ CONDUCTIVITY METER	\$495.00
CS750	NaHCO ₃ CONDUCTIVITY STANDARD (FOR USE WITH RS-2130 METER ABOVE) (8) 225 ml. Bottles/Case	\$24.00/case
RS-2140	COBE (26.14X) BICARBONATE CONCENTRATE CONDUCTIVITY METER	\$495.00
CS440	NaHCO ₃ CONDUCTIVITY STANDARD (FOR USE WITH RS-2140 METER ABOVE) (8) 225 ml. Bottles/Case	\$24.00/case

Terms are Net, 30 days with approved credit. F.O.B. Minneapolis, Minnesota.
 Effective January 1, 1989.

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CENTRISOL™ BICARBONATE CONCENTRATE

FORMULATIONS AND PRICE LIST

To be used with Cobe Centry RX or properly calibrated Fresenius A200B Equipment (45X dilution) only.

Not for Parenteral Use

Directions: The SB-100 liquid acid concentrate series is formulated to be used in conjunction with Renal Systems MB-330 Series Sodium Bicarbonate Concentrate only in a compatible 45X dilution three stream artificial kidney (hemodialysis) machine. Refer to instructions provided by artificial kidney machine manufacturer prior to starting dialysis. For every 45 volume parts of dialysate: mix 1 volume part of this concentrate and 1.72 volume parts of properly mixed MB-330 Series Sodium Bicarbonate Concentrate with 42.28 volume parts of Purified Water (U.S.P. or equivalent).

SODIUM BICARBONATE PROPORTIONING FORMULAS (45X)

Liquid acid concentrate plus MB-330 Series Bicarbonate Concentrate Powder will yield the following concentrations when properly diluted and proportioned:

Formula	Na +	Ca + +	K +	Mg + +	Chloride	Acetate	Bicarbonate	Dextrose
SB-111	137	3.0	2.0	0.75	105.75	2	35	200 mgm%
SB-119	137	3.0	1.0	0.75	104.75	2	35	200 mgm%
SB-123	137	3.0	0.0	0.75	103.75	2	35	200 mgm%
SB-127	137	3.0	3.0	0.75	106.75	2	35	200 mgm%
SB-129	137	3.0	4.0	0.75	107.75	2	35	200 mgm%
SB-130	137	0	0	0.75	100.75	2	35	200 mgm%

Custom formulations available upon request.

B-100 Series Liquid Acid Concentrate:

Package	Standard Formulas Gallons	Price	Custom Formulas Order Quantities	Case Price	Drum Price
Cases	Four (4) 1 gallon containers per case	\$ 20.00	220 Gallons 875 Gallons	\$30.00 \$27.00	\$300.00 \$270.00
Drums	55 gallon	\$200.00	1840 Gallons	\$23.00	\$230.00

*Delivery must be accepted on all custom formulations within 90 days.

Bicarbonate (Part B) Proportioning Components

MB-330 series bicarbonate concentrate powder is packaged in the following configurations

FORMULA	DESCRIPTION and PACKAGING	PRICE
MB-330	Packaged 20 packets per case. Each packet dilutes to 8 liters (2.1 U.S. gallons) of liquid concentrate.	\$55/case
MB-330-L	Liquid bicarbonate concentrate packaged four (4) 1 U.S. gallon (3.78 liters) containers per case.	\$25/case
MB-330-25*	Packaged 2 bags per case. Each bag dilutes to 94.6 liters (25 U.S. gallons) of liquid concentrate.	\$65/case
MB-330-50*	Packaged 1 bag per case. Dilutes to 189.2 liters (50 U.S. gallons) of liquid concentrate.	\$60/case

*MB-330-25 and MB-330-50 are used in conjunction with the Renal Systems RS-2500 Mixing System.

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57

RENASOL™ BICARBONATE CONCENTRATE

FORMULATIONS AND PRICE LIST

These formulas are designed to be used with the following 36.83 dilution Three Stream Equipment: Gambro, Drake-Willock (CD Medical), Hospal, Travenol and Fresenius.

NOT FOR PARENTERAL USE

Direction: The SB-1000 liquid acid concentrate series is formulated to be used in conjunction with Renal Systems BC-1 Series Sodium Bicarbonate Concentrate only in a compatible 36.83X dilution three stream artificial kidney (hemodialysis) machine. Refer to instructions provided by artificial kidney machine manufacturer prior to starting dialysis. For every 36.83 volume parts of dialysate; mix 1 volume part of this concentrate and 1.83 volume parts of Sodium Bicarbonate Concentrate (BC-1 Series) with 34 volume parts of Purified Water (U.S.P. or equivalent).

SODIUM BICARBONATE PROPORTIONING FORMULAS (36.83X)

Liquid acid concentrate plus BC-1 Series Bicarbonate Concentrate Powder will yield the following concentrations when properly diluted and proportioned:

Formula	Na +	Ca + +	K +	Mg + +	Chloride	Acetate	Bicarbonate	Dextrose
SB-1003	139	3.5	2.0	1.0	106.5	4	35	200 mgm%
SB-1004	139	3.5	3.0	1.0	107.5	4	35	250 mgm%
SB-1005	139	3.5	0	1.0	104.5	4	35	200 mgm%
SB-1030	139	0	0	1.0	101.0	4	35	200 mgm%
SB-1040	139	0	2.0	1.0	103.0	4	35	200 mgm%

Package	Price	Custom Formulas Order Quantities	Case Price	Drum Price
2.5 gallon/case	\$ 20.00	220 Gallons	\$30.00	\$300.00
		875 Gallons	\$27.00	\$270.00
55 U.S. Gallon Drum	\$200.00	1840 Gallons	\$23.00	\$230.00

*Delivery must be accepted on all custom formulations within 90 days.

BICARBONATE (PART B) PROPORTIONING COMPONENTS

BC-1 Series Bicarbonate Concentrate Powder is packaged in the following configurations:

FORMULA	DESCRIPTION and PACKAGING	PRICE
BC-1	Packaged 20 packets per case. Each packet dilutes to 9.46 liters (2½ U.S. gallons) of liquid concentrate.	\$55/case
BC-1-L	Liquid bicarbonate concentrate packaged four (4) 1 U.S. gallon (3.78 liters) containers per case.	\$25/case
BC-1-25*	Packaged 2 bags per case. Each bag dilutes to 94.6 liters (25 U.S. gallons) of liquid concentrate.	\$65/case
BC-1-50*	Packaged 1 bag per case. Dilutes to 189.2 liters (50 U.S. gallons) of liquid concentrate.	\$60/case

*BC-1-25 and BC-1-50 are used in conjunction with the Renal Systems RS-2500 Mixing System.

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58

NEPHROSOL™ ACETATE CONCENTRATE

FORMULATIONS AND PRICE LIST

ACETATE Concentrate plays a critical role in the hemodialysis procedure. In order to ensure exact concentrate composition, Renal Systems scientifically blends each formulation. Concentrate formulas are available from stock for both batch and proportioning systems. Custom formulations can be prepared upon request to meet your patients' individual needs.

For use with the following equipment: Gambro, Drake-Willock (CD Medical), Hospital, Travenol, Fresenius, Cobe, Bio Systems, Organon-Teknika (Redy™)

ACETATE CONCENTRATE STOCK FORMULATIONS

For Acetate Proportioning and Batch Systems

Formula	Na +	Ca + +	K +	Mg + +	Chloride	Acetate	Dextrose
RS-202	134 mEq/L	2.50 mEq/L	0.0 mEq/L	1.50 mEq/L	101.00 mEq/L	37.00 mEq/L	250 mgm %
RS-223	134	3.00	2.0	1.50	105.50	35.00	200 mgm %
RS-220	135	3.00	1.0	1.00	105.00	35.00	200 mgm %
RS-81	135	3.50	2.0	1.00	105.50	36.00	200 mgm %
RS-2	140	3.50	2.0	0.75	108.00	38.25	0 mgm %
RS-62	140	3.50	2.0	1.50	106.00	41.00	100 mgm %
RS-246	138	3.50	0.0	1.50	106.00	37.00	200 mgm %
RS-284	140	3.25	1.0	1.00	110.25	35.00	200 mgm %
RS-217	140	2.50	1.3	1.50	109.30	36.00	250 mgm %
RS-84	140	3.25	1.5	1.00	110.75	35.00	200 mgm %
RS-27	140	3.50	2.0	1.00	111.50	35.00	200 mgm %
RS-225	140	3.25	2.0	1.00	111.25	35.00	200 mgm %
RS-607	140	3.25	3.0	1.00	107.25	40.00	200 mgm %

All of above formulas are available in both drums and 3.43 liter containers.

Custom formulations available upon request.

Package	Price	Custom Formulas Order Quantities	Case Price	Drum Price
4x3.43 liter/cs	\$ 20.00	220 Gallons	\$30.00	\$300.00
		875 Gallons	\$27.00	\$270.00
55 U.S. Gallon Drum	\$200.00	1840 Gallons	\$23.00	\$230.00

*Delivery must be accepted on all custom formulations within 90 days.

For Proportioning Systems: Set machine at 1:34 dilution ratio.

For Batch Systems:

To make 100 liters of dialysate, measure 2.86 liters of concentrate and dilute with water to 100 liters.

To make 120 liters of dialysate, measure 3.43 liters of concentrate and dilute with water to 120 liters.

To make 385 liters of dialysate, measure 11.0 liters of concentrate and dilute with water to 385 liters.

Terms are Net, 30 days with approved credit. F.O.B. Minneapolis, Minnesota.

Effective January 1, 1989.

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54

**NEPHROSOL™
RENAPAK® ACETATE CONCENTRATE**

The following formulas are to be used only with the RP2-8400 Renapak® Concentrate Manufacturing System, an easy-to-use, professional concentrate manufacturing system. It allows dialysis center personnel to prepare hemodialysis concentrate on site.

FORMULATIONS AND PRICE LIST

STOCK FORMULATIONS

Formula	Na +	Ca + +	K +	Mg + +	Chloride	Acetate	Dextrose
RP2-223	134	3.00	2.0	1.50	105.50	35.00	200 mgm %
RP2-2	140	3.50	2.0	0.75	108.00	38.25	0 mgm %
RP2-284	140	3.25	1.0	1.00	110.25	35.00	200 mgm %
RP2-225	140	3.25	2.0	1.00	111.25	35.00	200 mgm %
RP2-607	140	3.25	3.0	1.00	107.25	40.00	200 mgm %

Custom formulations available upon request.

Powdered Formulations	Gallons Produced	Dextrose Content		
		0 mgm%	100 mgm%	200 mgm%
RP2-XXX Acetate Series	130	\$195.00	\$208.00	\$221.00

Terms are Net, 30 days with approved credit. F.O.B. Minneapolis, Minnesota.

BICARBONATE PROPORTIONING KITS

KIT C

Fifteen (15) cases of SB-100 series Liquid Acid Concentrate
 Three (3) cases of MB-330 Bicarbonate Concentrate Powder

	<u>With Dextrose</u>	<u>Without Dextrose</u>
1-9 Kits	\$411.00	\$400.00
10 plus Kits	\$347.00	\$338.00

KIT D

One (1) 55 gallon drum SB Liquid acid Concentrate
 Three (3) cases of MB-330 Bicarbonate Concentrate Powder

	<u>With Dextrose</u>	<u>Without Dextrose</u>
1-9 Kits	\$396.00	\$397.00
10 plus Kits	\$308.00	\$307.00

Please note Bicarbonate Concentrate may be purchased in kits or individual components.

Terms are Net, 30 days with approved credit. F.O.B. Minneapolis, Minnesota.

CENTRISOL™ RENAPAK® BICARBONATE CONCENTRATE

The following formulas are to be used only with the RS-8400 Renapak® Concentrate Manufacturing System an easy-to-use, professional concentrate manufacturing system. It allows dialysis center personnel to prepare hemodialysis concentrate on site. SB-100-R series powdered acid concentrate is formulated to be used in conjunction with Renal Systems MB-330-R series.

