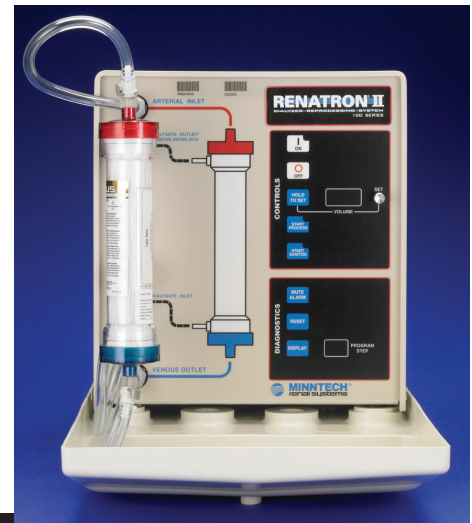


# renatron® II

## 100 Series Dialyzer Reprocessing System

MODEL RS 8335

100 Series



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**Read this Manual and the Renalin 100 Cold Sterilant Instructions for Use prior to using the Renatron II 100 Series Dialyzer Reprocessing System. Failure to follow the instructions for use may result in injury.**

**Retain this manual for future reference.**

**CAUTION - ONLY HOLLOW FIBER DIALYZERS SHOULD BE PROCESSED AS SPECIFIED IN THIS MANUAL.**

**CAUTION – U.S.A. FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON ORDER OF A PHYSICIAN.**

**WARNING**

**THE RENATRON II 100 SERIES SYSTEM IS INTENDED EXCLUSIVELY FOR IN VITRO CLEANING, TESTING, AND DELIVERY OF PROPORTIONED RENALIN® 100 SOLUTION TO THE DIALYZER AND RECORD KEEPING FOR THESE FUNCTIONS. ANY SUBSEQUENT CLINICAL APPLICATION OR USE OF A HOLLOW FIBER DIALYZER THAT HAS BEEN PROCESSED BY THE MACHINE IS THE SOLE RESPONSIBILITY OF THE ATTENDING PHYSICIAN.**

**WARNING**

**A HOLLOW FIBER DIALYZER THAT IS PROCESSED ON THIS MACHINE IS FILLED WITH A PROPORTIONED RENALIN 100 COLD STERILANT SOLUTION. THE PROPORTIONED RENALIN 100 COLD STERILANT SOLUTION MUST BE ADEQUATELY AND THOROUGHLY RINSED OUT OF THE DIALYZER PRIOR TO CLINICAL USE.**

## Indications

The Renatron II 100 Series Dialyzer Reprocessing System is indicated for the in vitro rinsing, cleaning, testing, and delivery of proportioned Renalin 100 Cold Sterilant solution to hollow fiber dialyzers. It is also indicated for record keeping of these functions. The Renatron II 100 Series system is indicated for use only with Renalin 100 Cold Sterilant solution.

## Contraindications

This device is not designed, sold, or intended for use except as indicated.

## Warnings and Precautions

ADDITIONAL WARNINGS AND PRECAUTIONS THAT APPLY TO SPECIFIC PROCEDURES ARE FOUND IN APPROPRIATE PLACES THROUGHOUT THIS MANUAL.

**DANGER — EXPLOSION HAZARD - DO NOT USE IN THE PRESENCE OF FLAMMABLE ANESTHETICS. RISQUE D'EXPLOSION – NE PAS EMPLOYER EN PRESENCE D'ANESTHESIQUES INFLAMMABLES.**

FAILURE TO FOLLOW INSTRUCTIONS IN THIS MANUAL MAY RESULT IN PATIENT OR USER INJURY.

**CAUTION – DISCONNECT POWER SUPPLY CORD BEFORE SERVICING.**

**ATTENTION: DEBRANCHER LE CORDON D'ALIMENTATION AVANT DE FAIRE LE DEPANNAGE**

**WARNING**

**GROUNDING RELIABILITY CAN ONLY BE ACHIEVED WHEN THIS DEVICE IS CONNECTED TO A RECEPTACLE MARKED "HOSPITAL GRADE" OR EQUIVALENT.**

**CAUTION – IF THE DEVICE IS USED IN A MANNER NOT SPECIFIED BY THE MANUFACTURER, THE PROTECTION PROVIDED BY THE DEVICE MAY BE IMPAIRED.**

**CAUTION – DO NOT USE CHEMICALS OTHER THAN RENALIN 100 COLD STERILANT WITH THIS MACHINE.**

**CAUTION – WATER SUPPLIED TO THIS SYSTEM MUST MEET THE REQUIREMENTS LISTED IN SECTION 5 SPECIFICATIONS. THE RS-8335 100 SERIES DOES NOT PERFORM WATER TREATMENT.**

**WARNING**  
**ELECTRIC SHOCK HAZARD: ONLY QUALIFIED PERSONNEL SHOULD REMOVE TOP COVER.**

**CAUTION** – DO NOT OPERATE THE RENATRON II 100 SERIES MACHINE WITH THE COVER OFF UNLESS SPECIFICALLY INDICATED IN THIS MANUAL.

**CAUTION** – ALL PERSONNEL USING THIS DEVICE SHOULD BE FAMILIAR WITH THE INFORMATION CONTAINED IN THIS MANUAL.

**CAUTION** – IT IS THE RESPONSIBILITY OF THE PRESCRIBING PHYSICIAN TO ENSURE THAT THE OPERATORS OF THIS DEVICE ARE PROPERLY TRAINED AND TECHNICALLY COMPETENT.

**CAUTION** – DO NOT REMOVE ANY WARNINGS, CAUTIONS, OR DESCRIPTIVE LABELING FROM THIS MACHINE OR THE POWER CORD SUPPLIED WITH THIS MACHINE.

**CAUTION** – ALL PLUMBING (HOSES AND LINES) ARE CUT TO LENGTH AND CALIBRATED AT THE FACTORY AND SHOULD NOT BE MODIFIED FROM THE ORIGINAL LENGTHS OR SIZES. ONLY FACTORY AUTHORIZED SERVICE PERSONNEL SHOULD REPAIR OR REPLACE THESE ITEMS.

**WARNING**  
**RENALIN 100 COLD STERILANT IS USED IN CONJUNCTION WITH THIS DEVICE. RENALIN 100 COLD STERILANT IS CORROSIVE AND CAN CAUSE EYE DAMAGE AND SKIN IRRITATION. WEAR EYE PROTECTION, GLOVES AND PROTECTIVE CLOTHING WHEN HANDLING THIS SOLUTION AND DURING THE OPERATION OF THE RENATRON II 100 MACHINE.**

**CAUTION** – THE OPERATOR SHOULD BE FAMILIAR WITH THE SAFE HANDLING TECHNIQUES FOR THE MACHINE AND THE RENALIN 100 COLD STERILANT AND WITH THE RECOMMENDED FIRST AID PROCEDURES IN CASE OF CONTACT WITH OR EXPOSURE TO RENALIN 100 COLD STERILANT.

**WARNING**  
**DO NOT ALLOW RENALIN 100 COLD STERILANT TO MIX WITH ALKALINE SUBSTANCES SUCH AS BLEACH (SODIUM HYPOCHLORITE)**

**CAUTION** — THIS MACHINE IS INTENDED EXCLUSIVELY FOR THE SOLE PURPOSE OF IN-VITRO CLEANING OF, TESTING OF DELIVERY OF RENALIN 100 SOLUTION TO AND RECORD KEEPING FOR PREVIOUSLY USED HOLLOW FIBER DIALYZERS. ANY SUBSEQUENT, CLINICAL APPLICATION OR USE OF A HOLLOW FIBER DIALYZER THAT HAS BEEN REPROCESSED BY THIS IS THE SOLE RESPONSIBILITY OF THE PRESCRIBING PHYSICIAN.

A. **Components:** the Renatron II 100 Series System consists of:

1. A Renatron II 100 Series station (1 to 12 can be used with the system):
  - a. The solid-state electronics control section
  - b. The RS-232 serial port, for data communications
  - c. The hydraulic section
  - d. The dialysate inlet and outlet port connection and the arterial and venous port connection lines
  - e. The Renalin 100 uptake hose
  - f. The drain line hose
2. Renalog® RM Data Management System:
  - a. IBM compatible computer
  - b. Renalog RM Dialyzer Reprocessing Data Management software package
  - c. Color monitor
  - d. Label printer
  - e. Report printer
  - f. Interface module

## Description

3. Materials for interconnection of the Renatron II 100 Series System:
  - a. Renatron II 100 Series station to Interface Module communication cable(s)
  - b. Computer to Interface Module communication cable (1 ea.)
  - c. Computer to Printer communication cable (1 parallel, 1 USB)
4. Materials for connection of the Renatron II 100 Series station to existing in-house water supplies consisting of:
  - a. Water pressure gauge block for attachment between one or two Renatron II 100 Series stations and the water outlet from the dialysis center. Mounts on the drip tray.
  - b. 1-6' water hose with a female Hansen type connector and a check valve for attachment to the water gauge block and a 3/4 inch female garden hose connector for attachment to the dialysis center water outlet.
  - c. 1-6' drain hose for each Renatron II 100 Series station.
5. One volumetric calibration cell for periodic checking of the Renatron II 100 Series operation.
6. Drip Tray - single or dual Renatron II 100 Series compatibility.

**B. Terminology:** For the purpose of clarity, the following terminology will be used throughout this manual.

1. "Water" or "AAMI quality water" is water that meets or exceeds the following requirements:
  - a. AAMI/ANSI Standard for Hemodialysis Systems and AAMI Recommended Practice for the Reuse of Hemodialyzers.
  - b. Containing no particles larger than 1 micron.
2. "Renalin 100 Cold Sterilant" or "Renalin 100" is a concentrated solution for use with the Renatron II 100 Series System. It is supplied as 3 liters of Renalin Cold Sterilant in a 1 gallon container for use by the Renatron II 100 Series machine and for use in making a 1% Renalin 100 mixture.
3. "Proportioned Renalin 100 Solution" is the final diluted solution, which has been proportioned by the Renatron II 100 Series machine. This is the solution actually used for cleaning and sterilizing the dialyzer.
4. "1% Renalin 100 Solution" - 1 part Renalin 100 Cold Sterilant to 99 parts AAMI quality water.
5. The terms equipment, machine, device, station or Renatron II 100 Series are synonymous with each Renatron II 100 Series Dialyzer Reprocessing unit of the overall Renatron II 100 Series system and may be used interchangeably throughout this manual.

**NOTE – ALL TIMES AND FLOW RATES SPECIFIED IN THIS MANUAL ARE APPROXIMATE.**

**C. General System Operation:** The Renatron II 100 Series is an automated system for rinsing, cleaning, and testing of hollow fiber dialyzers and for delivery of Proportioned Renalin 100 Cold Sterilant solution to the dialyzers. The Renatron II 100 Series System can also perform record keeping for a dialyzer reprocessing operation. The Renatron II 100 Series can be operated in a manual mode by the operator or in an automatic mode controlled by the Renalog RM Data Management System. In the manual mode the operator enters a predetermined (priming) volume into the machine and enters the pre-selected program mode for the dialyzer being reprocessed. If the Renatron II 100 Series is being controlled by the Renalog RM Data Management system, the predetermined (priming) volume for the selected dialyzer and the required program mode are automatically set on the Renatron II 100 Series by the computer using data stored in the Renalog RM data base. Record keeping for reprocessed dialyzers can be accomplished by manual data entry from the computer's keyboard or by scanning the bar code labels on the dialyzer, Renatron II 100 Series and user authentication label with the bar code scanner.

After rinsing and cleaning the dialyzers, the Renatron II 100 Series compares the blood compartment filling volume (priming volume) against the predetermined volume set manually or automatically into the machine. The machine also conducts pressure leak tests on the dialysate compartment of the dialyzer. If either the blood compartment volume test or the pressure leak test is unsatisfactory, the machine will automatically stop functioning and activate audible and visual alarms. When the automatic record keeping operation is functioning and the Renatron II 100 Series is reset, the Renalog RM Data Management system will record the actual volume measured, the volume test pass or fail and the pressure test pass or fail into that dialyzer's file record, and it will print new labels for the dialyzer.