Formula	Na +	Ca + +	K +	Mg + +	Chloride	Acetate	Bicarbonate	Dextrose
SB-111-R	137	3.0	2.0	0.75	105.75	2	35	200 mgm%
SB-119-R	137	3.0	1.0	0.75	104.75	2	35	200 mgm%
SB-123-R	137	3.0	0.0	0.75	103.75	2	35	200 mgm%
SB-127-R	137	3.0	3.0	0.75	106.75	2	35	200 mgm%

	Gallons Produced	Dextrose Content		
		0 mgm%	100 mgm%	200 mgm%
SB-100-R Series	130	\$174.00	—	\$194.00
MB-330-R	130	\$117.00	—	—

OR \$1.49/gal

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BICARBONATE PROPORTIONING KITS

KIT A

One (1) 55 gallon drum SB Liquid Acid Concentrate
Two (2) cases of BC Dry Chemical Packs

	<u>With Dextrose</u>	<u>Without Dextrose</u>
1-9 Kits	\$240.00	\$230.00
10 or more Kits	\$210.00	\$200.00

KIT B

Eleven (11) cases of SB Liquid Acid Concentrate (two) 2.5 gallon containers per case
Two (2) cases of BC Dry Chemical packs

	<u>With Dextrose</u>	<u>Without Dextrose</u>
1-9 Kits	\$264.00	\$254.00
10 or more Kits	\$234.00	\$224.00

Please note Bicarbonate Concentrate may be purchased in kit or component form.

Terms are Net, 30 days with approved credit. F.O.B. Minneapolis, Minnesota.

RENASOL™ RENAPAK® BICARB CONCENTRATE

The following formulas are to be used only with the RS-8400 Renapak® Concentrate Manufacturing System an easy-to-use, professional concentrate manufacturing system. It allows dialysis center personnel to prepare hemodialysis concentrate on site. SB-1000-R series powdered acid concentrate is formulated to be used in conjunction with Renal Systems BC-1-R series.

Formula	Na +	Ca + +	K +	Mg + +	Chloride	Acetate	Bicarbonate	Dextrose
SB-1003-R	139	3.5	2.0	1.0	106.5	4	35	200 mgm%
SB-1004-R	139	3.5	3.0	1.0	107.5	4	35	250 mgm%
SB-1005-R	139	3.5	0	1.0	104.5	4	35	200 mgm%

	Gallons Produced	Dextrose Content		
		0 mgm%	100 mgm%	200 mgm%
SB-1000-R Series	130	\$174.00	—	\$194.00
BC-1-R	130	\$117.00	—	—

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Toll Free (800) 328-3340
FAX 612-553-3387

**NEPHROSOL™
RENAPAK® ACETATE CONCENTRATE**

The following formulas are to be used only with the RP2-8400 Renapak® Concentrate Manufacturing System, an easy-to-use, professional concentrate manufacturing system. It allows dialysis center personnel to prepare hemodialysis concentrate on site.

FORMULATIONS AND PRICE LIST

STOCK FORMULATIONS

Formula	Na +	Ca + +	K +	Mg + +	Chloride	Acetate	Dextrose
RP2-223	134	3.00	2.0	1.50	105.50	35.00	200 mgm %
RP2-2	140	3.50	2.0	0.75	108.00	38.25	0 mgm %
RP2-284	140	3.25	1.0	1.00	110.25	35.00	200 mgm %
RP2-225	140	3.25	2.0	1.00	111.25	35.00	200 mgm %
RP2-607	140	3.25	3.0	1.00	107.25	40.00	200 mgm %

Custom formulations available upon request.

Powdered Formulations	Gallons Produced	Dextrose Content		
		0 mgm%	100 mgm%	200 mgm%
RP2-XXX Acetate Series	130	\$195.00	\$208.00	\$221.00

Terms are Net, 30 days with approved credit. F.O.B. Minneapolis, Minnesota.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, Maryland 20850

MAY 29, 1991

FRESENIUS USA, INC.
ATTN: TOM FOLDEN
4090 PIKE LANE
CONCORD, CA 94520

510(k) Number: K911459
Product: GRANULYTE POWDER
DIALYSATE
CONCENTRATE AND MIXI

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefax material as part of your official premarket notification submission unless specifically requested of you by an FDA official.

If after 30 days the requested information is not received, we will discontinue review of your submission and proceed to delete your file from our review system. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 427-1190.

Sincerely yours,

Robert I. Chissler
Chief, Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

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63

DO NOT REMOVE THIS ROUTE SLIP!!!!

K-91-1459

5/29/91

FROM: FRESENIUS USA, INC. ATTN: TOM FOLDEN 4090 PIKE LANE CONCORD, CA 94520 SHORT NAME: FRESENIUS		LETTER DATE 04/02/91	LOGIN DATE 04/03/91	DUE DATE 07/02/91
		TYPE OF DOCUMENT: 510 (k)		CONTROL # K911459
		PHONE NO: 415-676-1600 ESTABLISHMENT NO: 1713747		
TO: ODE/DMC	CONT. CONF.: ? STATUS : H REV PANEL : GU PAN/PROD CODE(S): GU/ / /			
SUBJECT: GRANULYTE POWDER DIALYSATE CONCENTRATE AND MIXING				
DECISION: DECISION DATE: / /	RQST INFO DATE: 05/29/91	INFO DUE DATE: 06/28/91		
	DATE: / /	DATE: / /		
	DATE: / /	DATE: / /		
	DATE: / /	DATE: / /		
	DATE: / /	DATE: / /		
	DATE: / /	DATE: / /		

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Memorandum

Date 5/24/91

From REVIEWER(S) - NAME(S) Ruth Hubbard, MD, CNJ

Subject 510(k) NOTIFICATION K911459

To THE RECORD

It is my recommendation that the subject 510(k) Notification:

- (A) Is substantially equivalent to marketed devices.
- (B) Requires premarket approval. NOT substantially equivalent to marketed devices.
- (C) Requires more data.
- (D) Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Additional Comments:

The submitter requests under 21 CFR §807.95:

Predicate Product Code w/Panel and class:

No Confidentiality

Confidentiality for 90 days

Continued Confidentiality exceeding 90 days

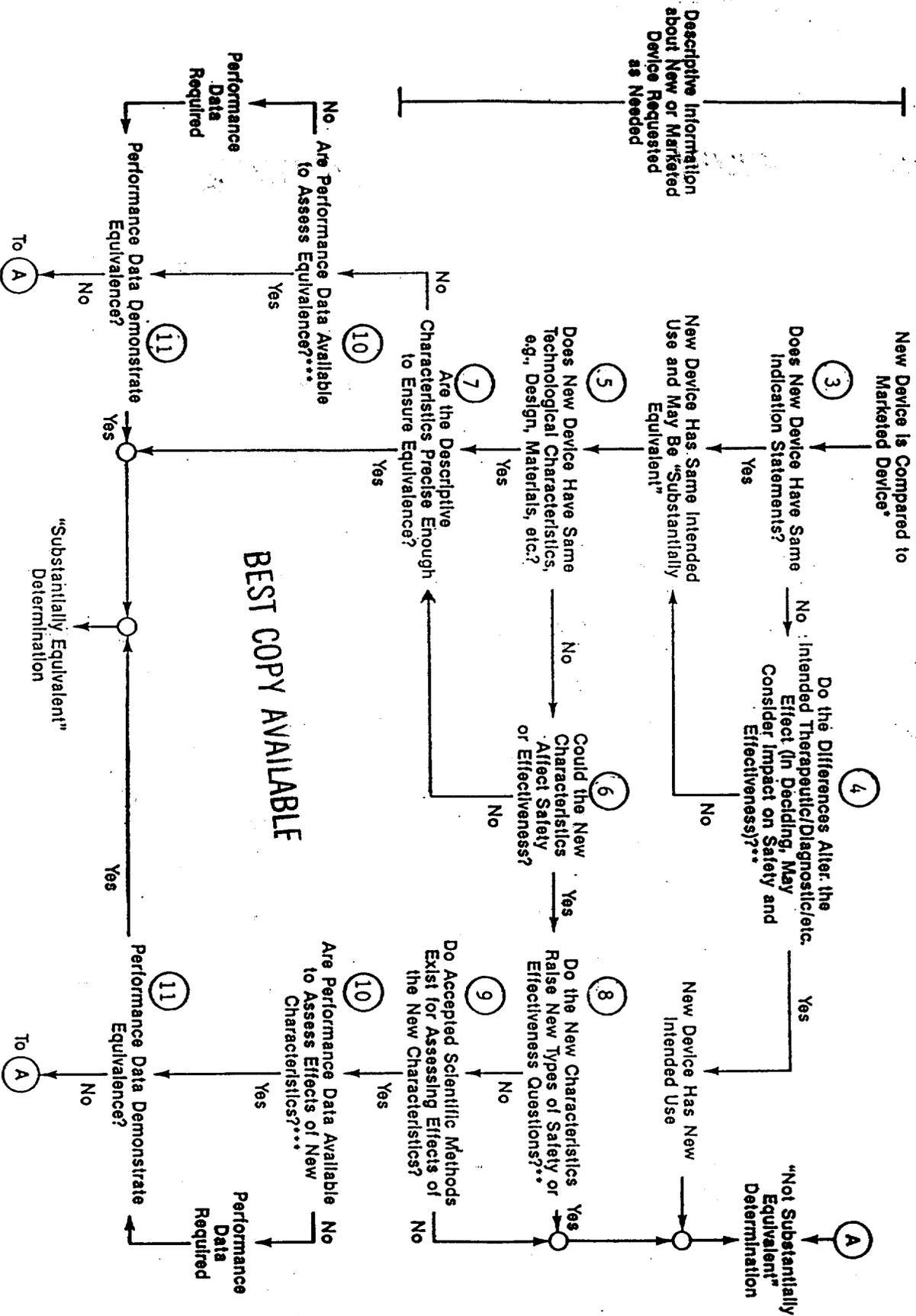
Additional Product Code(s) w/Panel (optional):

REVIEW: <u>E. Chen</u> (BRANCH CHIEF)	<u>AERDB</u> (BRANCH CODE)	<u>05-24-91</u> (DATE)
--	-------------------------------	---------------------------

FINAL REVIEW: _____
(DIVISION DIRECTOR) (DATE)

Handwritten signature and number 65

510(k) "Substantial Equivalence" Decision-Making Process (Detailed)



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Substitutions Compare New Devices to Marketed Devices. FDA Requests Additional Information if the Relationship Between Marketed and "Predicate" (Pre-Amendments or Reclassified Post-Amendments) Devices is Unclear.

Decision is Normally Based on Descriptive Information Alone, But Additional Testing Information is Sometimes Required. May Be in the 510(k), Other 510(k), The Center's Classification Files, or the Literature.

GC

MEMO TO THE RECORD

DATE: 23 MAY 91
FROM: RUTH W. HUBBARD

OFFICE: HFZ-420
DIVISION: DGGD/GU

SUBJECT: K911459 Fresenius USA, Inc.
Granulyte Powder Dialysate Concentrate and Mixing Device

CONTACT: Tom Folden

PHONE: (415)676-1600

This premarket notification is submitted for both hemodialysate bath concentrates and a machine to mix the powdered concentrates. The following additional information is needed in order to complete the review of these devices:

Dialysate Concentrates

1. Data must be provided on the range(s) of deviation of ionic concentration for each component in the concentrate(s) and the method by which this was established.
2. All instructions for use must instruct the user to use "AAMI quality water" for mixing all solutions.
3. Instructions should state that the user is to mix the concentrate in a "clean" and "calibrated" container.
4. Data must be provided demonstrating the length of time the acid concentrate may be stored once it is constituted and this time must be included on the label.
5. A comparison of the similarities and differences to the devices to which equivalence is claimed, must be provided.

Granulyte Concentrate Mixing System

1. A detailed description of all components of the "mixing system" must be provided.
2. All list of materials must be provided for all component parts as well as biocompatibility testing for materials that have direct contact with the dialysate concentrate.
3. The Quality Control section as referred to in the Operator's Manual must be provided.

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4. Details must be provided on the "computer" that controls the dissolution unit. Details must include any software modifications that have been made as this device is described as being microprocessor controlled. The firm must explain to what extent software controls the device including, but not limited to software requirements, device performance requirements, software development activities (hazard analysis, verification and validation activities, pass/fail requirements, software maintenance and change control during development and after the device is on the market), and verification and validation protocols and results demonstrating that safeguards were implemented and that the device performed over its intended range. It must be noted whether testing was performed before and/or after software/hardware integration and the firm must provide written affirmation stating that the described software was developed and tested according to the stated procedures and that the testing demonstrates that the requirements were met.
5. A comparison of the similarities and differences to the device to which equivalence is claimed must be provided.

I have discussed these issues with Mr. Folden and informed him that the document is being placed on hold. Review will continue upon receipt of this information.