The Renatron II 100 Series stations use Renalin 100 Cold Sterilant as the only chemical needed to reprocess dialyzers. THE QUALITY OF WATER USED TO SUPPLY RENATRON II 100 SERIES STATIONS MUST EQUAL OR EXCEED REQUIREMENTS LISTED IN SECTION 5, SPECIFICATIONS. The Renalin 100 Cold Sterilant used by the Renatron II 100 Series can cause a pressure build up within the machine and/or the dialyzer under certain conditions. To prevent this possible pressure build up, the Renatron II 100 Series will automatically perform a venting operation every 10 seconds after filling the dialyzer with Proportioned Renalin 100 Solution.

**CAUTION** – IN THE EVENT A DIALYZER HAS BEEN LEFT ON THE MACHINE AND DOUBT EXISTS WHETHER VENT ACTION HAS OCCURRED, (I.E. POWER FAILURE TO RENATRON II 100 SERIES) THE DIALYZER MUST BE REMOVED CAREFULLY. REMOVE THE DIALYZER AFTER WRAPPING ALL CONNECTIONS WITH DISPOSABLE ABSORBENT MATERIAL. PRESSURE BUILD UP MAY CAUSE FLUIDS TO SPRAY.

The Renatron II 100 Series station(s) sit on a single or dual unit drip tray that will catch fluid drippage from the machine(s). A water pressure gauge block, with one or two outlets as appropriate, is attached to the drip tray. The pressure gauge displays the pressure of the water supplied to the Renatron II 100 Series station(s). The steps of the reprocessing process are given below:

1. Performed by Operator

- a. Operator connects the dialysate outlet port on the dialyzer to the connector mounted on the front panel marked "DIALYSATE OUTLET SANITIZE INTERLOCK." This connection acts as the dialyzer holding fixture.
- b. Operator connects the system's "ARTERIAL INLET," "VENOUS OUTLET," and "DIALYSATE INLET" lines to the dialyzer.
- c. In the manual operation mode, the operator sets the blood compartment reference volume by touching the "HOLD TO SET" switch and turning the "SET" knob until the desired value is displayed in the "VOLUME" display. The value for the blood compartment reference volume must be determined by the attending physician for the type and size of the dialyzer to be reprocessed.\* The operator also selects the appropriate reprocessing program mode by pressing the "MUTE" and "RESET" switches.
- d. In the automatic operation mode, the operator scans the bar code label on the dialyzer, the serial number bar code label on the Renatron II 100 Series on which the dialyzer is to be reprocessed and their authentication label. The computer will then automatically set the appropriate Renatron II 100 Series priming volume and program mode (i.e., "00," "CH," "HF," "PC") for the dialyzer to be reprocessed.

**\* NOTE – It is recommended that the operator set the reference volume of the dialyzer to be reprocessed to 80% of the new dialyzer priming volume. New dialyzer measured priming volume may differ from advertised volume by as much as 20%. It is recommended that the operator measure new dialyzer volume with a known calibrated Renatron II 100 Series to determine actual new dialyzer priming volume.**

Document	Code	Program	Kuf	Time
20601-183	(00)	Low Flux Dialyzer	< 8	8 min.
20601-184	(CH)	Mid-Range/High Efficiency and Hemophan Type Dialyzers	8 - 15	10 min.
20601-185	(HF)	High-Range/High Flux Dialyzers and Hemofilters	15+	10 min.
20601-186	(PC)	Pre-clean Program for all Dialyzers	ALL	4 min.

2. Automatic Reprocessing Steps

- a. After the "START PROCESS" switch is pressed to initiate the reprocessing cycle, the Renatron II 100 Series will reprocess the dialyzer according to the steps outlined in the appropriate Operation Format and Program Outline document.

**\* NOTE – The Renatron II 100 Series machine should be sanitized a minimum of ONCE PER DAY.**

The machine can automatically sanitize itself when the "Volume" display indicates "SEL" and program mode "00," "CH," or "HF" are displayed in the "PROGRAM STEP" display. The operator touches the "START SANITIZE" switch to start the sanitize cycle. The steps of the sanitize cycle are given below:

- b. Operator first visually verifies that the "RENALIN 100 CONTAINER" has at least one inch of unexpired Renalin 100.

**NOTE – If an insufficient amount of Renalin 100 exists to complete one full "SANITIZE" cycle, the machine will automatically alarm. The message "ADD CHEMICAL" will appear on the front panel and remain visible until the alarm situation has been corrected and the "START SANITIZE" switch has been pressed.**

- c. Operator connects the system's "ARTERIAL INLET" and "VENOUS OUTLET" lines to the calibration cell and connects the "DIALYSATE INLET" line to the "DIALYSATE OUTLET - SANITIZE INTERLOCK" connector using the male/male fitting attached to the front of the machine.
- d. Operator touches the "ON" switch, selects a program by pressing the "MUTE" and "RESET" switches then touches the "START SANITIZE" switch which activates the sanitize cycle. The machine will automatically fill and flush all internal blood contact surfaces and the dialysate circuit with Proportioned Renalin 100 Solution. The machine then enters "PROGRAM STEP" **83**, at which time the "SANITIZE COMPLETE" message will be displayed and a 3 second continuous tone will sound.

- e. Operator presses the "OFF" switch, and allows the machine to sit for a minimum of 6 hours before using again.

**NOTE – A sanitize holding period of six hours or more will expose the machine’s fluid pathways to Proportioned Renalin 100 Solution for a time consistent with the disinfection time indicated in the Renalin 100 Cold Sterilant labeling. If the "START PROCESS" switch is pressed after entering "PROGRAM STEP" 83, total sanitize cycle time will be approximately seventeen (17) minutes which includes a 10 minute hold time. This will sanitize the machine fluid pathways. This cycle will also allow the purging of the Renatron II 100 Series hydraulic pathways for shipping purposes. Use the methods described in c - d above for a routine sanitization procedure.**

- f. Operator wipes clean the external machine surfaces with a lint free disposable towel saturated with fresh 1% Renalin 100 solution or undiluted Actril® Cold Sterilant.
- g. The Renatron II 100 Series System is now ready for reprocessing of dialyzers.

- A. **Materials of Construction:** Acrylic, PVC, ABS, Polypropylene, Delrin®, Ethylene Propylene, Viton® Rubber, Stainless Steel.
- B. **Electrical Leakage Current (risk current):** Each Renatron II 100 Series is allowed a leakage current less than 100 micro amps RMS MAX at 115 VAC per UL standard 61010-1.
- C. **Electrical Requirements:**

- 1. Renatron II 100 Series station:

<b>Voltage:</b>	Selectable 100, 120, 230, 240 VAC 50/60 Hz single phase
<b>Fuses:</b>	100-120 VAC, one 4A 3AG (1.25 inches x 0.25 inches) 220-240 VAC, two T2A (5mm x 20mm)
<b>Equipment Classifications:</b>	Class 1
<b>Electrical Leakage Current (risk current):</b>	From cabinet to ground: <100 µA From ground to outlet: < 100 µA
<b>Power Consumption:</b>	460 VA maximum
<b>Mode of Operation:</b>	Continuous operation

- 2. Interface Module:

<b>Voltage:</b>	Selectable 115, 230 VAC 50/60 Hz single phase
<b>Fuses:</b>	175 ma, 250V Time Delay Fuse
<b>Equipment Classification:</b>	Class 1
<b>Electrical Leakage Current (risk current):</b>	< 500 µA
<b>Power Consumption:</b>	20 Va maximum
<b>Mode of Operation:</b>	Continuous operation

- 3. Label Printer:  
100-240 VAC., 50/60 HZ., 1.5 AMP, 39.1 Watt Max.
- 4. Report Printer:  
100-240 VAC., 50-60 HZ., 30 Watt Max.
- 5. Monitor-CRT:  
100-120 VAC., 50/60 HZ., 0.8 AMP, 100 Watt Max.
- 6. Monitor-Flat Screen:  
100-240 VAC., 50-60 HZ., 30 Watts Max.
- 7. Computer:  
100-120 VAC., 50/60 HZ., 230 Watt Max.

## Specifications

**D. Physical Properties and Dimensions:**

1. Renatron II 100 Series station:

<b>Width</b>	14.5 inches	41 cm
<b>Depth</b>	12.3 inches	31 cm
<b>Height</b>	16 inches	33 cm
<b>Weight</b>	50 lbs	23 kg

2. Interface Module:

<b>Width</b>	12 inches	30.5 cm
<b>Depth</b>	11 inches	28 cm
<b>Height</b>	3.5 inches	8.9 cm
<b>Weight</b>	6 lbs	2.7 kg

3. Label Printer: approximately

<b>Width</b>	7.9 inches	20.0 cm
<b>Depth</b>	9.75 inches	24.8 cm
<b>Height</b>	6.8 inches	17.3 cm
<b>Weight</b>	3.2 lbs	1.5 kg

4. Report Printer: approximately

<b>Width</b>	17.7 inches	50 cm
<b>Depth</b>	14.6 inches	37 cm
<b>Height</b>	5.7 inches	15 cm
<b>Weight</b>	11.7 lbs.	5.3 kg

5. Monitor-CRT: approximately

<b>Width</b>	14.2 inches	36 cm
<b>Depth</b>	15.6 inches	39 cm
<b>Height</b>	14.8 inches	38 cm
<b>Weight</b>	28 lbs	12.5 kg

6. Monitor-LCD: approximately

<b>Width</b>	13.4 inches	34 cm
<b>Depth</b>	6 inches	15 cm
<b>Height</b>	13.4 inches	34 cm
<b>Weight</b>	7 lbs	3.2 kg

7. Computer: approximately

<b>Width</b>	7.3 inches	18 cm
<b>Depth</b>	17.3 inches	44 cm
<b>Height</b>	16.3 inches	41 cm
<b>Weight</b>	27.2 lbs	112.34 kg

**8. Drip Tray:**

	Version 1 (single)		Version 2 (dual)	
<b>Width</b>	15.25 inches	39 cm	33.25 inches	85 cm
<b>Depth</b>	28 inches	71 cm	28 inches	71 cm
<b>Height</b>	3.5 inches	9 cm	3.5 inches	9 cm
<b>Weight</b>	3 lbs	1.36 kg	6 lbs	2.73 kg

**E. Environmental Limits:**

The Renatron II 100 Series is designed to be safe for indoor use at temperatures from 5°C (41°F) to 40°C (104°F), maximum relative humidity of 80% at 31°C (87.8°F) decreasing linearly to 50% relative humidity at 40°C (104°F) and altitudes up to 6500 ft (2000 meters). The supply line voltage fluctuations may not exceed ±10% of the nominal voltage.

**F. Water Requirements:**

1. Flow
  - a. Feed line flow 0.46 gallons per minute (1.75 liters/minute) average pressure at 20-55 psig (137.9 - 379 K Pa, 1.38 - 3.79 Bars) per Renatron II 100 Series station.
  - b. Peak flow rate is approximately 1.6 gallons per minute (6 liters/minute) per Renatron II 100 Series station. This peak flow is 15-35 seconds in duration and occurs at approximate three (3) minute intervals.
2. Water must meet quality requirements listed in the current versions of the ANSI/AAMI Standard for Hemodialysis Systems and ANSI/AAMI Recommended Practice for Reuse of Hemodialyzers. It must meet both endotoxin and bacterial specifications listed in the current version of the ANSI/AAMI Recommended Practice for Reuse of Hemodialyzers.
3. Inlet water must be filtered to particle size not larger than 1 micron.
4. Temperature must be in a range of 59°F - 75°F (15°C - 24°C).
5. Static (no flow) pressure should not be in excess of 55 psig (379K Pa, 3.79 Bars). For optimal performance adjust the pressure to 30-35 psig dynamic output pressure while all Renatron II 100 Series are operating in step 04 and all the other equipment on the same water system are in operation.

**G. Drain:**

The drain must be capable of accepting a minimum water flow of 1.6 gal/min. (approx. 6 liters/minute) per Renatron II 100 Series station. Optimal placement is at counter top level, and the drain should be placed no higher than the top of the machine. Sanitary drain connections must be used in accordance with state and local plumbing codes. Drain must be vented to atmosphere. Drain piping should be made from PVC, CPVC or other corrosion resistant materials.

**H. Dialyzer Testing:**

The Renatron II 100 Series station performs a blood compartment (priming) volume measurement, and a pressure leak test on each dialyzer.

1. Header Leak Test - The Renatron station will perform a header leak test, between program Step 2 and 3. If a "Pressure Fail" message appears in Step H-2, verify that the blood port connections are secure and that the dialyzer header caps and O-rings are properly placed. This test can be repeated indefinitely by pressing the "START PROCESS" switch. If the "pressure fail" message re-appears after the blood port connections and header cap and O-ring placement has been verified, the "RESET" switch should be pressed to fail the dialyzer. This error message is exactly the same error message as in program Step 39 and will fail the dialyzer for "pressure". Therefore, the operator should keep track of the step in which the error occurred.
2. Blood Compartment (Priming) Volume Measurement - The Renatron II 100 Series measures, displays and holds each reprocessed dialyzer's blood compartment volume with a repeatability of ± 5%, typically within 5.0 ml of true volume. If this volume is less than the blood compartment reference volume (selected by prescribing physician) the dialyzer fails the volume test.
3. Volume Fail - The Renatron station will only allow a dialyzer to be re-tested two times after it initially fails the volume test during the reprocessing cycle.

If a "volume fail" message appears, press the "START PROCESS" switch to repeat the test. After the initial "volume fail" message appears, the test may only be repeated two more times. After the third "volume fail" message appears, the "START PROCESS" switch will be deactivated and you must press the "RESET" switch to fail the dialyzer.

4. Pressure Leak Test - The dialysate compartment of each dialyzer is subjected to a minimum of 250 mmHg negative pressure while the blood compartment remains at atmospheric pressure. A dialyzer that loses pressure at a rate equal to or greater than 0.83 mmHg  $\pm$  10% per second fails the pressure leak test (low flux - 00 and mid-range CH programs). A dialyzer that loses pressure at a rate equal to or greater than 1.25 mmHg  $\pm$  10% per second fails the test for the high flux (HF) program.

#### **I. Chemicals Required:**

The Renatron II 100 Series station is designed to function with Renalin 100 Cold Sterilant. This solution is described in the Renalin 100 Cold Sterilant Instructions for Use (P/N 50090-679).

#### **A. Renatron II 100 Series Station Controls (Figure 1)**

1. "OFF" switch de-energizes electronic circuitry in the Renatron II 100 Series. POWER WILL STILL BE TRANSMITTED TO THE MACHINE UNLESS THE MACHINE IS DISCONNECTED FROM THE ELECTRICAL POWER SUPPLY.
2. "ON" switch energizes electronic circuitry. Sets Renatron II 100 Series station in standby mode (i.e., "volume" display reads ["SEL"] and "PROGRAM" step display indicates [--]).
3. "START PROCESS" switch initiates dialyzer reprocessing only when a priming volume has been set and a dialyzer reprocessing program selected i.e., "00," "CH," "HF," "PC". Note: "PC" program can only be accessed in the automatic mode controlled by the computer. "START PROCESS" also allows user to repeat most program steps after an alarm situation in a process cycle.
4. "START SANITIZE" switch initiates a machine cleaning cycle and repeats most program steps after an alarm situation in sanitize cycle.

**NOTE – Sanitize can only be initiated if reprocessing program "00," "CH" or "HF" is being displayed in the "step display," not from the standby [--] or pre-clean [PC] mode and the volume display reads ["SEL"].**

5. "MUTE" switch mutes audio alarm.
6. "RESET" switch returns machine to last program mode used and "VOLUME" display to "SEL". Reset must be used at the end of a cycle or in an alarm state (locked out or disabled at all other times) to guarantee automatic transfer of reprocessing data to the computer.
7. "DISPLAY" switch allows operator to blank the display from viewing the actual program steps.
8. "HOLD TO SET" switch when touched, activates "VOLUME" display. Allows operator to view displayed value of minimum acceptable blood compartment reference volume "SET" into the machine manually or automatically by the computer.
9. "SET" knob used in conjunction with the "HOLD TO SET" switch allows the operator to set the minimum acceptable blood compartment reference volume prescribed by the attending physician in the manual mode of operation.

#### **B. Interface Module Controls:**

1. "BAR CODE SCANNER" allows the operator to automatically enter dialyzer and Renatron II 100 Series station serial number information into the computer by simply scanning the bar code labels on the dialyzer, the Renatron II 100 Series serial number barcode label, and the user authentication label.
2. "Power ON/OFF" switch is located at the back of the Interface Module where the power cord enters the unit. It allows electrical power to the Interface Module to be switched on and off.

#### **C. Renatron II 100 Series Station Indicators and Error Messages:**

1. "VOLUME DISPLAY" indicates:
  - a. Blood compartment volume test measurement; or
  - b. Blood compartment reference volume
2. "PROGRAMSTEP" is a display that allows the operator to view the actual program step number and programmed mode of operation. Display is deactivated/activated by sequentially touching "DISPLAY" switch.

## **Description of Controls**

3. "TANK VOLUME" error message appears when the internal mixing/measuring tank should be empty but is not or when an improper action has occurred within the tank.
4. "CLEAN" message appears during the dialyzer cleaning steps.
5. "ADD CHEMICAL" error message appears when machine detects that an insufficient amount of Renalin 100 Cold Sterilant has been drawn into the mixing/measuring tank.
6. "TEST" message appears during the dialyzer testing steps.
7. "VOLUME FAIL" error message appears when measured dialyzer blood compartment (priming) volume is less than the blood compartment reference volume.
8. "PRESSURE FAIL" error message appears when a dialyzer fiber leak or compromised dialyzer header integrity has been detected by the machine.
9. "DISINFECT" message appears during the dialyzer disinfection steps.
10. "ALARM" error message flashes continuously while the machine is in alarm mode.
11. "PROCESS COMPLETE" message appears when dialyzer reprocessing cycle is complete.
12. "INTERLOCK" error message appears when the "START SANITIZE" switch has been pressed and the sanitize interlock is not engaged.
13. "SANITIZE COMPLETE" message appears when the machine sanitization cycle is complete.

**D. Interface Module Indicators**

1. "POWER" is the light emitting diode (LED) on the front panel. When illuminated, it indicates electrical power is switched on.
2. "SCANNER" is the light emitting diode (LED) on the front panel. When illuminated, it indicates bar code scanner can be used to input data. Bar code scanner is disabled at all other times.

**NOTE – Separate manuals are provided with the computer system. Refer to the respective manuals for detailed information about the computer, monitor, and printer controls and indicators.**

***IMPORTANT – TO ISOLATE THE STATION FROM THE ELECTRICAL SUPPLY YOU MUST DISCONNECT THE CORD FROM THE POWER ENTRY MODULE LOCATED IN THE LOWER RIGHT (WHEN VIEWED FROM THE FRONT) SIDE OF THE UNIT BACKSIDE. THE UNIT SHOULD BE SITUATED TO ALLOW AS MUCH ROOM ON THE RIGHT SIDE AS POSSIBLE, ALLOWING EASY ACCESS.***

## **Renatron II 100 Installation Instructions**

**CAUTION – TOTAL SYSTEM CHASSIS RISK CURRENT SHOULD NOT EXCEED 100 MICRO AMPS.**

**ATTENTION – LE COURANT DE RISQUE TOTAL ADMISSABLE AU CHASSIS NE DOIT PAS DEPASSER 100 MICRO AMPS.**

**NOTE – Report any damage promptly to the shipping company and make claim for compensation. Damage incurred during shipment is not covered by the machine warranty. Please save the shipping container for use in returning machine if repairs are necessary.**

**NOTE – All plumbing (hoses and lines) are cut to length and calibrated at the factory and must not be modified from the original lengths or sizes. Only factory authorized service personnel should repair or replace these items.**

**CAUTION – PRIOR TO CONNECTING, ALL WIRING MUST BE CHECKED TO ENSURE PROPER POLARITY AND ALL GROUNDS MUST BE CHECKED TO ENSURE CONTINUITY.**

**CAUTION – WHEN THE WATER SUPPLY FEED LINE IS CONNECTED TO THE RENATRON II 100 SERIES, IT MUST BE EQUIPPED WITH AN "ON-OFF" VALVE THAT WILL PERMIT SHUTTING OFF THE FLOW OF WATER TO THE RENATRON II 100 SERIES WHEN NOT IN USE.**

**CAUTION – PROPER WATER SYSTEM OPERATION MUST BE VERIFIED. SEE SPECIFICATION SECTION FOR WATER REQUIREMENTS.**

**NOTE – THE RENALIN 100 COLD STERILANT CONTAINER IS TRANSLUCENT TO ALLOW THE USER TO VIEW THE LEVEL OF SOLUTION. ALWAYS USE THE RENALIN 100 COLD STERILANT**