RUTH W. HUBBARD, R.N., C.N.N.
Division of Gastroenterology-Urology
and General Use Devices

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFE-401)
1390 Piccard Drive
Rockville, Maryland 20850

APRIL 4, 1991

FRESENIUS USA, INC.
ATTN: TOM FOLDEN
4090 PIKE LANE
CONCORD, CA 94520

510(k) Number: K911459
Received: 04-03-91
Product: GRANULYTE POWDER
DIALYSATE
CONCENTRATE AND MIXI

We have received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required.

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so within 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

This legislation also requires anyone who asserts that a device is substantially equivalent to a class III device to: (1) certify that they have conducted a reasonable search of all information known, or otherwise available, about the generic type of device; and (2) provide a summary description of the types of safety and effectiveness problems associated with the type of device and a citation to the literature, or other sources of information, upon which they have based the description. The description should be sufficiently comprehensive to demonstrate that an applicant is fully aware of the types of problems to which the device is susceptible. If you have not provided this certification and description (with citations) in your premarket notification, please provide it as soon as possible. We cannot complete the review of your submission until you do so.

Please note that the Safe Medical Devices Act of 1990 may have additional requirements affecting your device. You will be informed of these requirements as they become effective.

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Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HPZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or their toll-free number (800) 638-2041, or contact me at (301) 427-1190.

Sincerely yours,

Robert I. Chissler
Chief, Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

FRESENIUS USA, INC.

K911459

090 Pike Lane
Concord, California 94520
(415) 676-1600

April 02, 1991

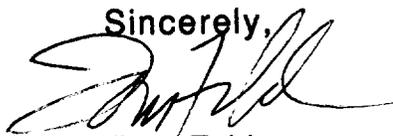
Food and Drug Administration
Center for Devices
Office of Device Evaluation
Document Control Center (HFZ-401)
1390 Piccard Drive
Rockville, Md. 20850

Re: 510 (k) Notification: Fresenius Granulyte™ Powder Dialysate
Concentrate with Mixing System

Gentlemen:

As required by 21 CFR Section 807, please find enclosed a 510 (k) submission by Fresenius USA for the Fresenius Granulyte™ Powder Dialysate Concentrate with Mixing System. Fresenius requests that the Commissioner determine that the Fresenius Granulyte Concentrate is substantially equivalent to existing products in US commercial distribution.

Sincerely,



Tom Folden
Director, Product Development
Fresenius, USA

™Trademark of Delmed, Inc.

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RECEIVED
3 APR 91 08 53
FBI/DOJ/OPS/PRIS

510 (k) PREMARKET NOTIFICATION

FRESENIUS USA

**GRANULYTE™ POWDER DIALYSATE
CONCENTRATE WITH AUTOMATED MIXING
SYSTEM**

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TABLE OF CONTENTS

PRODUCT NAME	1
ESTABLISHMENT REGISTRATION IDENTIFICATION	1
PRODUCT CLASSIFICATION	2
COMPLIANCE WITH SECTION 514	2
LABELING AND PACKAGING	2
PRODUCT DESCRIPTION	3
STATEMENT OF EQUIVALENCE	4
APPENDICES	5-15
OPERATORS MANUAL	16

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PRODUCT NAME:

The proposed product name for the product indicated in this registration is:

Fresenius Granulyte™ Powder Dialysate Concentrate and
Mixing System

The common name of this type of product is granulated dry dialysate for hemodialysis.

ESTABLISHMENT REGISTRATION IDENTIFICATION

The product indicated in this submission is manufactured by:

Delmed, Inc.
475 West 13th Street
Ogden, Utah 84404
Manufacturers Registration Number: 1713747

Fresenius USA is the sole distributor of the Granulyte concentrate and Mixing System. Fresenius' address is:

Fresenius USA
4090 Pike Lane
Concord, Ca 94520
Manufacturers Registration Number: 2937457

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PRODUCT CLASSIFICATION

Dialysate concentrate has been classified under section 510 of the Food, Drug and Cosmetic Act by the Gastroenterology and Urology Device panel as a Class II device.

COMPLIANCE WITH SECTION 514: PERFORMANCE STANDARDS

At this time there have been no standards established for this device. Therefore no action has been taken to comply with section 514 of the act.

LABELING AND PACKAGING

A sample of the proposed labeling for the Granulyte dialysate concentrate is enclosed in Appendix A1-A6.

The dry concentrates will be packaged in multi-ply, paper bags with a moisture barrier (~~polyethylene~~). The weight of each bag will be approximately 25 lbs., (weight will vary depending on formulation). The bags will be shipped in a "unit pack" consisting of an outer box (corrugated paper) and containing 15 bags of dry concentrate, enough to produce one 500 liter batch of liquid concentrate.

The acid component for the "acid bath" concentrates will be supplied by sodium diacetate in our formulations. (see appendix C). Each "unit pack" will contain, in addition to 14 bags of dry concentrate, one bag of sodium diacetate to be added to the mixing tank along with the other bags of dry concentrate.

Each "unit pack" container will have an individual stick-on label (Appendix A-1). Each bag will have an individual stick-on label with a peel-off section that is to be attached to the Batch Control Record at the time the bag is poured into the mixing tank, (Appendix A-2 and A-3).

All formulas of Granulyte Dry Concentrate (acid bath and acetate) will only be sold in the 500 liter equivalent "unit pack".

PRODUCT DESCRIPTION

The Fresenius Granulyte Powder Dialysate Concentrate is a dry, granulated, homogeneous powder that when dissolved into a prescribed quantity of R/O water provides a dialysate concentrate, whether acetate or bicarbonate, which can be used in proportioning type dialysis machines. A schematic of the mixing container and a detailed instructions for use is included in the enclosed operator's manual.

The raw materials used in the production of the dry granulate are:

- Sodium Chloride
- Potassium Chloride
- Calcium Chloride
- Magnesium Chloride
- Sodium Acetate
- Sodium Diacetate
- Dextrose, anhydrous
- Sodium Bicarbonate

All materials meet or exceed where appropriate. The dry granulate is packaged in 3-ply moisture resistant paper bags. Approximately 15 25 lb. bags are "unit packed" together and are added to 500 liters of R/O water; agitated to dissolve the granules and tested for conductivity. The operating procedures include a cleaning cycle, batch manufacturing record for bag accountability and performance testing. A variety of material concentrations can be ordered and mixed. A copy of the variable concentrate list is included in Appendix B and B-1.

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STATEMENT OF EQUIVALENCE

Since the inception of hemodialysis dialysate concentrate has been commercially available in a number of final solute concentrations and formulations. Most concentrates have been supplied in wet formulations in a various package sizes usually up to 55 gallon drum quantities. Due to the cost of shipment of liquids over long distances a number of manufacturers have made and obtained approval for the sale of dry dialysate compositions. ~~Baxter~~ sold both ~~wet (Baxter) and dry (Baxter Dry)~~ through the late 70's through the late 80's. Renal systems also sold dry dialysate concentrate and a mixing system under the trade name ~~Renapak™ Concentrate Mixing System~~ which was reviewed in 1984 and found by the FDA as substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976 (reference their DCN ~~XXXXXX~~)

Based on the above explanation and the enclosed information Fresenius requests that the Commissioner find, under 21 CFR, section 807, that the Fresenius Granulyte Powder Dialysate Concentrate is substantially equivalent to similar devices manufactured prior to May 28, 1976 and to devices currently sold in interstate commerce.

™Trademark of Renal Systems, Minneapolis, Mn.

Appendix A-1

Granulyte "Unit Pack"
Container Label

GRANULYTE

380001 **Acid Concentrate**
for Bicarbonate Dialysis

Part A - 15 Bags (one containing Sodium Diacetate)

36.83

For use only with Granulyte Concentrate Mixing System for dissolution.
Contents of this container dilute to 500 liters (132.1 gallons)

Caution: Federal (USA) law restricts sale of this device by, or on order of a physician.

Not for Parenteral Use

Final Dialysate Concentration		Dialysate	
Part A/Part B/Water 1 : 1.83 : 34	Part A Chemical Concentration	Gm/L	Concentrate (1:35.83) Gm/L
Total mEq/Liter			
Sodium.....139.0 mEq/L	Sodium Chloride.....NaCl	167.9.....	4.58
Calcium.....3.5 mEq/L	Calcium Chloride.....CaCl ₂ • 2H ₂ O	9.5.....	.26
Potassium.....2.0 mEq/L	Potassium Chloride.....KCl	5.5.....	.15
Magnesium.... 1.0 mEq/L	Magnesium Chloride.....MgCl ₂ • 6H ₂ O	3.7.....	.10
Chloride.....104.5 mEq/L		10.4.....	.28
Acid.....4.0 mEq/L	Dextrose.....C ₆ H ₁₂ O ₆	73.7.....	2.0
Bicarbonate...35.0 mEq/L			
Dextrose.....200 mg/dL			

Final Dialysate
Conductivity: 14.1 (± 0.2), pH Range: 7.3 - 7.5 /

DIRECTIONS: This concentrate is formulated to be used in conjunction with Fresenius Formula 36 Sodium Bicarbonate Concentrate (Part B) in a compatible 36.83X dilution, three stream artificial kidney machine. Please refer to instructions of the kidney machine manufacturer before use.

MIXING INSTRUCTIONS: Contents are to be mixed only in the Fresenius "Granulyte Concentrate Mixing System". **EMPTY ENTIRE CONTENTS OF ALL 15 BAGS INTO MIXING TANK.** Read and follow directions in the mixing system Operator's Manual. Upon completion of the dissolution cycle, follow quality control guidelines in the Operator's Manual, verifying conductivity and pH, and reviewing the quality control "Dissolution Document" for accuracy.

CAUTION: This concentrate is designed to be used in conjunction with Fresenius Formula 36 Bicarbonate Concentrate. Mix bicarbonate in a separate container, **NOT** in the Granulyte Mixing Tank. Completed product (liquid concentrate) should be stored between 40° F to 90° F. Avoid freezing. Keep storage containers tightly sealed.

Fresenius USA
Concord, CA. 94520



Lot #:
Formula #:
Exp. Date:

PN: 000121

Appendix A-2

Granulyte Bag Label

GRANULYTE

380001 Acid Concentrate 36.83
 1 of 15 Bags For Bicarbonate Dialysis
 For 500 Liter Batch **Part A**

For use only with Granulyte Concentrate Mixing System for dissolution.
 EMPTY ENTIRE CONTENTS OF THIS BAG INTO MIXING TANK.
 Refer To Operator's Manual For Complete Instructions

Caution: Federal (USA) law restricts sale of this device by, or on order of a physician.
 Not for Parenteral Use

Final Dialysate Concentration		Dialysate (1 : 35.83)	
Part A/Part B/Water 1 : 1.83 : 34 Total mEq/Liter	Part A Chemical Concentrations	Gm/L	Gm/L
Sodium.....139.0 mEq/L	Sodium Chloride.....NaCl	167.9.....	4.58
Calcium.....3.5 mEq/L	Calcium Chloride.....CaCl ₂ • 2H ₂ O	9.5.....	.26
Potassium.....2.0 mEq/L	Potassium Chloride.....KCl	5.5.....	.15
Magnesium.....1.0 mEq/L	Magnesium Chloride.....MgCl ₂ • 6H ₂ O	3.7.....	.10
Chloride.....104.5 mEq/L	Dextrose.....C ₆ H ₁₂ O ₆	73.7.....	2.0
Acid.....4.0 mEq/L			
Bicarbonate.....35.0 mEq/L			
Dextrose.....200 mg/dL			

PN: 000122

Fresenius USA
Concord, CA. 94520



Lot #:
Formula #:
Exp. Date:

Peel Off Label For Control Record

APPENDIX A-3

SODIUM DIACETATE
BAG LABEL

GRANULYTE

380001
1 of 15 Bags
For 500 Liter Batch

**Sodium Diacetate for
Acid Concentrate**
For Bicarbonate Dialysis
Part A

36.83

For use only with Granulyte Concentrate Mixing System for dissolution.
EMPTY ENTIRE CONTENTS OF THIS BAG INTO MIXING TANK.

Caution: Federal (USA) law restricts sale of this device by, or on order of a physician.
Not for Parenteral Use

Final Dialysate Concentration
Part A/Part B/Water
1 : 1.83 : 34
Total mEq/Liter

Sodium.....	139.0 mEq/L
Calcium.....	3.5 mEq/L
Potassium.....	2.0 mEq/L
Magnesium.....	1.0 mEq/L
Chloride.....	104.5 mEq/L
Acid.....	4.0 mEq/L
Bicarbonate.....	35.0 mEq/L
Dextrose.....	200 mg/dL

**REFER TO OPERATOR'S MANUAL
FOR COMPLETE INSTRUCTIONS**

Part A

Acid Chemical Concentration	Gm/L	Dialysate (1 : 35.83) Gm/L
Sodium Diacetate.....	10.4.....	.28
$CH_3COONa \cdot x(CH_3COOH)$		

PN: 000123

Fresenius USA
Concord, CA. 94520



Lot #:
Formula #:
Exp. Date:

Peel Off Label For Control Record

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80

FORMULA **35**



BIO-CARB[®]

Hemodialysis Grade Sodium Bicarbonate

BULK PACKAGE

Chemical Composition:	12,500 grams Sodium Bicarbonate (NaHCO₃)	
Ionic Composition when mixed as directed:	Sodium Bicarbonate	35 mEq/L 35 mEq/L

This product is intended for use with the Fresenius A2008 Dialysis System. Bicarbonate pumps must be calibrated to this formulation prior to its use (1:276), see technicians manual. This solution must be used in conjunction with an appropriate acidified concentrate for hemodialysis. Check pH and conductivity of the dialysate before use.

Preparation Instructions:

- 1) Add 145 liters of purified water meeting the AAMI standards for dialysis and local hemodialysis water quality standards into a bulk mixing container.
- 2) Add the contents of this package slowly while mixing by stirring or recirculating until completely dissolved. Use the entire contents of this package. The water temperature must be between 25°C and 30°C. Avoid vigorous or over agitation.

Upon completion, this procedure will yield twenty-five (25) sodium bicarbonate bath preparations. Each preparation contains 6.95 liters of 8.4% solution of sodium bicarbonate.

NOTE: This solution must be used the same day in which it is prepared. Storage in a closed container is recommended. Loss of CO₂ may cause precipitation and change in pH.

CAUTION: Federal (USA) Law restricts the use of this product to sale by or on the order of a physician.

Not for parenteral use.

DO NOT USE IF SEAL IS BROKEN OR PACKAGE IS DAMAGED.

Net for Parenteral use.

BEST COPY AVAILABLE

LOT NO:
DATE OF MANUFACTURE:
FVN 48087A

81

APPENDIX A-5

SODIUM BICARBONATE LABEL

FORMULA 45

Single Treatment Package for USE WITH COBE (45X) EQUIPMENT ONLY.

This solution ~~must be used in conjunction with Fresenius 45X Formula Acid Bath Concentrate~~ for Bicarbonate Dialysis. Check pH and conductivity of the dialysate before use.

Chemical Composition: Sodium Bicarbonate, 650 grams

Ionic Composition: Electrolyte concentration in dialysate is determined by Proportioning Ratio used in the Cobee machine.

When mixed with Purified Water as directed, each liter of concentrate will contain 81.25 g/L of Sodium Bicarbonate.

PREPARATION INSTRUCTIONS:

1. Add 2 liters of purified water (AAMI std) to a suitable mixing container.
2. Add contents of this package slowly into the water in the container.
3. Add sufficient quantity of purified water to bring the total volume to 2.1 gallons, 8.0 liters.
4. Mix solution thoroughly until Bicarbonate is completely dissolved. Avoid vigorous or over agitation.

NOTE: This solution must be used the day in which it is prepared. Storage in a closed container is recommended. Loss of CO₂ may cause precipitation and change in pH.

CAUTION: Federal (USA) Law restricts the use of this product to sale by or on the order of a physician.

DO NOT USE IF SEAL IS BROKEN OR PACKAGE IS DAMAGED.

Not for Parental use.

Lot #
Date of Mfg.
P/N450088

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72

APPENDIX A-6

SODIUM BICARBONATE LABEL

FORMULA 36

847 grams

Single Treatment Package for USE WITH 36.83X EQUIPMENT ONLY.

This solution must be used in conjunction with Fresenius 36X formula Acid Bath Concentrate for Bicarbonate Dialysis. Check pH and conductivity of the dialysate before use.

Chemical Composition: Sodium Bicarbonate, 626 grams
Sodium Chloride, 221 grams

Ionic Composition Sodium 59 mEq/L
when mixed: Bicarbonate 39 mEq/L
 Chloride 20 mEq/L

PREPARATION INSTRUCTIONS:

1. Add 2 liters of purified water (AAMI std) to a suitable mixing container.
2. Add contents of this package slowly into the water in the container.
3. Add sufficient quantity of purified water to bring the total volume to 2.5 gallons, 9.5 liters.
4. Mix solution thoroughly until Bicarbonate is completely dissolved. Avoid vigorous or over agitation.

NOTE: This solution must be used the day in which it is prepared. Storage in a closed container is recommended. Loss of CO₂ may cause precipitation and change in pH.

CAUTION: Federal (USA) Law restricts the use of this product to sale by or on the order of a physician.

DO NOT USE IF SEAL IS BROKEN OR PACKAGE IS DAMAGED.

Not for Parental use.

Lot #
Date of Mfg.
P/N450089

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Appendix B

FORMULAS

The following list is representative of the formulas we will be manufacturing. The list includes both ACID and ACETATE formulas. (The Sodium Bicarbonate formulations we will offer are detailed in Appendix B-1 on the following page.) This list will be amended in response to market demand for additional formulas.

Dil 1:	Dextr mg%	Na+ mEq/L	Ca++ mEq/L	K+ mEq/L	Mg++ mEq/L	Cl- mEq/L	Acet- mEq/L
44.00	000	100.0	3.00	2.0	0.75	105.75	2.0
	100	100.0	0.00	2.0	1.00	103.00	2.0
	200	100.0	2.50	0.0	0.75	103.25	2.0
	200	100.0	2.50	2.0	0.75	105.25	2.0
	200	100.0	3.00	0.0	0.75	103.75	2.0
	200	100.0	3.00	1.0	1.00	105.00	2.0
	200	100.0	3.00	2.0	0.75	105.75	2.0
	200	100.0	3.00	3.0	0.75	106.75	2.0
35.83	000	79.0	3.50	2.0	1.50	86.00	4.0
	100	81.0	0.00	2.0	1.00	84.00	4.0
	100	81.0	3.50	2.0	0.70	87.20	4.0
	150	80.0	3.50	2.5	1.00	87.00	4.0
	200	79.0	3.50	2.0	1.50	86.00	4.0
	200	80.0	2.00	2.0	1.50	85.50	4.0
	200	80.0	3.50	0.0	1.00	84.50	4.0
	200	80.0	3.50	1.0	1.00	85.50	4.0
34.00	100	103.0	2.50	2.0	0.75	108.25	3.0
	100	103.0	3.00	2.0	1.00	109.00	3.0
	100	103.0	3.50	0.0	1.00	107.50	3.0
	100	103.0	3.50	2.0	1.00	109.50	3.0
	200	103.0	3.50	3.0	1.00	110.50	3.0

ACETATE CONCENTRATE

Dilution is 1:34.00	100	140.0	3.50	2.0	1.00	108.50	38.00
	100	140.0	3.50	2.0	1.50	106.00	41.00
	150	140.0	3.25	2.0	1.50	108.75	38.00
	200	132.0	3.50	2.0	1.50	104.00	35.00
	200	134.0	3.00	2.0	1.00	105.00	35.00
	200	135.0	3.50	2.0	1.00	105.50	36.00
	200	135.0	3.50	2.0	1.50	105.00	37.00
	200	137.5	0.00	2.0	1.50	104.70	36.30
	200	140.0	2.50	2.5	1.00	106.00	40.00
	200	140.0	3.00	0.0	1.00	108.00	36.00
	200	140.0	3.00	1.0	1.00	108.00	37.00
	200	140.0	3.00	2.0	1.50	108.00	38.50
	200	140.0	3.25	2.0	0.75	108.00	38.00
	200	140.0	3.50	1.0	1.50	109.00	37.00
	200	140.0	3.50	2.0	1.00	111.50	35.00
	250	134.0	3.50	2.0	1.50	104.40	36.60

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24

APPENDIX B-1

SODIUM BICARBONATE

FORMULA 35 (for Fresenius equipment)

Sodium 35 mEq/L (at dilution of 1:27.57)

FORMULA 36 (for Drake, Baxter/SPS, Hospal, or Gambro equipment)

as Dialysate

Sodium	59 mEq/L
Bicarbonate	39 mEq/L
Chloride	20 mEq

FORMULA 45 (for Cobe equipment only)

Sodium 81.25 grams of Sodium Bicarbonate per liter of concentrate. (Electrolyte yields of dialysate vary with dilution ratio)

Sodium Bicarbonate Packaging: Single Treatment Bags - 20/case
25 Treatment Bag
45 Treatment Bag

APPENDIX C

MEMO TO: Jerry Courso

FROM: Warner Woolfenden, PhD

SUBJECT: Sodium Diacetate versus Acetic Acid

DATE: February 6, 1991

cc Brent Ahimer
Lon Heiner

Acetic acid exists in aqueous solutions in two forms, as the free acetate ions and as acetic acid molecules. The use of sodium diacetate as a substitute for acetic acid for solutions requiring the acetate moiety is inherent in the fact that the amounts of acetate and acetic acid in the solution are determined by the pH of the solution and not by the source of the acetate ion. This is why the Merck Index refers to ~~Sodium Diacetate as~~ "Acetic acid in solid form". The real difference between the use of sodium diacetate and acetic acid is in the amount of sodium introduced into the solution, but since the sodium ion is also introduced by the use of other sodium containing salts, the sodium ion can be controlled with their adjustment.

~~If sodium hydroxide or hydrochloric acid is used to adjust the pH of the final solution, the use of sodium diacetate or acetic acid will have no effect on the final content of the solution. One would not be able to tell, in fact, whether acetic acid or sodium diacetate had been used.~~

I have included pages from two references:

- (1) The Merck Index, Tenth Edition page 1234 item# 8441.
- (2) The Condensed Chemical Dictionary, Ninth Ed. page 789.

W. R. Woolfenden

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mail paper bags, 100 lb net; fiber

manufacture; corrosion inhibition; other chromium compounds.

sodium citrate) C₆H₅O₇Na₃ · 2H₂O. Crystals or granular powder; odorless; pleasant acid taste. Soluble in alcohol. M.p. loses 2H₂O at 100°C. Composes at red heat. Combustible.

sodium sulfate solution is treated with filtered, concentrated and crystallized.

purify, medicinal; pure; commercial; 100%.

5 drums; bags.

soft drinks; photography; frozen desiccants; detergents; special cheeses, sequestrant and buffer; nutrient for milk; removal of sulfur dioxide from tea; blood anticoagulant.

oxide. See copper sodium chloride.

cyanide (copper sodium cyanide; sodium ACu(CN)₂).

crystalline, double salt of copper sodium cyanide. Sp. gr. 1.013 (20°C); 100°C. Soluble in water.

5 drums.

5 mg per cubic meter of air. Used for maintaining cyanide copper used on sodium cyanide.

zinc cyanide.

crystalline powder; soluble in water, alcohol and ether. Sp. gr. 1.937.

5 drums; bottles.

synthesis: heat treating of steel; inter-manufacture of medicinals; treatment of emia.

a cyanide.

white deliquescent, crystalline powder; slightly soluble in alcohol; m.p. 100°C. The aqueous solution is strongly composed rapidly on standing, absorption of hydrocyanic acid in a sodium hydroxide, with subsequent vacuum.

concentration: 73 to 75%; 96 to 98%; reagent; tablets granular.

5 packages; 100-, 160-, 200-lb drums.

by ingestion and inhalation. Tolerable 5 mg per cubic meter of air. Safety data from manufacturing Chemists Assn., D.C.

of gold and silver from ores; electro-treatment of metals; making hydro-soluble; cleaning metals; fumigation; dyes and pigments; nylon intermediates; ore flotation.

Labels: (Rail, Air) Poison label.

ite. See sodium gold cyanide.

urate. See sodium copper cyanide.

sodium cyclohexylsulfamate

100%.

white, crystalline, practically odorless taste. Freely soluble in water; practically insoluble in alcohol, benzene, chloroform and

ether; pH (10% solution) 5.5-7.5. Sweetening power approximately 30 times that of sucrose.

Grades: N.F.; F.C.C.

Containers: 100-lb drums.

Hazard: Claimed to cause cancer in laboratory animals. Prohibited by FDA for food use.

Use: Nonnutritive sweetener.

sodium decametaphosphate. See sodium metaphosphate.

sodium dehydroacetate C₄H₇NaO₄ · H₂O.