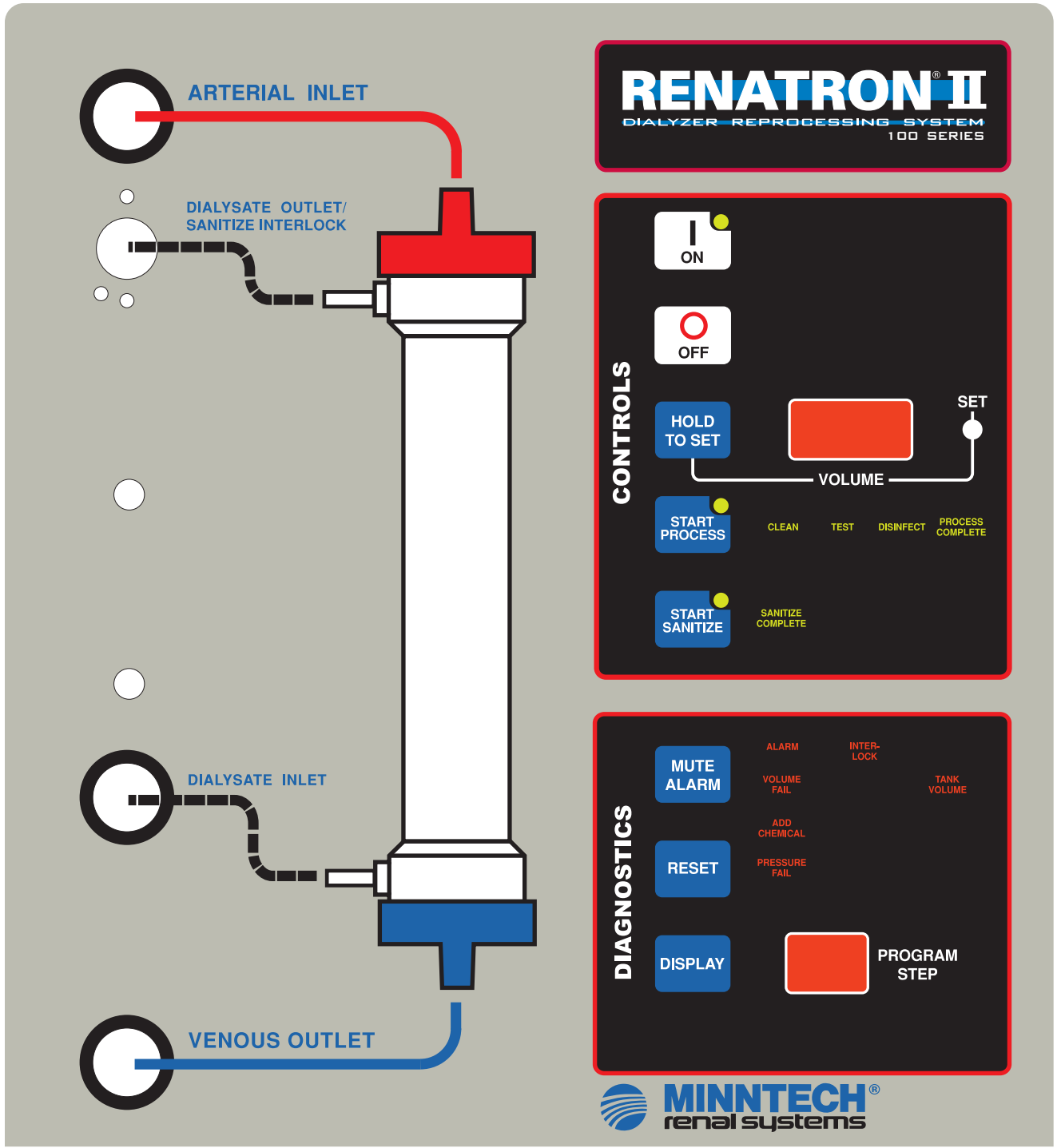


Figure 1

**CONTAINER AS A SUPPLY TANK FOR THE RENATRON II 100 SERIES. DO NOT USE ANY OTHER TYPE TANK OR CONTAINER.**

**CAUTION – ALWAYS STORE THE RENALIN 100 COLD STERILANT CONTAINER UPRIGHT AND OUT OF DIRECT SUNLIGHT. EXPOSURE TO DIRECT SUNLIGHT DAMAGES THE CLEANING AND DISINFECTING QUALITIES OF THE RENALIN 100 COLD STERILANT.**

**NOTE - STORING RENALIN 100 COLD STERILANT IN ITS ORIGINAL SHIPPING CARTON PREVENTS EXPOSURE TO SUNLIGHT.**

**A. Verify suitable service connection**

1. Water quality must meet or exceed water requirements listed in Section 5 specifications.
2. If static (no flow) water pressure exceeds 55 psig (379K Pa, 3.79 Bars) make sure the static pressure is reduced to below 55 psig. Dynamic pressure displayed must be 20 psig or greater in step **04**. Optimal dynamic water pressure is between 30-35 psig.

**B. Remove the machine from shipping carton** and inspect for possible damage incurred during shipment. Lift the machine by placing fingers under the rear corners of the station, pulling the station close to the body, and lifting while keeping the back straight. Keep the station close to the body while carrying to the new location.

**C. Remove Hose Connection Assembly, Instruction Manual and Calibrated Volume Cell.** Save carton for future use in service or evaluation return.

**D. Remove drip tray(s) from shipping carton(s) and place in desired location on sturdy,** level bench. Place the machines in appropriate mounts on the drip tray. The Renatron II 100 Series Station must be level. Machines that are not level may have a 0-8 ml error in the initial volume that is displayed when measuring Calibrated Volume Cell.

**E. Place the uptake tube marked with the word Renalin 100 in a container of Renalin 100.**

**F. Make service connections to power, water and drain in accordance with Specifications listed in Section 5.** Make sure that the water pressure gauge block is connected between the water inlet source and the Renatron II 100 Series Station. Secure the water pressure gauge block to the back of the drip tray using the screws provided. Be absolutely certain that no water leaks exist and all connections are secure.

**G. Connect the dialysate line quick disconnects together** using the plastic male to male connector (interlock connector).

**H. Open the water supply valve completely.**

**I. Push the switch labeled "ON."** "SEL" will be displayed in the "VOLUME" display and "--" will appear in the "PROGRAM STEP" display window.

**J. Push the "MUTE ALARM" switch and the "RESET" switch at same time.** "00" will be displayed in the "PROGRAM STEP" display window.

**K. Touch and hold the "HOLD TO SET" switch and adjust the "SET" knob until the "VOLUME" window displays (003). Release the "HOLD TO SET" switch.**

**L. Press the "START PROCESS" switch.** The machine will finish the process cycle and then the "PROCESS COMPLETE" message and tone will be activated.

**M.** The calibration cell volume should be within  $\pm 3$  cc. of the volume value displayed on the Renatron II 100 Series Station. If the value is not within this range, refer to Sections 14.

**N. Press the "RESET" switch.** The "VOLUME" display will read "SEL" and the "PROGRAM STEP" display will indicate "00" or the last program mode used.

**O. Press the "START SANITIZE" switch.** A amber light will appear in corner of switch. Ensure that the machine completes all sanitize steps and stops at step **83**. After the "START PROCESS" switch is pressed, the machine should complete the cycle after approximately seventeen (17) minutes. Steps higher than **83** are used only when a complete hydraulic purge is needed (e.g. preparation for shipment).

**P.** Installation is complete. **Repeat for each Renatron II 100 Series station.**

**Q.** Reference the following section for Computer System installation instructions.

**CAUTION – RENATRON II 100 SERIES STATIONS ARE NOT SANITIZED AT THE FACTORY. THE SANITIZE PROCEDURE MUST BE PERFORMED PRIOR TO REPROCESSING DIALYZERS INTENDED FOR PATIENT USE.**

# Computer Installation Instructions

- A. **Remove the computer system from shipping cartons** and inspect for possible damage incurred during shipment. Save carton for future use in service or evaluation return.
- B. **Computer systems includes:**
1. IBM compatible computer
  2. Color monitor
  3. Printer(s)
  4. Interface module
  5. Bar code scanner
  6. Interconnecting cables
- C. **Place the computer, monitor, and printer in desired location** on a sturdy bench or counter top away from the Renatron II 100 Series Station's wet area (or protected from fluid spray). Place the "Interface Module" near the Renatron II 100 Series Station location (i.e. top or side).
- D. **Attach the interconnecting cables as shown in Figure 2.**
- **Connect the communications cable** from the COM 1 serial port on the computer to the connector marked "Computer" on the "Interface Module." Reference the computer manufacturer's manual.
  - **Connect the printer cable** from the LPT1/Parallel port on the computer to the label printer parallel port. Reference the computer manufacturer's manual.
  - **Connect the "Bar code scanner"** to the "Scanner" port on the "Interface Module."
  - **Connect the USB cable** from any of the USB ports on the computer to the report printer.
- E. **Connect the Renatron II 100 Series station's communication cable** to the connector marked "Comm. Port" on the back of the Renatron II 100 Series Station to the lowest "port" number connector available on the "Interface Module." Reference Figure 2.
- F. **Refer to the computer manufacturer's manual** for instructions for connecting the monitor, keyboard and mouse.
- G. **Power on sequence of computer system:**
1. Printer(s)
  2. Monitor
  3. Computer
  4. Interface module
  5. Renatron II 100 Series Station(s)

**Note – Use a multiple outlet, surge protected, power strip with a single switch if desired, powering everything on at once.**

**Note – The computer should be plugged into the "ALWAYS ON" outlet of the power strip, and will have to be powered On or Off independently of the power strip.**

H. Power on the equipment in the order listed in Section "G". The computer will boot into the Windows operating system, double click on the Renalog RM icon to access the login screen.

**Note – For instructions on the Automatic Mode of Renatron II 100 Series operation using Renalog RM Dialyzer Reprocessing Data Management System refer to the Instruction Manual P/N: 50090-859.**

**Note – It is very important to use the proper procedure when turning off the computer. NEVER TURN OFF THE COMPUTER VIA THE POWER SWITCH. When turning off the computer, exit completely out of Renalog RM. At the Windows desktop, click START, then SHUT DOWN, then SHUT DOWN again. Windows will perform its shut down procedure and turn the computer off. If the power switch on the front of the computer is used to turn off the computer, corruption to Windows, Renalog RM, or your data may occur.**

# Daily Machine Sanitize Procedure

## A. The Renatron II 100 Series station must be sanitized once each day. Perform the following procedure at end of reprocessing day:

1. Ensure that the Renalin 100 container has at least 1" of unexpired Renalin 100.
2. Connect the "ARTERIAL INLET" and "VENOUS OUTLET" lines to the calibration cell.
3. Attach the "DIALYSATE INLET" line to the "DIALYSATE OUTLET/SANITIZE INTERLOCK" connector using the male/male fitting attached to the front of the machine.
4. Wipe clean all external surfaces on the Renatron II 100 Series station with fresh 1% Renalin 100 Solution or full strength Actril Cold Sterilant.
5. Check that the "VOLUME" display indicates "SEL" and program mode "00," "CH" or "HF" are displayed in the "PROGRAM STEP" display.
6. Push the "START SANITIZE" switch to start the cycle. The machine will automatically sanitize itself.
7. Press machine "OFF" switch when the machine cycles to "PROGRAM STEP" 83. A "SANITIZE COMPLETE" message will be displayed.

**NOTE – A sanitize holding period of six hours or more will expose the machine's fluid pathways to Proportioned Renalin 100 Solution for a time consistent with the disinfection time indicated in the Renalin 100 Cold Sterilant labeling. If the "START PROCESS" switch is pressed after entering "PROGRAM STEP" 83, total sanitize cycle time will be approximately seventeen (17) minutes which includes a 10 minute hold time. This will sanitize the machine fluid pathways. This cycle will also allow the purging of the Renatron II 100 Series system hydraulic pathways for shipping purposes.**

8. Turn off water supply to the Renatron II 100 Series station.
9. If the Renatron II 100 Series station is not used within 7 days time after sanitize is complete, it should be sanitized again and allowed to sit for at least 10 minutes prior to use.

### IMPORTANT NOTE

THE REPROCESSING MANAGER MUST READ AND ACT ON THE INSTRUCTIONS FOR SETTING UP THE RENALOG RM PROGRAM BEFORE NORMAL ONLINE USE OF THE SYSTEM IS ATTEMPTED. THERE IS A SEPARATE RENALOG RM INSTRUCTION MANUAL P/N: 50090-859.

## A. General Considerations and Cautions

**CAUTION – MINNTECH RENAL SYSTEMS STRONGLY RECOMMENDS THAT ANY HOLLOW FIBER DIALYZER REPROCESSED BY THIS MACHINE ACCORDING TO THE INSTRUCTIONS IN THIS MANUAL, BE USED ONLY BY THE PATIENT WHO ORIGINALLY USED THE DIALYZER.**

1. When the Renatron II 100 Series station is not in use, the "ARTERIAL INLET" and "VENOUS OUTLET" lines should be connected to the Calibrated Volume Cell. The "DIALYSATE INLET" line should remain attached to the male/male fitting on the "DIALYSATE OUTLET/SANITIZE INTERLOCK" connector.
2. At the end of each day the operator should sanitize each Renatron II 100 Series station. The "SANITIZE" cycle sanitizes the machine and prepares it for overnight storage.
3. Renalin 100 Cold Sterilant and its diluted versions are sensitive to direct sunlight. The Renalin 100 Cold Sterilant storage carton can be used to hold the Renalin 100 containers and reduce the light exposure of Renalin 100 Cold Sterilant. Before using the Renatron II 100 Series station each day, ensure that:
  - a. The Renalin 100 Cold Sterilant has not passed the expiration date marked on the Renalin 100 container.
  - b. The Renalin 100 container will hold sufficient Renalin 100 Cold Sterilant to reprocess approximately 77 dialyzers (low flux and mid-range programs), or 50 dialyzers (high flux program).
4. Prior to the removal of the dialyzer from the blood circuit, the operator must ascertain that all identification and information on the dialyzer is legible and current (Section 13, part I).
5. After storage and prior to preparation for use, a sample of fluid should be removed from the dialyzer and tested for the presence of Renalin 100 solution using the Renalin 100 presence test procedure and Perassay 500® Peracetic Acid Indicator Test Strips (Part #78378-000). The Renalin 100 presence test procedure is described in the Renalin 100 Cold Sterilant Instructions for Use, Part #50090-679.