Properties: Tasteless white powder. Soluble in water and propylene glycol. Insoluble in most organic solvents. See also dehydroacetic acid.

Grade: F.C.C.

Uses: Fungicide; plasticizer; toothpaste; pharmaceutical; preservative in food; mold inhibitor for strawberries and similar fruits.

sodium deoxycholate. See deoxycholic acid.

sodium dextran sulfate (dextran sulfate).

Properties: Solid; soluble in water.

Derivation: Derivatives of dextran (q.v.) having a molecular weight of 500 thousand to 2 million.

Uses: Fractionation and separation of biological preparations.

sodium 3,5-diacetamido-2,4,6-trifluorobenzoate. See sodium diatrizoate.

sodium diacetate CH₃COONa · x(CH₃COOH), anhydrous, or CH₃COONa · x(CH₃COOH) · yH₂O, technical.

Properties: White crystals with an acetic acid odor; soluble in water; slightly soluble in alcohol; insoluble in ether. Decomposes above 150°C. Combustible. Low toxicity.

Containers: 5- to 250-lb drums.

Grade: F.C.C.

Uses: Buffer; mold inhibitor; souring agent; intermediate for acid salts; mordants, varnish hardeners; antitarnishing agents; sequestrant and preservative in foods.

sodium diatrizoate (sodium 3,5-diacetamido-2,4,6-trifluorobenzoate) C₆F₃(COONa)(NHCOCH₃)₂.

Properties: White crystals; soluble in water. Solutions are radiopaque.

Grade: U.S.P. (as solution for injection).

Use: Radiopaque medium; medicine.

sodium 1-diazo-2-naphthol-4-sulfonate. See 1-diazo-2-naphthol-4-sulfonic acid.

sodium dibutylthiocarbamate. See "Tapidone."

sodium dibutyl naphthalene sulfonate. See "Sorbit" AC.

sodium alpha, beta-dichloroisobutyrate. A plant growth regulator.

sodium dichloroisocyanurate (sodium salt of dichloro-1,3,5-triazine-2,4,6-trione) NaNC(O)NC(Cl)(O)NC(Cl)(O).

Properties: White, slightly hygroscopic, crystalline powder; loose bulk density (approx.) powder 37 lb/cu ft, granulate 57 lb/cu ft. Active ingredient; approx 60% available chlorine; decomp. at 230°C.

Containers: 200-lb fiber drums.

Hazard: Strong oxidizing material; fire risk near organic materials. Toxic by ingestion.

Uses: Active ingredient in dry bleaches, dishwashing compounds, scouring powders; detergent-sanitizers.

swimming pool disinfectants, water and sewerage treatment; replacement of calcium hypochlorite. Shipping regulations: (Dry, containing more than 39% available chlorine) (Rail) Yellow label. (Air) Oxidizer label.

sodium 2,4-dichlorophenoxyacetate (2,4-D, sodium salt) C₆H₃(OCH₂COONa)Cl₂.

Properties: Crystalline solid. Decomposes at 215°C. Slightly soluble in water.

Hazard: Toxic and irritant by inhalation.

Use: Herbicide. See 2,4-D.

sodium 2,4-dichlorophenoxyethyl sulfate. See seacon.

sodium 2,2-dichloropropionate. See dalapon.

sodium dichromate (sodium bichromate). Na₂Cr₂O₇ · 2H₂O.

Properties: Red or red-orange deliquescent crystals. Sp. gr. 2.52 (13°C); m.p. 357°C; decomposes at 400°C; loses 2H₂O on prolonged heating at 100°C.

Soluble in water; insoluble in alcohol. Noncombustible.

Derivation: (a) From chromite ore by alkaline roasting and subsequent leaching; (b) action of sulfuric acid on sodium chromate.

Grades: Technical crystalline; technical liquor containing 69-70% Na₂Cr₂O₇ · 2H₂O; anhydrous.

Containers: Crystals: multiwall paper bags; 5 drums. Liquor: tank cars or tank trucks.

Hazard: Toxic by inhalation and ingestion; strong irritant. Safety data sheet available from Manufacturing Chemists Assn., Washington, D.C.

Uses: Chemical reactant for oxidation reactions; chromic acid; corrosion inhibitor; manufacturing pigments; tanning of leather; electroplating; dyeing; defoliating agent; catalyst; wood preservative.

sodium diethyldithiocarbamate. (C₂H₅)₂NCS₂Na. Inhibition inhibitor in ethyl ether; in trace quantities prevents peroxide formation.

sodium dihydrogen phosphate. See sodium phosphoric monobasic.

sodium dihydroxyethylglycine (N,N-bis(2-hydroxyethyl)-glycine) NaOOCCH₂N(CH₂CH₂OH)₂.

Properties: Clear straw-colored liquid; sp. gr. 1.17-1.20 (25/25°C); f.p. below -10°C.

Use: Complexing agent for the transition metals.

sodium dimethylarsenate. See sodium cacodylate.

sodium dimethyldithiocarbamate (SDDC) (CH₃)₂NCS₂Na.

Properties: 40% solution is amber to light green; sp. gr. 1.17-1.20 (25/25°C).

Derivation: Reaction of dimethylamine, carbon disulfide and sodium hydroxide.

Containers: 5-gal cans; 55-gal drums; tanks (solvent).

Hazard: Moderately toxic.

Uses: Fungicide; corrosion inhibitor; rubber accelerator; intermediate; polymerization shortstop.

sodium dinitro-ortho-cresylate CH₃C₆H₃(NO₂)₂CO₂Na.

Properties: Brilliant orange-yellow dye which stains clothing and wood.

Derivation: By treating 4,6-dinitro-ortho-cresol with sodium hydroxide.

Hazard: Toxic by ingestion and inhalation.

Uses: Herbicide (control of musard and other susceptible weeds); fungicide.

See also 4,6-dinitro-ortho-cresol.

Superior numbers refer to Manufacturers of Trade Mark Products. For page number see Contents.

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87

APPENDIX C-2

8441

Sodium Diacetate

Ventron). Review of prepn. properties and use: C. F. Lane. *Synthesis* 1975, 135-146.

White, hygroscopic powder, mp 240-242° (dec). d₄²⁰ 1.199. Soly (g/100 g solvent) in water (29°): 212; in THF (25°): 37.2; in diglyme (25°): 17.6. Very sol in methanol; slightly sol in ethanol, isopropylamine; insol in ethyl ether, benzene, hexane. Stable in acid to pH 3; undergoes rapid hydrolysis in 12.N HCl. Rate of hydrolysis 10⁻³ that of NaOH.

USE: Selective reducing agent for aldehydes, ketones, oximes, enamines; does not reduce amides, ethers, lactones, nitriles, nitro compds and epoxides. Also used for reductive amination of ketones and aldehydes, reductive alkylation of amines and hydrazines, reductive displacement of halides and tosylates, deoxygenation of aldehydes and ketones. See Lane, loc. cit.

8441. Sodium Diacetate. Sodium acid acetate: Dykon. CH₃COONa.CH₃COOH. Described as a "bound" compd of sodium acetate and acetic acid. Commercial development: Union Carbide; Stein, Hall & Co.

White powder, des above 150°. Sol in water, liberating 42.25% available acetic acid.

USE: Acetic acid in solid form; as an inhibitor of molds and rosp-forming bacteria in bread: *Glabo. Food Inds.* 14, no. 2, 46 (1942); as sequestrant.

8442. Sodium Dichromate(VI). Sodium bichromate; bichromate of soda. Cr₂Na₂O₇; mol wt 261.96. Cr 39.70%, Na 17.55%, O 42.75%. Na₂Cr₂O₇. Usually prepd from Na₂CrO₄ and H₂SO₄. Description of industrial processes: Müller, Glissmann in *Ullmann's Encyklopädie der Technischen Chemie* vol. 5 (Munich, 3rd ed., 1954) p 573; Faith, Kayes & Clark's *Industrial Chemicals*, F. A. Lowenheim, M. K. Moran, Eds. (Wiley-Interscience, New York, 4th ed., 1975) pp 731-736.

Dihydrate, reddish to bright orange, somewhat deliquescent crystals. Crystal system: monoclinic sphenoidal. Crystal habit: elongated prismatic. d₄²⁰ 2.348. Bulk density: 96 lbs/cu ft. Becomes anhyd on prolonged heating at about 100°. The anhyd salt mp 336.7° and starts to dec at about 400°. Heat of soln -28.2 cal/g. Very sol in water. A satd aq soln contains at 0°: 70.6% Na₂Cr₂O₇·2H₂O; at 20°: 73.18%; at 40°: 77.09%; at 60°: 82.04%; at 80°: 88.39%; at 100°: 91.43%. A 20% soln freezes at -3.5°, a 30% soln at -6°, a 60% soln at -26°, a 69% soln at -48°. Specific heat of 20% soln at 25°: 0.83 cal/g·°C. Solns are acidic: pH of 1% soln: 4.0; pH of 10% soln: 3.5.

USE: Oxidizing agent in manuf of dyes, many other synthetic organic chemicals, inks, etc.; in chrome-tanning of hides; in electric batteries; bleaching fats, oils, sponges, resins; refining petroleum; manuf chromic acid, other chromates and chrome pigments; in corrosion-inhibitors, corrosion-inhibiting paints; in many metal treatments; electro-graving of copper; mordant in dyeing; for hardening gelatin; for the defoliation of cotton plants and other plants and shrubs. La Lande, U.S. pat. 2,760,884 (1956 to Pennsylvania Salt). *Caution*: Irritant and caustic to skin, mucous membranes.

THERAP CAT: Topical anti-infective.

8443. Sodium Diarysacetate(O). Gold sodium cyanide; sodium aurocyanide. C₂AuN₂Na; mol wt 372.03. C 2.82%, Au 72.44%, N 10.29%, Na 8.45%. NaAu(CN)₂.

White, cryst powder. Sol in water. *Poison!*
USE: Goldplating.

8444. Sodium Diethylthiocarbamate. Diethylcarbamothioic acid sodium salt; diethylthiocarbamic acid sodium salt; Dithiocarb. C₄H₁₀NNaS₂; mol wt 171.27. C 35.06%, H 5.89%, N 8.18%, Na 13.43%, S 37.45%. (C₂H₅)₂NCS₂·Na. Prepn: Clifford, Lihty, *J. Am. Chem. Soc.* 94, 1183 (1932); Klebanik, Fomina, *Z. Obshch. Khim.* 30, 794 (1960).

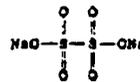
When anhyd, mp 94-96°. Used as the trihydrate. Freely sol in water; sol in alcohol. The aq soln is alkaline to litmus and phenolphthalein and slowly dec. The addition of an acid to the aq soln produces a white turbidity due to the liberation of carbon disulfide.

USE: For colorimetric determination of small quantities of copper and for its separation from other metals.

THERAP CAT: Chelating agent. Used in Wilson's disease.

8446. Sodium Dithionite. Dithionous acid disodium salt.

Na₂O₂S₂; mol wt 206.10. Na 22.31%, O 46.58%, S 31.11%. Prepd according to the equations MnO₂ + 2SO₂ -> MnSO₄ and MnSO₄ + Na₂CO₃ -> MnCO₃ + Na₂SO₄; de *Rec. Trav. Chim.* 48, 237 (1926); *Pflanztel. Inorg. Syn.* 1, 11 (1946).



Dihydrate, colorless, water-clear, orthorhombic crystals. Very stable in air. d 2.189. Loses all of its water of hydration at 110°. When heated to 267° it is dissociated into Na₂SO₃ and SO₂. Soly in water at 0°: 6.05% (w/w); at 20°: 11.5% at 30°: 17.32%. Insol in alc.

8446. Sodium Dodecylbenzenesulfonate. Dodecylbenzenesulfonic acid sodium salt; dodecylbenzene sodium sulfonate; Santomerse #1; Conoco C-50; Conoco SD 40; Conoco C-60. C₂₁H₃₉NaO₂S; mol wt 348.49. C 62.04%, H 8.39%, Na 6.60%, O 13.77%, S 9.20%. C₁₂H₂₅C₆H₅SO₃Na. *Mam. Chem. Eng.* 61, no. 6, 372 (1954); Huber et al. *J. Am. Chem. Soc.* 33, 57 (1956); Brit. pat. 781,096 (1956 to Monsanto); Santon, U.S. pat. 2,782,230 (1957 to Monsanto); Brit. pat. 773,423 (1957 to Continental Oil); Gerhart, Kawaoki, U.S. pat. 2,820,086 (1958 to Continental Oil).