# Operating Procedures

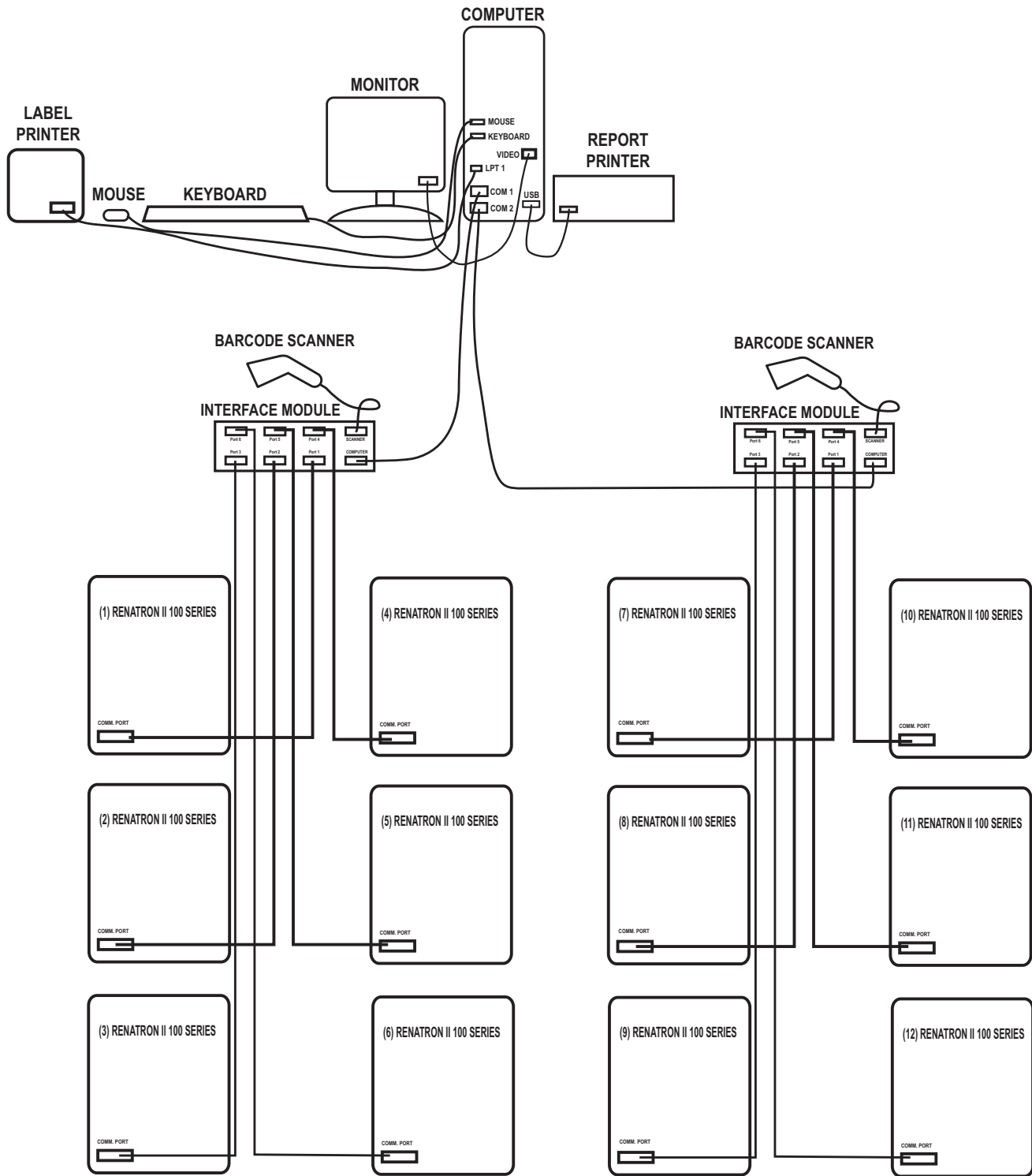


Figure 2

**WARNING**  
**THE PROPORTIONED RENALIN 100 SOLUTION CONTAINED IN THE REPROCESSED DIALYZER MUST BE ADEQUATELY AND THOROUGHLY RINSED OUT OF THE DIALYZER PRIOR TO ITS CLINICAL USE. THIS SHOULD BE DONE IN ACCORDANCE WITH THE INSTRUCTIONS SET FORTH IN THE RENALIN 100 COLD STERILANT INSTRUCTIONS FOR USE (PART #50090-679).**

**B. Start Up**

1. Prior to the first use of day, **wipe off the front panel of the Renatron II 100 Series station** with a disposable wipe saturated with fresh 1% Renalin 100 Solution or full strength Actril Cold Sterilant. Discard the used wipe.
2. **Verify that the Calibration Cell is attached to the Renatron II 100 Series Station.**
3. **Turn on the water supply and check static water pressure reading** (should be between 20-55 psi).
4. **Verify that there is sufficient Renalin 100 in the container** to reprocess the dialyzer that will be installed on the Renatron II 100 Series station in step D, below and that the Renalin 100 Cold Sterilant is not expired. Approximately 1" of Renalin 100 Cold Sterilant is required. Verify that the uptake hose is connected to the container.
5. **Touch the "ON" switch and select program mode "00".**
  - a. To change the program mode, simultaneously press "MUTE/ALARM" and "RESET".
  - b. "START PROCESS" will not initiate if "SEL" is displayed in the upper window. To clear, press "HOLD TO SET" and turn "SET" knob to 67.
6. **Check dynamic water pressure.** In step 4, the dynamic pressure should optimally be between 30-35 psi.
7. **Verify that the Calibration Cell volume displayed is within  $\pm 3$  ml of the recorded reference volume.**
8. **Remove the Calibration Cell.**
9. **Press "RESET."**

**Note – When calibrating the Renatron II 100 using the Renalog RM Dialyzer Reprocessing Management System, follow the calibration procedure outlined in the Renalog RM User Guide (P/N: 50090-859).**

**C. Remove the Dialyzer from the Extracorporeal Blood Circuit** using standard facility protocols.

**Note – Prior to removing the dialyzer from the extracorporeal circuit, the operator must ensure that all identification and information on the dialyzer is legible and current before proceeding.**

**WARNING**  
**THE OPERATOR SHOULD WEAR PROTECTIVE EYEWEAR, GLOVES, AND OTHER PROTECTIVE CLOTHING. FOLLOW UNIVERSAL SAFETY PRECAUTIONS FOR DEALING WITH BLOOD CONTAMINATED DEVICES.**

**CAUTION – THE TIME INTERVAL BETWEEN REMOVING THE DIALYZER FROM THE EXTRACORPOREAL CIRCUIT AND REPROCESSING IT SHOULD BE KEPT WITHIN THE LIMITS PRESCRIBED BY THE PHYSICIAN. THE SUGGESTED MAXIMUM TIME INTERVAL IS TWO (2) HOURS.**

**D. Installation of the Dialyzer on the Renatron II 100 Series station.**

1. Remove the blood port cap from the venous blood port of the dialyzer.
2. Wipe the venous blood port with a wipe saturated with 1% Renalin 100 Cold Sterilant Solution or full strength Actril Cold Sterilant and attach a disinfected reprocessing connector.
3. Attach the Renatron II 100 venous outlet line to the reprocessing connector attached to the venous port of the dialyzer.
4. Connect the dialyzer dialysate inlet to the Renatron II 100 dialysate inlet.
5. Connect the dialyzer dialysate outlet to the Renatron II 100 dialysate outlet/sanitize interlock.
6. Remove the blood port cap from the arterial blood port.
7. Wipe the arterial blood port with a wipe saturated in 1% Renalin 100 Cold Sterilant Solution or full strength Actril Cold Sterilant and attach a disinfected reprocessing connector.
8. Attach the Renatron II 100 Series station arterial inlet line to the reprocessing connector attached to the arterial blood port of the dialyzer. Dialyzer placement should be vertical to the Renatron II 100 Series station.

**CAUTION** – IT IS THE SOLE RESPONSIBILITY OF THE PRESCRIBING PHYSICIAN TO DETERMINE THE ACCEPTABLE BLOOD COMPARTMENT REFERENCE VOLUME AND PROGRAM MODE FOR A PARTICULAR TYPE AND SIZE HOLLOW FIBER DIALYZER. THIS REFERENCE VOLUME AND PROGRAM MODE MUST BE SET FROM THE FRONT PANEL MANUALLY OR INITIALLY ENTERED INTO THE DATABASE TO ALLOW THE COMPUTER TO AUTOMATICALLY SET THESE VALUES BEFORE REPROCESSING A DIALYZER. IT IS STRONGLY RECOMMENDED THAT THE MINIMUM ACCEPTABLE REFERENCE VOLUME BE AT LEAST 80% OF THE PRE-PROCESS VOLUME.

**CAUTION** – IT IS IMPORTANT FOR THE OPERATOR TO VERIFY THAT THE BLOOD COMPARTMENT REFERENCE VOLUME SET ON THE MACHINE MANUALLY OR AUTOMATICALLY IS CORRECT FOR EACH DIALYZER TO BE REPROCESSED.

#### **E. Reprocessing the Dialyzer on the Renatron II 100 Series station in manual operation**

1. **Push the switch labeled "ON."** "SEL" will be displayed in the "VOLUME" display window and "--" will appear in the "PROGRAM STEP" display window.
2. **Push the "RESET" switch and the "MUTE" switch at same time** to display the proper program mode in the "PROGRAM STEP" display window for the dialyzer to be reprocessed, i.e. "00," "CH," "HF."

**Note** – Pre-clean (PC) mode is disabled when using the Renatron II 100 Series station in manual operation.

3. **Touch and hold the "HOLD TO SET" switch.**
4. **Adjust the "SET" knob until the "VOLUME" display indicates the physician's prescribed blood compartment reference volume** for the dialyzer to be reprocessed.
5. **Touch the "START PROCESS" switch.** The Renatron II 100 Series station will now reprocess the dialyzer in the manner described in the section General Systems Operation, of this manual.
6. When the "PROCESS COMPLETE" message appears the reprocessed dialyzer is ready to be removed from the Renatron II 100 Series station.
7. If a "VOLUME FAIL" or "PRESSURE FAIL" message appears **press the "START PROCESS" switch to repeat the test which was failed.** The dialyzer may pass the test when retested by the Renatron II 100 Series station.

#### **F. Reprocessing the dialyzer on the Renatron II 100 Series station in automatic operation**

1. **Push switch labeled "ON."** "SEL" will be displayed in the "VOLUME" display window and "--" will appear in the "PROGRAM STEP" display window.
2. In the automatic reprocessing screen of the Renalog RM Program, when the green light is illuminated on interface module, **scan the bar code label on the dialyzer to be reprocessed, scan the bar code label on the Renatron II 100 Series station which corresponds to the cycle that is to be run and scan your authentication label.** The order of the labels being scanned does not make a difference.

**Note** – The two cycles available are the complete reprocessing cycle and the pre-clean cycle. To select a complete reprocessing cycle, scan the barcode label on the Renatron II 100 Series station, the dialyzer's bar coded label. After the third label, your authentication label is scanned, the computer will automatically set the prescribed blood compartment reference volume and correct program mode for the dialyzer to be reprocessed. To select the pre-clean option, scan the bar code labeled pre-clean, the dialyzer's bar code label and your authentication label.

**Note** – Maximum effectiveness of the pre-clean mode is attained in two hours. During this period, if the dialyzer is not removed from the Renatron II 100 Series, the machine will vent the dialyzer every 10 seconds to prevent pressure build up. One label will be printed at the end of the pre-clean cycle warning you that the dialyzer has been pre-cleaned only and must go through the complete reprocessing cycle before being placed in storage.