LD₅₀ in mice: 2 g/kg orally; 105 mg/kg i.v.; Hoppa et al. *J. Am. Pharm. Assoc. Sci. Ed.* 38, 428 (1949).

USE: Anionic detergent. *Caution*: May cause skin irritation. If swallowed will cause vomiting.

8447. Sodium Ethoxide. Sodium ethylate; caustic alcohol. C₂H₅NaO; mol wt 68.06. C 35.29%, H 7.61%, Na 33.79%, O 23.51%.

White or yellowish, hygroscopic powder. Dec on exposure to air and becomes darker on keeping. Dec by contact with NaOH and alcohol; sol without decomposition in alc. *Keep tightly closed, protected from light and in a cool place.*

8448. Sodium Ethyl Sulfate. Sodium sulfovinolate. C₂H₅NaO₂S; mol wt 148.11. C 16.22%, H 3.40%, Na 15.32%, S 43.21%, S 21.65%. NaC₂H₅SO₃.

Monohydrate, white, very hygroscopic crystals. Sol in 20 parts water, in alcohol. *Keep well closed.*

USE: In organic syntheses.

8449. Sodium Ferricyanide. Trisodium hexacyano-ferrate(3-); sodium hexacyanoferrate(III). C₆F₃Na₃; mol wt 260.91. C 25.65%, Fe 19.85%, N 23.02%, Na 24.56%. Na₃Fe(CN)₆.

Monohydrate, ruby-red, deliquescent crystals. Sol in 20 parts cold water, 1.5 parts boiling water. *Keep well closed.*

8450. Sodium Ferrocyanide. Tetrasodium hexacyano-ferrate(2-); sodium hexacyanoferrate(II); yellow prussiate of soda; sodium prussiate yellow. C₆FeN₆Na₄; mol wt 303.91. C 23.71%, Fe 18.38%, N 27.65%, Na 20.26%. Na₄Fe(CN)₆. Review of properties, chemistry and synthesis: *The Chemistry of Ferrocyanides*, American Cyanamid Co. (London Press, New York, 1953) 112 pp.

Decahydrate, pale yellow, monoclinic, slightly deliquescent crystals. Steady dehydration occurs above 50°. Becomes anhyd at 81.5°. Dec 435°, forming sodium cyanide, carbon, and nitrogen. Soly in water at 15°: 10.25% (anhyd salt); at 17°: 14.7%; at 25°: 17.6%; at 37°: 25.5%; at 55°: 39%; at 96.6°: 39.7%. Practically insol in most organic solvents.

USE: Addition of sodium ferrocyanide to acidic solns of iron salts causes precipitation of insoluble Prussian blue (ferric ferrocyanide), Fe₄[Fe(CN)₆]₃. Alkaline solns of sodium ferrocyanide form gels with heavy metals in general. Used in cyanide forms gels with heavy metals in general. Used in photography for bleaching, toning, and fixing. To prevent eating of rock salt and foods. Added to swimming baths. Peppering agent in rubber. Used in welding rod coatings. Emulsion polymerization. *Toxicity*: Because of strong chemical bonds between cyanide groups and the iron, ferrocyanides have a low degree of toxicity. *Caution*: Do not mix with hot or caustic and do not expose solns to sunlight for any length of time.

88

FRESENIUS USA
GRANULYTE CONCENTRATE MIXING SYSTEM
OPERATOR'S MANUAL

P/N Rev. 1

GRANULYTE CONCENTRATE MIXING SYSTEM

WARNINGS AND PRECAUTIONS

- * Anyone operating this system should read and be thoroughly familiar with the operator's manual.
- * Only AAMI quality water, (RD5), should be used in this system.
- * Use only dry chemicals supplied by Fresenius USA, Inc. and specifically designed for use in this system.
- * Do not use any chemicals if their package is damaged or torn, a portion of the contents have been spilled, or if the contents are wet.
- * CAUTION: Disconnect electrical supply before servicing. Only qualified personnel should remove access panel or attempt repairs.
- * ~~Federal law restricts this device to sale by or on order of a physician.~~
- * It is the responsibility of the prescribing physician to ensure that this system is properly installed and that personnel are adequately trained in its operation.
- * Subsequent testing and clinical application of concentrates processed in the Granulyte Concentrate Mixing System is the sole responsibility of the attending physician.
- * A floor drain is required for proper operation.
- * Ensure that the floor on which the mixing system will be installed has sufficient load bearing capacity. When filled with water, the system will weigh approximately 1650 lbs.

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Table of Contents

- I. GENERAL
 - 1. Safety
 - 2. Transport and storage conditions
- II. SET UP
 - 1. Receipt of equipment
 - 2. Installation space
 - 3. Drainline connection
 - 4. Water line connection
 - 5. Transfer line connection
 - 6. Connection to the electrical supply
 - 7. Leveling of the mixing system
- III. DEACTIVATING MIXING SYSTEM
 - 1. Deactivation
 - 2. Transport and shipment
- IV. APPLICATIONS
- V. OPERATING INSTRUCTIONS
 - 1. Overview
 - 2. Rinse/Disinfection Cycle
 - 2.1 Rinse cycle
 - 2.2 Disinfection cycle
 - 3. Dissolution/mixing cycle
 - 3.1 Quality Control testing
 - 4. Maintenance
 - 5. Manual Control operations
- VI. TROUBLE SHOOTING
- VII. TECHNICAL CHARACTERISTICS
 - 1. Hydraulic parts
 - 2. Electrical parts
 - 3. Exterior parts

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VIII. APPENDICES

- Fig. 1 Top view of dissolution mixing system
- Fig. 2 Top view of the control panel
- Fig. 3 Electrical diagram of the dissolution system
- Fig. 3.1 I/O Address table
- Fig. 4 Hydraulic diagram

Appendix A: Batch Control Record
(Dissolution Document)

IMPORTANT: Read Operator's Manual completely before operating equipment.

I. GENERAL

1. Safety

The Granulyte Concentrate Mixing System consists of a 500 liter mixing tank, control panel and hydraulic system.

The Granulated salts for use in the system are packed and shipped separately. The standard shipping container for the salts is called a "unit pack". Each unit pack contains 15 bags of salt which will dilute to 500 liters in the mixing tank.

Warranties from the manufacturer will be in effect only if instructions and warnings given in this booklet have been followed, and only if accessories from Fresenius USA, Inc. have been exclusively used.

The measures that have to be taken for the set up, modifications or repairs which involve an opening of the module, must be done by trained technicians with authorization, and only with the manufacturers spare parts.

Use only AAMI standard water for hemodialysis.

2. Transport and Storage Conditions

The equipment must not to be exposed to the elements and should be kept dry during transport and storage.

II. SET UP

The following will describe the steps that are necessary to make your equipment operational.

1. Receipt of Equipment

A complete inventory as well as a verification of the condition of the equipment should be carried out.

The system contains:

- the module which includes:
 - a 500 liter tank with a propeller
 - a control panel which contains electric components and removable hydraulic circuits
 - electric wiring and solid state circuitry

II. SET UP (cont.)

- a transfer filling "pistol"
- a dilution water line
- a concentrate transfer line
- a tank drain line
- a cutter to open the bags
- a spanner to unscrew the filter housing
- 5 ea. 9" 3/4--1 micron filtration cartridges
- a male 3/4" cam connector
- an instruction manual
- a key to unlock "emergency stop" switch
- a male 3/4" threaded quick connector for the water inlet

2. Installation Space

The mixing area must comply with the following requirements:

- be dust-free and easily cleaned
- close to purified water and electric supply
- have a main floor drain
- close to a storage area

3. Drain Line Connection

Connect the drain line hose to:

- the drain line connection under the control panel module
- the main floor drain (n 5 Fig. 4)

4. Water Line Connection

Connect the water line (n 4 Fig. 1) to:

- the water line connector under the control panel module
- the distribution tap of the purified water source

5. Transfer Line Connection

5.1 Connect the transfer line either to a concentrate storage tank, or

5.2 to the filling pistol, if the concentrate is transferred in jerrycans.

NOTE: The transfer line (n 10 fig. 1) is already connected to the filtration cover.

6. Connection to the Electrical Supply

- Check that your electrical supply is 115 AC, grounded outlet.
- Then connect the lead (n 1 fig. 1) to the plug. (16A+ ground).
- Turn the main power disconnect to "Start". (n 7 fig. 1).
- The green indicator (n 4 fig. 2) light is on.

7. Leveling of the Mixing System

- Check that the equipment is horizontal with a level. The legs can be adjusted individually to level the machine.

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III. DEACTIVATING MIXING SYSTEM

1. Deactivation

- Disconnect the water line, drain line and transfer line.
- Turn the main power disconnect switch (n 7 fig. 1) to "stop" position.
- Disconnect the electric lead cord.

2. Transport and Shipment

- Make sure that the module is dry.
- Pack the module in its original packing or if not available, in adequate packing to ensure protection.
- Keep the system dry!

IV. APPLICATIONS

The system allows for the ~~automated mixing/dissolution of the Granulyte products with the appropriate amount of purified water~~ in order to obtain dialysate concentrate in specific formulations.

Water to be used: AAMI quality water for hemodialysis,

NOTE: ~~This system should not be used for the dissolution of sodium bicarbonate.~~

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95

FRESENIUS
CONCENTRATE MIXING SYSTEM
OPERATOR'S MANUAL

V 1.0 OVERVIEW

The Fresenius concentrate mixing unit is automated and designed to operate with a minimum of operator supervision.

There are ~~two (2) pre-programmed cycles~~ built into the Fresenius mixing unit, the "Rinse Cycle" and the "Dissolution Cycle". The control panel will display the machine's status at any given time, making it easy for the operator to follow the progress of these cycles.

? sufficient
? will replace

The right side of the panel displays the "Rinse Cycle", and the left side displays the "Dissolution Cycle".

CAUTION: Prior to initiating a rinse cycle or dissolution cycle, adequate power and water connections must be made. The Fresenius dissolution unit is designed to operate on a standard 115 V / 60 CYCLE / SINGLE PHASE / AC circuit. The purified water source connection is made with the water hose located inside the access panel, and the drain hose must be routed to a floor drain. (Refer to Figure 1)

2.0 RINSE / DISINFECTION CYCLE

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2.1 Rinse Cycle

CAUTION: Before initiating the rinse cycle, the fill gun must be attached to the transfer line and placed above a suitable drain with the trigger locked open. Care should be taken to avoid contaminating the fill gun nozzle. The ~~water will pump the solution~~ from the tank, through the hose and filter housing, and finally through the fill gun in order to completely clean and rinse the transfer system. In addition, the operator must insure that the tank access port lid is closed. (Refer to Figure 1)

What Solution
? will replace

If necessary, the ~~concentrate filter~~ should be removed, and the empty housing reset as described in section 4.

Water also

In order to minimize microbial growth, the rinse cycle should only be performed just prior to the dissolution cycle. The 1 micron filter should not be allowed to stand in fresh water, it should only be left completely filled with concentrate.

- 1) The rinse cycle consists of two complete rinsing operations. Pressing the rinse START/HOLD button on the right side of the panel will fill the tank to the LOW WATER level sensor. The # 1 amber light (see figure 2) will turn on indicating the first rinse cycle is in progress.

- 2) Once the low water level is reached, the recirculation pump will start and the mixer motor will run for a 5 minute period. During the last 2 minutes of the 5 minute period, the dissolution unit will switch to **Transfer** and the rinse water will be pumped through the transfer line and fill gun to drain. Next, the Fresenius dissolution unit will switch to **Drain** and empty any residual rinse water from the process piping to the floor drain.
- 3) Once the **DRAIN** period is completed, the tank will refill to the **LOW WATER** level. The #2 amber indicator will light indicating the second stage of the rinse cycle is in progress. Once the low water level is made, the recirculation pump will start and the mixer motor will run for a 5 minute period. During the last two minutes of the 5 minute period the unit will switch to **Transfer** and the rinse water will be pumped through the transfer line and fill gun to drain. Next, the Fresenius dissolution unit will switch to **Drain** and empty any residual rinse water from the process piping to the floor drain.
- 4) The rinse **CYCLE COMPLETE** indicator will light. The unit is now ready to mix concentrate.