**CAUTION** – THE PRE-CLEAN MODE IS INTENDED TO AUTOMATICALLY STOP THE RENATRON II 100 SERIES STATION AFTER THE RENALIN 100 CLEANING PHASE. THIS ACTION ALLOWS THE OPERATOR TO REMOVE THE DIALYZER AND SET IT ASIDE FOR AN ADDITIONAL SOAK/DWELL CLEANING PERIOD. THIS PROCESS HELPS CLEAN DIFFICULT DIALYZERS. PRECLEANED DIALYZERS MUST UNDERGO A FULL REPROCESSING CYCLE BEFORE USE.

3. **Touch the "START PROCESS" switch.** The Renatron II 100 Series station will now reprocess the dialyzer in the manner described in the section General Systems Operation, of this manual.
4. **Push the "RESET" switch on the Renatron II 100 Series station** after a "PROCESS COMPLETE", "VOLUME FAIL", or "PRESSURE FAIL" message has appeared. The "PROGRAM STEP" display will indicate step 98. Within a few seconds, the computer will read and reset the Renatron II 100 Series station and the last program mode used will be displayed in the "PROGRAM STEP" display. After the computer has read the data, labels are printed out indicating the dialyzer's status. Place one label on the dialyzer. Post one label to a manual logbook. The remaining label is a spare (this can be used for a flow sheet).

**Note – The amount of processed and failed dialyzer labels can be specified in the Administrators Mode of the Renalog RM program.**

5. If a "VOLUME FAIL" or "PRESSURE FAIL" message appears, **press the "START PROCESS" switch** to perform the test again. The dialyzer may pass when retested by the Renatron II 100 Series station.

**Note – Pushing "START PROCESS" after a "VOLUME FAIL" alarm will cause the machine to attempt to draw additional fluid from the blood compartment for measurement. If additional fluid is obtained the total volume drawn may now be enough to allow a dialyzer that was only a few ml below the minimum acceptable volume to pass the volume test. Multiple attempts to draw additional fluid from the dialyzer have not proved to be effective at improving the likelihood of passing the volume test.**

6. Volume Fail - the Renatron station will only allow a dialyzer to be re-tested two times after it initially fails the volume test during the reprocessing cycle.

If a "Volume fail" message appears, press the "START PROCESS" switch to repeat the test. After the initial "volume fail" message appears, the test may only be repeated two more times. After the third "volume fail" message appears, the "START PROCESS" switch will be deactivated and you must press the "RESET" switch and fail the dialyzer.

7. If the dialyzer fails either the pressure test (Step 39) or the volume test, **discontinue use of the dialyzer.**

#### **G. Removal of the dialyzer from the Renatron II 100 Series station.**

**CAUTION – CAREFUL ASEPTIC TECHNIQUE MUST BE FOLLOWED WHILE REMOVING THE REPROCESSED DIALYZER FROM THE RENATRON II 100 SERIES TO PREVENT CONTAMINATION OF THE DIALYZER BLOOD PATHWAY.**

**CAUTION – DIALYZERS REPROCESSED WITH PROPORTIONED RENALIN 100 SOLUTION MAY UNDERGO AN INTERNAL PRESSURE BUILDUP DURING STORAGE. THEREFORE, USE MINNTECH RENAL SYSTEMS DIALYSATE PORT CAPS ONLY.**

1. **Assure a supply of disinfected port caps.** Disinfection of the dialysate port caps, blood port caps and the reprocessing connectors from the dialyzer can be achieved by one of the following ways:
  - a. Place the caps and reprocessing connectors to be disinfected into fresh 1% Renalin 100 Solution for a minimum of 30 minutes.
  - b. Place the caps and reprocessing connectors to be disinfected in full strength Actril Cold Sterilant for a minimum of 30 minutes.

**CAUTION – RENAL SYSTEMS' DIALYSATE PORT CAPS, DIALYZER BLOOD PORT CAPS AND REPROCESSING CONNECTORS ARE NOT AUTOCLAVABLE.**

2. **Wear protective clothing** as indicated in the Renalin 100 Cold Sterilant Directions for Use (Part # 50090-679) and the Material Safety Data Sheet (MSDS) for Renalin 100 Cold Sterilant.

**Note – Remove the dialyzer from the Renatron II 100 Series station ONLY when the "PROCESS COMPLETE" message is displayed or when the dialyzer has failed the volume or pressure test. If the dialyzer has failed the volume or pressure test, it must be either retested (press "START PROCESS" switch), or removed and discarded. When the "PROCESS COMPLETE" message is displayed, automatic venting of any pressure buildup in the dialyzer or machine will occur. Press "RESET" before removal of the dialyzer.**

3. **Disconnect the "ARTERIAL INLET" line from the reprocessing connector attached to the dialyzer arterial blood port. Remove the reprocessing connector and place it in fresh 1% Renalin 100 Solution or full strength Actril Cold Sterilant for a minimum of thirty (30) minutes.**
4. **Wipe the external surfaces of the dialyzer arterial blood port** using gauze soaked in fresh 1% Renalin 100 Solution or full strength Actril Cold Sterilant.
5. **Place a disinfected blood port cap on the dialyzer arterial blood port.**
6. **Disconnect the dialysate outlet of the dialyzer from the "DIALYSATE OUTLET/SANITIZE INTERLOCK" connector on the Renatron II 100 Series station.**
7. **Wipe the external surfaces of the dialyzer outlet port** with gauze soaked in fresh 1% Renalin 100 Solution or full strength Actril Cold Sterilant. **Place a disinfected dialysate port cap on the dialysate outlet port of the dialyzer.**
8. **Disconnect the "DIALYSATE INLET" line from the dialysate inlet port** and temporarily clip it on the holding bracket mounted on the side of the "DIALYSATE OUTLET/ SANITIZE INTERLOCK" post on the Renatron II 100 Series station.
9. **Wipe the external surfaces of the dialysate inlet port** with gauze soaked in fresh 1% Renalin 100 Solution or full strength Actril Cold Sterilant. **Place a disinfect dialysate port cap on the dialysate inlet port of the dialyzer.**

10. **Disconnect the "VENOUS OUTLET" line from the reprocessing connector attached to the dialyzer venous blood port.** Remove the reprocessing connector and place it in fresh 1% Renalin 100 Solution or full strength Actril Cold Sterilant for a minimum of thirty (30) minutes.
11. **Wipe the external surfaces of the dialyzer venous blood port** with gauze soaked in fresh 1% Renalin 100 Solution or full strength Actril Cold Sterilant.
12. **Place a disinfected blood port cap on the dialyzer venous blood port.**

#### H. Suggested Cleaning of the Dialyzer Case

1. **Wipe the entire capped, reprocessed dialyzer** with a disposable wipe soaked in fresh 1% Renalin 100 solution or full strength Actril Cold Sterilant or place the entire dialyzer in a container of 1% Renalin 100 solution or full strength Actril Cold Sterilant.
2. **Discard the disposable wipe.**

#### I. Suggested Manual Dialyzer Identification and Documentation Procedures.

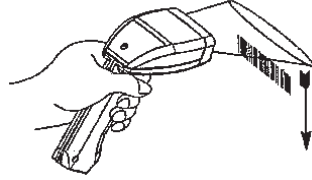
**IMPORTANT NOTE**—IT IS THE RESPONSIBILITY OF THE PRESCRIBING PHYSICIAN TO DETERMINE WHAT INFORMATION IS RECORDED AND THE MANNER IN WHICH THE RECORDS ARE MAINTAINED.

1. The use of indelible, waterproof, or permanent ink or other indelible marking systems to label the dialyzer is recommended when the Renatron II 100 Series station is operated without Renalog RM. In the automatic mode, the information listed below is recorded automatically or entered manually into the Renalog RM computer database and an appropriate label is automatically provided for the dialyzer. Additional labels for use with Renalog RM are available from Minntech P/N: 78398-179.
2. When reprocessing and not using the Renalog RM, it is recommended that the following information be recorded legibly on each dialyzer.
  - a. Patient's Identification (required).
  - b. Dialyzer use number (required).
  - c. Date the dialyzer was last reprocessed (required).
  - d. Pressure leak test results (optional).
  - e. Measured volume of blood compartment test (optional).
  - f. The initials of the operator who reprocessed the dialyzer (optional).
  - g. Any other information required by the prescribing physician.
3. It is recommended that a label with the above information be used on every reprocessed dialyzer. A label meeting these requirements is provided when using the automatic (bar code scanning) features of the Renatron II 100 Series system.

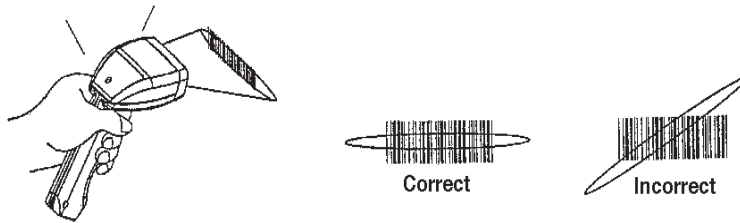
# Bar Code Scanner Procedures:

## J. Bar code scanning procedure

1. Aim the red illuminated beam of the scanner directly above the bar code. The red beam should be parallel to the bar code and the gun should be held 6 to 9 inches from the bar code.



2. With a straight, vertical motion, move the scanner down over the label so that the red beam passes over the bar code. The illustration below shows where the beam should be aimed for an accurate read of the bar code.



3. When you complete the scan, you will hear a single "good read" beep. If this does not occur, repeat the scan again.

- A. The storage area should be a well-ventilated, cool area that is out of direct sunlight.
- B. Reprocessed dialyzers should not be exposed to freezing temperature or sources of heat. The recommended temperature range is 59°F (15°C) to 75°F (24°C).

**WARNING**  
**MINIMUM STORAGE TIME FOR REPROCESSED DIALYZERS IS 11 HOURS**

**CAUTION** –AFTER STORAGE AND BEFORE THE REPROCESSED DIALYZER IS RINSED AND CLINICALLY USED, A SAMPLE OF FLUID SHOULD BE REMOVED FROM THE DIALYZER AND TESTED FOR THE PRESENCE OF RENALIN 100 SOLUTION USING PERASSAY 500 PERACETIC ACID INDICATOR STRIPS (PART #78378-000). REFER TO THE RENALIN 100 PRESENCE TEST PROCEDURE OUTLINED IN THE RENALIN 100 COLD STERILANT INSTRUCTIONS FOR USE (PART #50090-679) AND THE TEST STRIP LABELING.

**WARNING**  
**A HOLLOW FIBER DIALYZER THAT IS REPROCESSED AND DISINFECTED BY THIS MACHINE IS FILLED WITH PROPORTIONED RENALIN 100 SOLUTION. THE PROPORTIONED RENALIN 100 SOLUTION MUST BE ADEQUATELY AND THOROUGHLY RINSED OUT OF THE DIALYZER PRIOR TO CLINICAL USE. USE THE RENALIN RESIDUAL TEST KIT (PART #78198-000) TO VERIFY RESIDUAL RINSE OUT AS OUTLINED IN THE RENALIN 100 COLD STERILANT INSTRUCTIONS FOR USE (PART #50090-679).**

**CAUTION** – EXPOSING DIALYZERS TO CYCLIC TEMPERATURE DIFFERENCES DURING ANY PART OF THE REUSE PROCEDURE MAY RESULT IN INCREASING OR INITIATING PRESSURE BUILDUP IN THE DIALYZER DURING STORAGE. IN THESE CONDITIONS, A VENTABLE DIALYZER DIALYSATE PORT CAP SHOULD BE USED. A VENTABLE DIALYZER DIALYSATE PORT CAP IS AVAILABLE FROM MINNTECH RENAL SYSTEMS (PART #78208-000). READ THE PORT CAPS LABELING BEFORE USE.