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2.2 Disinfection Cycle

- 1) Remove the filter housing and discard the filter element. Replace the filter housing, but do not insert a replacement filter at this time.
- 2) Follow the Rinse Cycle procedures in 2.1. When the water reaches the low water level during the second rinse step (#2 amber indicator will light), add 1 liter (.26 gallons) of bleach (sodium hypochlorite, 5.25%) to the rinse water in the tank and allow to recirculate for the duration of the rinse cycle.
- 3) At the completion of the last rinse step (to which the bleach has been added), initiate another complete Rinse Cycle by following the steps in 2.1.
- 4) When completed, test for residual bleach in system at the fill gun nozzle and inside the filter housing. Follow your facility protocol for testing for residual quantities of bleach.

If residual bleach levels are higher than what your facility protocol allows, initiate another complete rinse cycle, after which you must again test for residual bleach. Continue this rinse and test procedure until bleach residuals are within your facility's acceptable limits.

- 5) Remove filter housing, then drain all residual water out and install a new filter element. Replace filter housing.

NOTE: Do not let tank sit with residual water in it or in any of the lines. A new batch of concentrate should be prepared following the Rinse and/or Disinfection Cycle.

This system should be periodically checked for contamination and bacterial growth.

3.0 DISSOLUTION CYCLE

NOTE: Just prior to initiating a dissolution cycle, the operator must insure a rinse cycle has been completed and that the 1 micron filter has been properly installed in the concentrate filter housing. (See section 4.3 for installation instructions.)

Mixing, documentation, and subsequent testing of each hemo concentrate batch should be completed in accordance with the applicable MIX DOCUMENT.

1. Pressing the dissolution **START/HOLD** button opens the water inlet valve and fills the tank to mid level.
2. Once mid level is reached, the water supply valve will turn off and the **ADD GRANULES** light will begin to flash. This flashing indicates that the Fresenius dissolution unit is in a hold state waiting for the operator to add the concentrate granules in accordance with the mix document. After the granules have been added, the operator presses the **CONTINUE / STEP** button and the machine will proceed to the **MIXING** operation.

NOTE: Add the entire contents of each bag in the "unit pack" to the mixer through the port cover on the top of the mixing tank. As each bag is emptied into the mixer, remove the peel-off label from the bag and place it on the Batch Control Record. When you have completed emptying all bags into the tank, you should have one peel-off label in each of the 15 spaces on the Batch Control Record.

3. During **MIXING** the solution is agitated for a preset time period allowing the granules to completely dissolve. After which, the Fresenius dissolution unit will automatically step to the **DEAERATION** phase of the cycle.
4. The **DEAERATION** portion of the cycle is a preset time period during which the entrained air is allowed to separate out of the solution. Upon completion, the Fresenius dissolution unit will automatically proceed to **FINAL FILL**.
5. In **FINAL FILL**, the supply water valve will open and fill the tank to the final level.
6. When the final water level is reached, the unit will step to **HOMOGENIZATION**. During **HOMOGENIZATION**, the mixer will stir the solution until it is completely mixed. After the homogenization phase, the indicator will flash. The flashing indicates the unit is holding its status, waiting for the operator to press the **CONTINUE / STEP** button once the **TRANSFER** operation is ready.

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7. Normally during **TRANSFER**, the solution is automatically pumped through the transfer hose to a concentrate holding tank. This is a timed operation. Alternately, the fill gun attachment may be connected to the transfer line, for filling of individual containers. When using the fill gun attachment, the transfer step is placed in the hold state by pressing the **START / HOLD** button. This holds the transfer pump timer and allows the operator time to empty the tank manually.

Upon completion of the **TRANSFER** operation the **CYCLE COMPLETE** indicator will light and the floor drain valve will open to drain any residual solution from the unit.

NOTE: Quality Control testing should be conducted at this time. Refer to the Quality Control section 3.1 for instructions on carrying out this mandatory process. Label concentrate in tank "HOLD" or "QUARANTINE" until QC tests are complete.

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4.0 MAINTENANCE

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

The recommended program for proper care of the Fresenius Dissolution Unit consists of three basic steps. They are: 1) **REGULAR VISUAL INSPECTION**, 2) **CLEANING**, and 3) **FILTER MAINTENANCE**.

4.1 VISUAL INSPECTION

The Fresenius Dissolution Unit should be visually inspected prior to each use. The operator should look for any defects which may inhibit the safe or proper operation of the unit. Items such as damaged hydraulic hoses or fittings, damaged electrical cables or connections, loose - missing - or damaged hardware, or process contamination should be corrected prior to the use of the Fresenius Dissolution Unit.

4.2 CLEANING

The exterior surface of the Fresenius Dissolution Unit should be thoroughly cleaned 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.

NOTE: Do not use chemical cleaning agents that may damage the materials used in the dissolution unit. Agents which contain ALCOHOL, BENZENE, TOLUENE, XYLENE, ACETONE or any other AROMATIC or KETONE solvents should be avoided.

4.3 FILTER MAINTENANCE

The 1 micron filter (refer to figure 1) should be changed under the following conditions:

1. The type of concentrate to be mixed has changed from the previous batch. (The system rinse procedure, described in section 2, must be followed prior to filter installation.)
2. A significant reduction occurs in the flow from the transfer line.
3. The system has been contaminated.

4.3.1 FILTER REMOVAL

1. Ensure the mixing tank is empty and that the dissolution unit power has been turned off.
2. Remove the lower filter housing with the housing wrench. Empty the housing.
3. Discard the used filter and reset the empty filter housing. Lightly lock the housing in place using the wrench.

4.3.2 FILTER REPLACEMENT

Note: When required, filter replacement should occur just prior to the dissolution cycle.

1. Ensure the mixing tank is empty and that the dissolution unit power has been turned off.
2. Remove the lower filter housing with the housing wrench. Empty the housing.
3. Insert a new 1 micron filter inside the lower housing.
4. Reset the filter and housing. Lightly lock the housing in place using the housing wrench.

5.0 MANUAL CONTROL OPERATIONS

5.1 HOLDING STATES

To allow for special occurrences, and allow some latitude in the operation of the Fresenius dissolution unit, a **STEP / HOLD** sequence has been included in the control system.

If at any time the operator needs to "hold" a timed state during the cycle, the **START / HOLD** button may be pressed.

This will cause the indicating light for the current step of the process to flash. Any equipment in operation when the hold button was depressed, such as the agitator or the pump, will continue operating. In "HOLD", only the timers are stopped.

To continue the cycle, press the **CONTINUE / STEP** button and the timers will resume.

NOTE: To prevent over filling, the fill states can not be placed on "HOLD".

CAUTION: DO NOT LEAVE THE UNIT ON "HOLD" IN THE TRANSFER STATE AFTER THE TANK IS EMPTY. THIS WILL CAUSE EXCESSIVE WEAR AND MAY CAUSE THE PUMP'S SANITARY SEAL TO FAIL.

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5.2 STEPPING STATES

In the operation of the Fresenius dissolution unit it may become necessary to "STEP" from the current state to another state, skipping one or several steps in between.

This is possible by pressing and holding down the **START / HOLD** button. After three seconds the system will enter the "STEPPING" mode, and all of the equipment will be shut down. By continuing to hold down the **START / HOLD** button and pressing the **STEP / CONTINUE** button, the states may be stepped sequentially. When the desired step is illuminated, the **STEP / HOLD** button is then released, the **STEP / CONTINUE** button is pressed and the operation is continued.

CAUTION: WHEN THE STEP / HOLD BUTTON IS RELEASED THE Fresenius dissolution unit WILL RESUME OPERATION.

5.3 STOPPING STATES

The **STOP** button has been provided to allow the operator to stop the process without having to re-initiate. When the stop button is pressed, the red indicator light will turn on and the current status light will flash, indicating a "HOLD" state. All operations will stop (ie. pumps, agitators, drains, fill valve etc.). The cycle may be resumed by pressing the **CONTINUE / STEP** button.

5.4 EMERGENCY STOP

The **EMERGENCY STOP** switch is provided in order to allow the operator to completely shut down the Fresenius dissolution unit in case of an emergency. Pressing the **EMERGENCY STOP** shuts off the main power to the Fresenius dissolution unit.

The **EMERGENCY STOP** switch requires a key to release it back to normal operation.

NOTE: When power is restored to the Fresenius dissolution unit, such as after use of the EMERGENCY STOP, the MAIN DISCONNECT switch, or a power failure, the Fresenius dissolution unit will resume operation where it was interrupted.

Operating the **STOP** button or placing the control into the **STEP** mode (**START / HOLD** button depressed for more than 3 seconds) will disable the working parts of the machine (ie. pump, agitator or water fill valve).

CAUTION: The Fresenius dissolution unit is controlled, extreme care should be exercised in its operation. When power is connected to the Fresenius dissolution unit, a failure of the computer could start any of the operations at any time. (Refer to Figure 3)

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TROUBLE SHOOTING

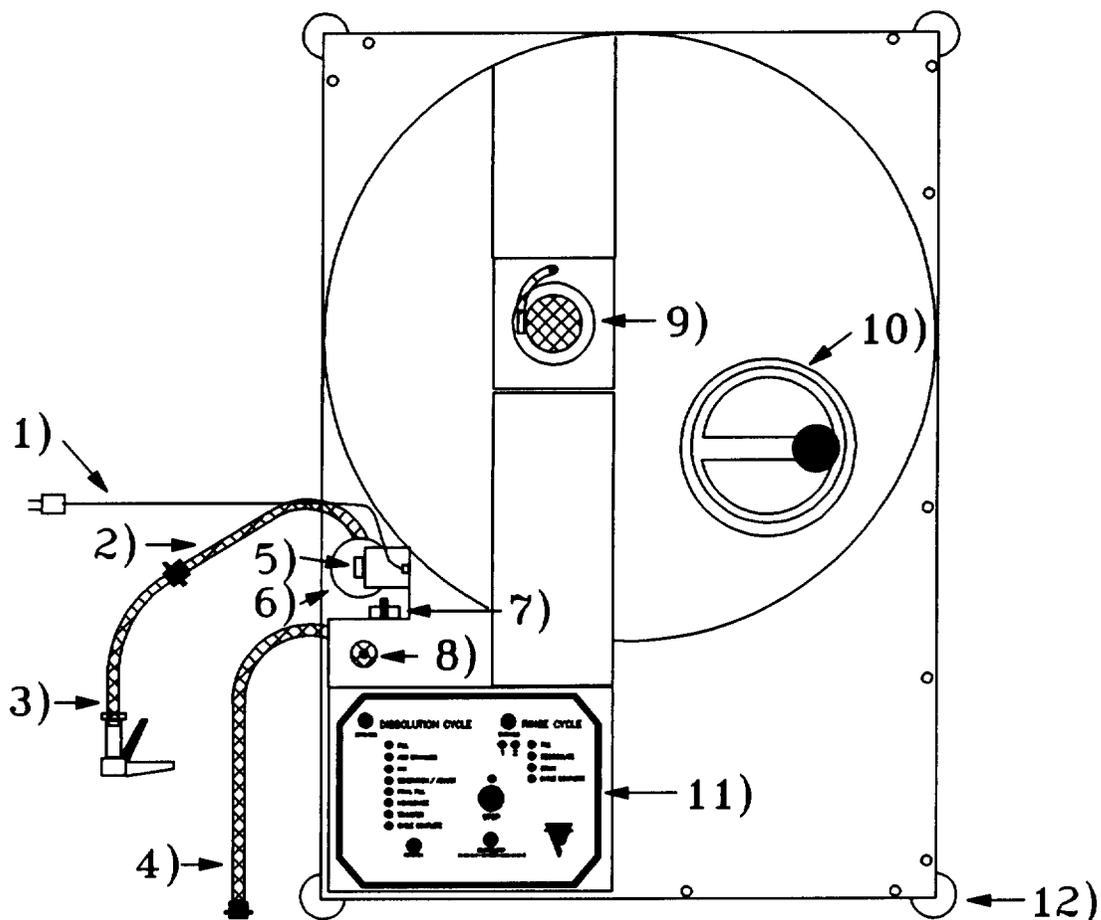
PROBLEM	POSSIBLE CAUSE	SOLUTION
1 No sign of working and the on/off light (6) is not lit	<ul style="list-style-type: none"> - No power on the network - The wire (7) is not or not correctly connected - The cutout switch (13) is "off" - The FU2 fuse is faulty - The indicator light (6) is faulty - The transformer 220/4V TR1 is faulty 	<ul style="list-style-type: none"> - Call the maintenance department - Connect it correctly - Turn it on "I" - Change it - Change it - Change it
2 No sign of working but the indicator light is on	<ul style="list-style-type: none"> - Emergency stop (1) on - Water inlet shut. - FU3 fuse is faulty - The water inlet electrovalve (Y1) is faulty. 	<ul style="list-style-type: none"> - Unlock (1) with wrench Nr 455. - Open it. - Change it. - Change The (Y1) electrovalve coil
3 Green light Nr 17A off	<ul style="list-style-type: none"> - The green light Nr 17A is faulty - The RK2 relay is faulty - There is already some liquid in the dissolution tank 	<ul style="list-style-type: none"> - Change light Nr 17A - Change RK2 - Empty the tank
4 Green light Nr 17B off	<ul style="list-style-type: none"> - The green light Nr 17B is faulty - The RK3 relay is faulty - The level probe is covered with powder 	<ul style="list-style-type: none"> - Change it - Change RK3 relay - Clean the level probe
5 Green light Nr 17C off	<ul style="list-style-type: none"> - It is faulty - The RK1 relay is faulty - There is already some liquid in the dissolution tank 	<ul style="list-style-type: none"> - Change it - Change it - Empty the tank
6 Filling does not stop	<ul style="list-style-type: none"> - The optical probe N1 is faulty - The probe relay K1 is faulty 	<ul style="list-style-type: none"> - Change probe N1 - Change K1