Each day, before reprocessing dialyzers, ensure that the Calibrated Volume Cell is installed between the arterial and venous lines. Before checking calibration, make sure machine is level and if machine is not level, retest measurement of Volume Cell **after** leveling machine. Push "ON" switch, select Program mode "00" then push and hold "SET" and put in 67. Push "START PROCESS" and operate until volume is displayed in Step 35. Compare this value to value etched on Volume Cell. These values should agree within  $\pm 3$  ml. If these values do not agree within  $\pm 3$  ml, check the Renatron II 100 Series system calibration as outlined below.

Alternatively, use the Automatic Calibration feature on Renalog RM. See the Renalog RM User Guide P/N: 50090-859.

**Note – If the Renatron II 100 Series station continues to fail the calibration verification day after day, contact Minntech Renal Systems Technical Services Department for assistance.**

## Storage and Handling for Reprocessed Dialyzers

## Calibration and Adjustment

# Renatron II 100 Series Calibration Procedure

This procedure should be used if your Renatron II 100 station has a board with three white buttons used for calibration.

**Note** — You should complete steps 4-6 within 60 seconds. If you do not complete the sequence within 60 seconds the Renatron II 100 station will return to an idle mode. You can terminate calibration and return to the idle mode by pressing "RESET" at anytime except during the calibration cell measurement test. If the process is terminated the new calibration parameters are voided and the previous calibration parameters are valid. You will need to start the calibration procedure from the beginning and complete it for the new calibration parameters to become valid.



**WARNING**  
SHOCK HAZARD, WHEN PRESSING SWITCHES BE CAREFUL NOT TO TOUCH ELECTRONIC CONNECTIONS.

**Note** — Before removing the top cover, **MAKE ABSOLUTELY CERTAIN** there are no loose water connections or potential for fluid leakage. **ANY FLUID DAMAGE** to internal electronics is **NOT COVERED** by machine warranty.

1. Insert Calibrated Volume Cell between arterial and venous lines.
2. Remove the two screws from each side of the cover and lift off the cover. Place the cover where it will not be damaged.
3. Press "ON" switch ("SEL" and "-" will be displayed).
4. Press and hold the "SETUP" switch (S3 on the microprocessor board) for 4 seconds until you hear the second "chirp". The "PROGRAM STEP" will display "c1" and "CAL" will be displayed on the Volume Display.
5. Press and hold the "INCR" switch (S2) or the "DECR" switch (S1) to adjust the liquid level in the tank to the "0" reference line (the lower tank scribe line).
6. Press and release the "SETUP" switch (S3). You will hear one chirp. The "PROGRAM STEP" will display "cA".
7. Using the "INCR" switch (S2) and the "DECR" switch (S1) adjust the liquid level in the tank to the 507 reference line (upper tank scribe line).
8. Press and release the "SETUP" switch (S3). You will hear one chirp. The unit will then begin to run through steps 1-15. This will fill and test the calibration cell. When the Renatron II 100 station has completed the cycle, "cb" will be displayed in the "PROGRAM STEP" and the calibration cell volume will be displayed in the "VOLUME" display.
9. Using the "INCR" switch (S2) and the "DECR" switch (S1) adjust the 3-digit "VOLUME" display to match the reference volume of the calibration cell.
10. Press and release the "SETUP" switch (S3). The Renatron II 100 unit will exit the calibration mode.

Figure 3

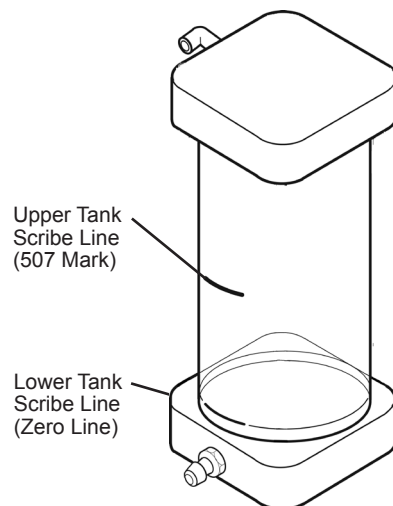
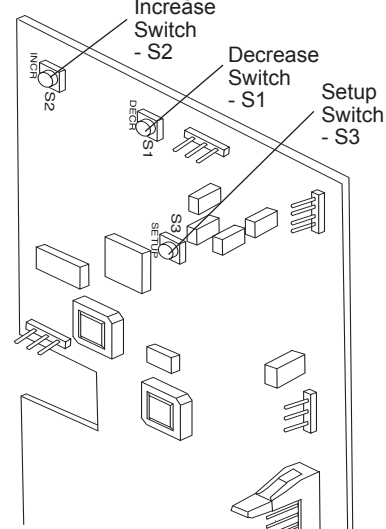


Figure 4



**NOTE – The new calibration values are not saved until you complete step 10 and exit the calibration mode.**

11. Press the "MUTE" and "RESET" switches together until program "(00)" is displayed.
12. Press the "HOLD TO SET" switch while adjusting the "SET" knob to display "a volume greater than 200" in the "VOLUME" window.
13. Press the "START PROCESS" switch. A light will appear in the corner of the "START PROCESS" switch.
14. Allow the Renatron II 100 Series station to continue operating until it enters "PROGRAM STEP 7".
15. Press the "OFF" switch.
16. Verify that the liquid level in the tank is at the zero reference line (lower tank scribe line).
17. If the liquid level is above or below the zero reference line repeat steps **3-16**.
18. Press the "ON" switch.
19. Press the "MUTE" AND "RESET" switches together until program "(00)" is displayed.
20. Press the "HOLD TO SET" switch while adjusting the "SET" knob to display "a volume greater than 200" in the "VOLUME" window.
21. Press the "START PROCESS" switch. A light will appear in the corner of the "START PROCESS" switch.
22. Allow the Renatron II 100 Series station to continue operating until it enters "PROGRAM STEP 14".
23. Press the "OFF" switch.
24. Verify that the liquid level in the tank is at the 507 reference line (upper tank scribe line).
25. If the liquid level is above or below the 507 reference line repeat steps **3-24**.
26. Press the "ON" switch.
27. Press the "MUTE" AND "RESET" switches together until program "(00)" is displayed.
28. Press the "HOLD TO SET" switch while adjusting the "SET" knob to display "a volume greater than 200" in the "VOLUME" window.
29. Press the "START PROCESS" switch. A light will appear in the corner of the "START PROCESS" switch.
30. Allow the Renatron II 100 Series station to continue operating until the "Volume Fail" alarm has occurred in "PROGRAM STEP 35". Push the "MUTE" switch to silence the audio alarm. **DO NOT PRESS THE "RESET" SWITCH.**
31. The displayed Renatron II 100 station volume value must be within  $\pm 3$  ml of the Calibrated Volume Cell. If the volume is not within  $\pm 3$  ml, press the "RESET" switch and repeat steps **4 - 30**.
32. Replace the Renatron II 100 Series station cover, securing it with the two screws on each side.

**CAUTION – THE COVER SHOULD ALWAYS BE ON THE RENATRON II 100 SERIES STATION FOR NORMAL OPERATION.**

**Note – If the Renatron II 100 Series station will not calibrate, please call Minntech Renal Systems Technical Services Department at 1-800-328-3324 for assistance.**

# Maintenance

The following procedures will help maintain peak performance of the Renatron II 100 Series Dialyzer Reprocessing Station. If at any time during this process you have a question or concern, please contact Minntech Renal Systems Technical Services Department for additional information.

The following procedures will help maintain peak performance of the Renatron II 100 Series Dialyzer Reprocessing Station. If any time during this process you have a question or concern, please contact Minntech Renal Systems Technical Services Department for additional information.

A. **Exterior Inspection** - the Renatron II 100 Series Station should be inspected periodically for any defects such as the following:

1. Bent or broken switches
2. Cracks in cover
3. Corroded metal parts
4. Loose or missing hardware
5. Cut or frayed hoses or electrical cords
6. Cracks in the Front Mask
7. Excessive protein deposits in the tubing. If necessary, see the Formula 409 Service Cleaning Procedure below.

**CAUTION** - USE OF A RENATRON II 100 SERIES STATION ON WHICH ONE OR MORE OF THE ABOVE CONDITIONS EXIST SHOULD BE DISCONTINUED UNTIL THE DEFECT IS CORRECTED AND THE SYSTEM OPERATION IS VERIFIED.

**CAUTION** - CARE SHOULD BE TAKEN TO AVOID EXCESS MOISTURE WHICH COULD FLOW INTO THE RENATRON II 100 SERIES CASE ASSEMBLY. BLOOD MAY BE REMOVED FROM THE EXTERIOR OF THE RENATRON II 100 SERIES STATION WITH FRESH 1% RENALIN 100 SOLUTION OR FULL STRENGTH ACTRIL SOLUTION. DO NOT USE ANY OTHER CLEANERS, AS THEY MAY BE INCOMPATIBLE WITH THE MATERIALS IN THE MACHINE.

B. **Cleaning.** The exterior of the Renatron II 100 Series Station should be cleaned as often as operating conditions require.

**CAUTION** - ANY LIQUID SPILLED ON THE MACHINE EXTERNAL SURFACES SHOULD BE WIPED OFF IMMEDIATELY TO REDUCE THE POSSIBILITY OF MOISTURE ENTERING THE MAIN CASE ASSEMBLY. IF SUCH A CONDITION WERE TO EXIST, IT COULD CREATE AN ELECTRICAL CONDUCTIVE PATH WHICH COULD RESULT IN INSTRUMENT FAILURE. NO LIQUID(S) SHOULD BE USED NEAR THE COMPUTER, KEYBOARD AND MONITOR.

**CAUTION** - DO NOT USE CHEMICAL CLEANING AGENTS THAT COULD DAMAGE THE PLASTICS USED IN THIS MACHINE, AVOID CHEMICALS WHICH CONTAIN ALCOHOL, BENZENE, TOLUENE, XYLENE, ACETONE OR OTHER AROMATIC OR KETONE SOLVENTS. **DO NOT USE BLEACH.**

## C. **Formula 409 Service Cleaning Procedure**

The internal fluid pathways must be cleaned periodically (typically once every two weeks or as required) as outlined below:

Renatron II 100 Series machines experience deposits which gradually build up inside the blood lines with continued machine use. The amount of build up is proportional to the extent of machine use, the number of dialyzers reprocessed, and such factors as heparin regime and rinseback method. This build up is a waxy, denatured substance with a slight yellow tint. If the build up is allowed to continue, the machine may give erroneous blood volume readings (low) and may stop operating altogether. Before this substance becomes visually evident in the blood lines, the procedure outlined below should be performed to remove the deposits.

**CAUTION** - THIS PROCEDURE CALLS FOR THE USE OF INSTITUTIONAL FORMULA 409 CLEANER/DEGREASER. THIS LIQUID CHEMICAL IS AN EYE IRRITANT. AVOID CONTACT WITH EYES OR SKIN. REFER TO LABEL INSTRUCTIONS FOR CAUTIONS AND REMEDY. DO NOT USE SUBSTITUTE CHEMICAL SOLUTIONS IN THIS PROCEDURE.

Institutional Formula 409 Cleaner/Degreaser (Formula 409) will not react with trace levels of Renalin 100 Cold Sterilant. To ensure Formula 409 contact with Renalin 100 solution is minimized and to ensure Formula 409 is rinsed completely from the Renatron II 100 Series station, this procedure should be performed, in the order listed below:

1. For Institutional Use Formula 409 Service Clean Cycle - The Renatron station will draw approximately five times as much Formula 409 using the Formula 409 cycle as it does when using the traditional "00" cycle. When you are drawing either treated water or Formula 409 into the Renatron II 100 Series station, complete the steps listed below. It is not necessary to use the steps listed below when drawing Renalin 100 Cold Sterilant into the Renatron II 100 Series Station.