TROUBLE SHOOTING

<p>7 No stop on step 5 : ADJUSTMENT/ Dissolution</p>	<ul style="list-style-type: none"> - The optical probe N2 is faulty - The probe relay K2 is faulty 	<ul style="list-style-type: none"> - Change probe N2 - Change K2
<p>8 No stop on step 1 : FILLING/Rinsing</p>	<ul style="list-style-type: none"> - The resistive probe N3 is faulty - The probe relay K3 is faulty 	<ul style="list-style-type: none"> - Change probe N3 - Change K3
<p>9 Mixing fault</p>	<ul style="list-style-type: none"> - Propeller timer switch not set - Wrong gauging of DM1 - Propeller timer switch is faulty - Mixing device locked 	<ul style="list-style-type: none"> - Set the timer on - Gauge DM1 - Change it - Check it
<p>10 Faulty transfer or circulation</p>	<ul style="list-style-type: none"> - The filter is full up - The concentrate storage tank inlet is shut - The pump timer switch is off - Wrong gauging of DM2 - Pump timer switch is faulty - Motorized valve Y2 is locked - The pump is locked 	<ul style="list-style-type: none"> - Change the filter - Open it - Set the timer on - Gauge DM2 - Change it - Clean it - Check it

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Figure 1 FRESNIUS DISSOLUTION UNIT

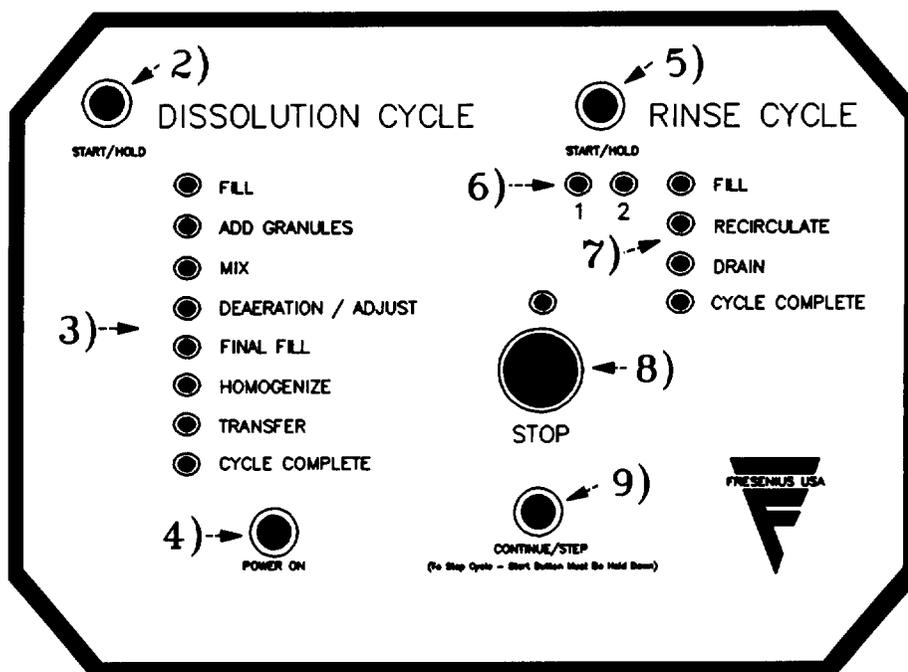


TOP VIEW

- 1.) 115 VAC POWER CORD
- 2.) SOLUTION TRANSFER LINE
- 3.) FILL GUN (OPTIONAL)
- 4.) WATER INLET LINE
- 5.) FILTER BACK PRESSURE GAUGE
- 6.) FILTER HOUSING
- 7.) **MAIN POWER DISCONNECT**
- 8.) **EMERGENCY STOP**
- 9.) MIXER MOTOR
- 10.) TANK ACCESS PORT
- 11.) CONTROL PANEL
- 12.) LEVELING FOOT

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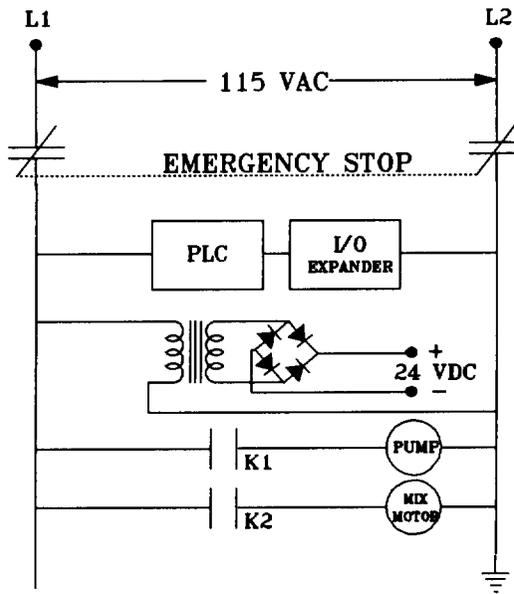
Figure 2 CONTROL PANEL



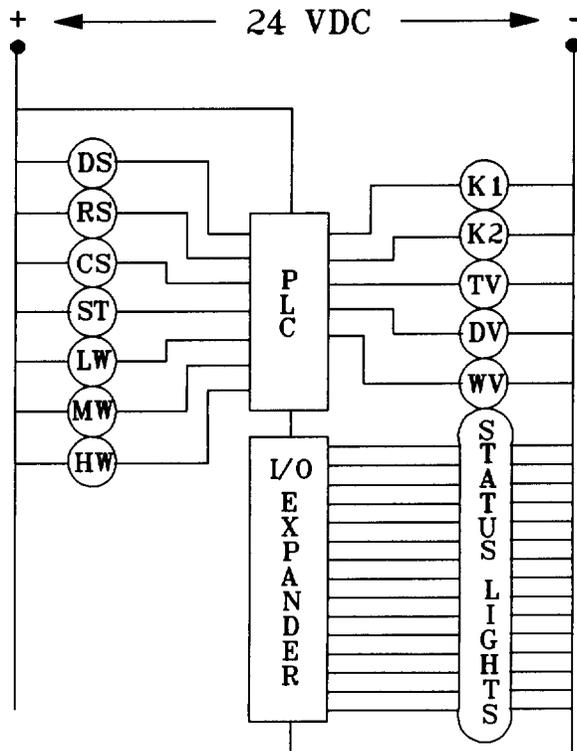
- 1.) **EMERGENCY STOP**
- 2.) DISSOLUTION CYCLE **START/HOLD** PUSH BUTTON
- 3.) DISSOLUTION CYCLE STATUS INDICATORS (**BLUE**)
- 4.) POWER ON INDICATOR (**GREEN**)
- 5.) RINSE CYCLE **START/HOLD** PUSH BUTTON
- 6.) RINSE CYCLE STEP INDICATORS (**AMBER**)
- 7.) RINSE CYCLE STATUS INDICATORS (**BLUE**)
- 8.) CYCLE **STOP** PUSH BUTTON
- 9.) CYCLE **CONTINUE/STEP** PUSH BUTTON

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FIGURE 3 ELECTRICAL SCHEMATIC



115 VOLT POWER DISTRIBUTION



24 VOLT DC POWER DISTRIBUTION

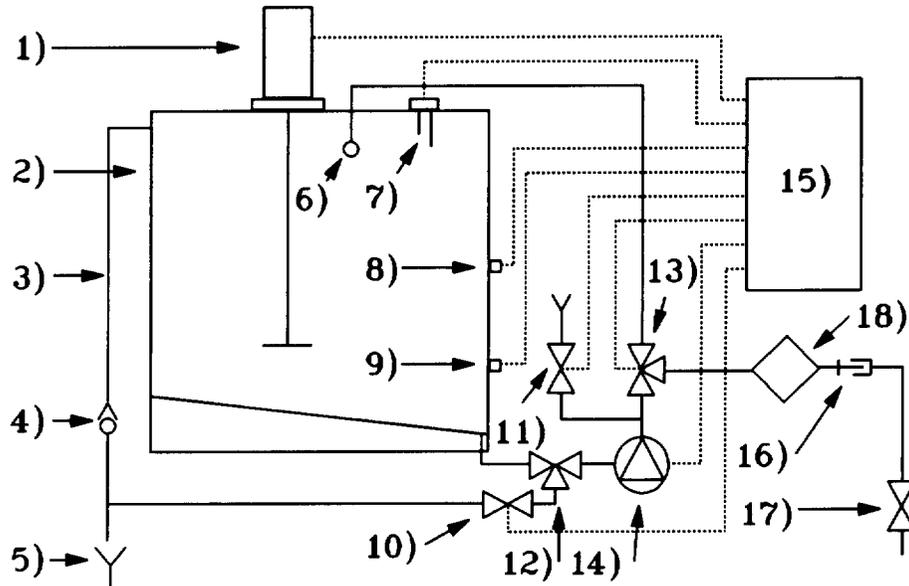
FIGURE 3.1

I/O ADDRESS TABLE

INPUTS		OUTPUTS	
001	Dissolution Start/Hold	011	Mixer Motor
002	Rinse Start/Hold	012	Pump Motor
003	Continue / Step	013	Transfer Valve
004	Stop Button	014	Drain Valve
005	Low Water Level	015	Fill Valve
006	Mid Water Level	314	Disso. Fill Light
007	High Water Level	111	Add Granules Light
		112	Mix Light
		113	Deaeration Light
		114	Final Fill Light
		115	Homogenize Light
		116	Transfer Light
		211	Cycle Complete Light
		212	Rinse Fill Light
		213	Recirculation Light
		214	Drain Light
		215	Cycle Complete Light
		216	Stop Indicator
		311	First Rinse Light
		312	Second Rinse Light

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Figure 4 HYDRAULIC DIAGRAM



- 1.) MIXER
- 2.) DISSOLUTION TANK
- 3.) OVERFILL PIPE
- 4.) BACKFLOW VALVE
- 5.) MAIN DRAIN
- 6.) RINSING SPRAY BALL
- 7.) HIGH LEVEL SENSOR
- 8.) MID LEVEL SENSOR
- 9.) LOW LEVEL SENSOR
- 10.) DRAIN VALVE
- 11.) FILL VALVE
- 12.) MANUAL DRAIN VALVE
- 13.) TRANSFER / RINSE VALVE
- 14.) TRANSFER / RINSE PUMP
- 15.) CONTROL ENCLOSURE
- 16.) TRANSFER LINE COUPLER
- 17.) FILL GUN
- 18.) FILTER HOUSING

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APPENDIX A

	GRANULYTE	
DATE	BATCH CONTROL RECORD (DISSOLUTION DOCUMENT)	OPERATOR

Formulation:

Batch No:

Mfg. Date:

Quality Control Testing:

Conductivity of Dialysate:

pH of Dialysate:

Empty Bag Count:

Other Tests:

Lot #:

Exp. Date

Note : The entire contents of each bag in the Granulyte "Unit Pack" must be emptied into the mixing tank to ensure proper electrolyte concentration.

Ionic Concentrations of Dialysate When Properly Diluted:

Sodium:

Potassium:

Calcium:

Magnesium:

Chloride:

Acid/Acetate:

Dextrose:

Sodium Diacetate		
	P L A C E	
	P E E L - O F F	
	L A B E L S	
	H E R E	

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