2. Remove the uptake tube from the Renalin 100 container and make sure excess Renalin 100 drains back into the container. Cover the open Renalin 100 container.
3. Place the uptake tube into a container of purified water (one gallon or more).
4. Connect external hoses in sanitize configuration.
5. Turn on the Renatron II 100 Series Station. Press the "MUTE ALARM" and "RESET" switches to change to the "HF" mode. Press the following switches in the following order:  
 "MUTE ALARM"  
 "RESET"  
 "DISPLAY"  
 The Volume display window will read "409" and the "PROGRAM STEP" display window will read "SC". Press the "START SANITIZE" switch to begin the cycle.
6. Allow the machine to operate to completion of "PROGRAM STEP" 75 and press the "OFF" switch. (No problems will occur if machine operates past step 75 before turning off).
7. Press the "ON" switch and repeat procedure steps 5 and 6 above. This action clears Renalin 100 from the uptake hose and replaces it with purified water.
8. Remove the uptake tube from the purified water and allow excess water to drain out of the uptake tube.
9. Place the uptake tube into container of Formula 409. **Do not use a substitute chemical as it may damage the materials in the machine.**
10. Press the "ON" switch and repeat procedure steps 5 and 6 above. This action clears the water from the uptake hose and replaces it with Formula 409.
11. Turn on the Renatron II 100 Series Station. Press the "MUTE ALARM" and "RESET" switches to change to the "HF" mode. Press the following switches in the following order:  
 "MUTE ALARM"  
 "RESET"  
 "DISPLAY"  
 The Volume display window will read "409" and the PROGRAM STEP display window will read "SC". Press the "START SANITIZE" switch to begin the cycle.
12. Allow the machine to continue operating to the "SANITIZE COMPLETE" message in "PROGRAM STEP" 83.
13. Press the "OFF" switch and turn the water supply to the machine off. Leave the machine overnight. **Wait at least 8 hours.**
14. Remove the uptake tube from the container of Formula 409 and make sure any excess Formula 409 drains from tube back into container. Place the uptake tube in a container of purified water (one gallon or more). Turn the water supply on.
15. Turn on the Renatron II 100 Series Station. Press the "MUTE ALARM" and "RESET" switches to change to the "HF" mode. Press the following switches in the following order:  
 "MUTE ALARM"  
 "RESET"  
 "DISPLAY"  
 The Volume display window will read "409" and the PROGRAM STEP display window will read "SC". Press the "START SANITIZE" switch to begin the cycle.
16. Allow the machine to operate to completion of "PROGRAM STEP" 75 and press the "OFF" switch. (No problems will occur if machine operates past step 75 before turning off.) This action clears the Formula 409 from the uptake hose and replaces it with water.
17. Turn on the Renatron II 100 Series Station. Press the "MUTE ALARM" and "RESET" switches to change to the "HF" mode. Press the following switches in the following order:  
 "MUTE ALARM"  
 "RESET"  
 "DISPLAY"  
 The Volume display window will read "409" and the PROGRAM STEP display window will read "SC". Press the "START SANITIZE" switch to begin the cycle.
18. Allow the machine to operate to "PROGRAM STEP" 83, and when machine completes step 83, press the "START PROCESS" switch. The machine will then enter step 84 and, after a ten minute hold period in step 84, will proceed with flushing and draining. The flushing and draining will continue until machine enters "PROGRAM STEP" 97 and the "SANITIZE COMPLETE" message reappears.
19. Press the "OFF" switch.

20. Remove the uptake tube from the container of purified water and allow excess water to drain from uptake tube.
21. Place the uptake tube in a container of unexpired Renalin 100 solution.
22. Press the "ON" switch, select program, "(00)," and press the "START SANITIZE" switch. Allow the machine to operate to completion of "PROGRAM STEP" 75 and press "OFF" switch (No problems will occur if machine operates past step 75 before turning off). This action clears the water from the uptake hose and replaces it with Renalin 100.
23. Press the "ON" switch, select program, "(00)," and press the "START SANITIZE" switch. Allow the machine to operate to "PROGRAM STEP" 83. When the machine enters step 83, press the "START PROCESS" switch. The machine will then enter step 84 and after a ten minute hold time will proceed to "PROGRAM STEP" 97. The "SANITIZE COMPLETE" message will reappear.
24. Your Renatron II 100 Series station is now ready for normal use.

**Note – Formula 409® is a registered trademark of the Clorox Co., Oakland, CA. It is available as Minntech Renal Systems Part #93250-092. Minntech Renal Systems' International Distributors should contact Minntech to obtain this product if not available locally.**

#### **D. Culture Sample Collection**

Water culture samples can be easily collected from the Renatron station by first running the Renatron Water Culture Sample Cycle.

1. Prepare the Renatron for sample collection
  - a. Ensure that the Renatron was sanitized with the calibration cell in place, allowed to dwell for at least 6 hours, and was undisturbed since the initiation of the Sanitize Cycle.
2. Initiate the Water Culture Sample Cycle
  - a. Press the "ON" switch.
  - b. Press the "MUTE ALARM" and "RESET" switches to change to the "CH" mode.
  - c. Press the following switches in the following order:  
"MUTE ALARM"  
"RESET"  
"DISPLAY"
  - d. The Volume Display window will read "CUL" and the Program Step display window will read "CC".
  - e. Press the "START PROCESS" switch
  - f. At the end of the program step 9, the "PROCESS COMPLETE" message will illuminate and the Program Step display window will read "SA".
3. Sample Collection
  - a. Using aseptic technique, collect a sample from the calibration cell for a culture of water from the Renatron station.
  - b. After the sample has been collected, press the "RESET" switch. The Renatron II 100 Series Station is now ready for calibration verification and then for reprocessing dialyzers.

#### **E. Storage When Not In Use**

The Renatron II 100 Series station should be stored in a protected location. Avoid high-traffic areas where the machine might get damaged and avoid high humidity.

The Renatron II 100 Series station is a high-quality, precision device and should be treated as such. The station has been designed to withstand the rigors of normal use and, with reasonable care and maintenance, should provide many hours of trouble-free operation.

Minntech Renal Systems maintains a special repair and calibration facility to provide its customers with expert service for its products. If your Renatron II 100 Series station requires servicing, we recommend that you contact our Technical Services Department. Minntech Renal Systems conducts periodic service/maintenance seminars for the Renatron II 100 Series. Contact our Technical Services Department or your sales representative for information regarding these classes.

**Note – Pressing the "START PROCESS" switch while Renatron II 100 Series station is turned on and is holding in Step 83 will result in a 10 minute hold in Step 84 with subsequent water rinse and air purge of hydraulic pathway.**

**CAUTION – ALL CHEMICALS SHOULD BE THOROUGHLY RINSED FROM UPTAKE LINES BEFORE REPACKING RENATRON II 100 SERIES STATION.**

**CAUTION – PERFORM A COMPLETE SANITIZE CYCLE, AS DESCRIBED IN THE NOTE ABOVE, BEFORE REPACKING RENATRON II 100 SERIES. THIS ACTION ENSURES NO FLUID WILL REMAIN IN HYDRAULIC SECTION. IF FLUID REMAINS IN THIS SECTION, IT MAY FREEZE AND CAUSE DAMAGE TO HYDRAULIC COMPONENTS.**

### A. Repacking

Before repacking, the Renatron II 100 Series station should be thoroughly cleaned and emptied. It is recommended that each unit be repackaged in the original manner for maximum protection. The original shipping carton can be saved and used for this purpose. If the original packing is not available, contact Minntech Renal Systems Technical Services Department for the appropriate packing and shipping instructions. Do not ship any part of the Renatron II 100 Series system to Minntech Renal Systems without first notifying the Technical Services Department.

### B. Documentation

Any system being returned for service should be accompanied by a letter stating:

1. The model number of the system device.
2. The serial number of the system device (if applicable).
3. The address to which the device is to be shipped after repair.
4. The address to which the repairs are to be billed if not covered by the warranty and a purchase order for the repairs.
5. A description of the problem for which the device is being returned.
6. A Return Material Authorization Number (RMA) received from Minntech Renal Systems' Technical Services Department. Do not return any equipment without an RMA.

## RENATRON II 100 DIALYZER REPROCESSING STATION PERFORMANCE INSPECTION SCHEDULE

Inspection Description	Monthly Intervals			
	3	6	9	12
Calibration Verification	Performed daily by the operator			
Renatron Exterior Inspection	Performed daily by the operator			
Formula 409 cleaning procedure	Perform this procedure every 2 weeks or as needed			
Inspect all external Quick Disconnects for defects and/or worn O-rings	X	X	X	X
Inspect Reprocessing Connections	X	X	X	X
Inspect Renalin 100 Uptake Tubing Assembly		X		X
Inspect valve Assembly (Large, Small, V15)				X
Inspect Hydraulic Compartment for any signs of fluid leakage				X
Test Jet Pump Assembly				X
Inspect Renatron II Scanner Gun	X	X	X	X
Inspect Barcode Labels for any visual defects	X	X	X	X
Inspect Front Mask for Visual Defects		X		X
Test Check Valve Water Hose Assembly				X
Replace Renalog RM Backup Disks				3 yrs.

## Warranties/ Limitations

**Important Note** – Because Minntech Renal Systems has no knowledge or control of how any third party's service work or the affect such work may have on the Renatron Systems's operation or performance of the Renatron II 100 station, Minntech Renal Systems disclaims any liability for any damages whatsoever resulting from a change in the operation or performance of the Renatron II 100 Station or any personal injury directly or proximately resulting from any repairs made or attempted to be made by any person other than a factory representative of Minntech Renal Systems. If Minntech Renal Systems replaces non-Renal Systems parts the customer will be charged in full for all replaced parts.

Minntech warrants to customer that Minntech possesses good and marketable title to the product sold to customer and that the product (i) shall be free from defects in material and workmanship at the time of shipment and under normal use and service for a period of one year from the date of shipment; and (ii) are in compliance with the specifications for the product. The liability of Minntech under this limited warranty does not extend to any abuse or misuse of the product or any repair or attempt to repair the product by the customer, which shall void this warranty. If the product does not meet this limited warranty, Minntech's sole obligation shall be to repair or replace the product (provided that the product is returned to Minntech prepaid within one year of the date of shipment), and this shall be customer's exclusive remedy. Under no circumstances will Minntech be liable for any direct or indirect, incidental or consequential loss, damage or expense of any kind (including without limitation, loss of profits, economic loss) whether such claim is based on warranty, contract, tort or otherwise. This limited warranty is in lieu of all other warranties, whether express or implied (including, without limitation, any warranty for suitability, fitness for a particular purpose or absence of hidden defects).

No person has any authority to bind Minntech Renal Systems to any other representation or warranty with respect to these products, and the purchaser accepts the products subject to all the terms hereof. Any product returned to Minntech Renal Systems for replacement becomes the property of Minntech Renal Systems.

## Explanation for Symbols



Attention, consult accompanying documents



Off; power disconnected from the mains



On; power connected to the mains



Off, connected to mains but in a wait or standby mode



On, active state as opposed to standby



Dangerous voltages within equipment

**IPX1**

Drip-proof equipment



As Operator Accessible Fuse Location

## Technical Service Centers

### U.S. Service Locations

Minntech Corporation  
14605 28th Avenue North  
Minneapolis, MN 55447 U.S.A.  
Telephone: (763) 553-3300  
Toll Free: (800) 328-3324  
Fax: (763) 553-3370  
web: [www.minntech.com](http://www.minntech.com)

### International Service Location

Minntech B.V.  
Sourethweg 11  
6422PC Heerlen  
The Netherlands  
Tel: (31) 45 5471471  
Fax: (31) 45 5429695

**Note:** Parts, service and a service manual with drawings, parts lists, circuit diagrams are available on request from Minntech's Technical Service Department.

## Part Number Listings

Item	Part Number
Renalin 100 Cold Sterilant Instructions for Use	50090-679
Renalog RM Instruction Manual	50090-859
RS 8351 (Renalog 3) Instruction Manual	50103-000
Perassay 500 Directions for Use	50086-010
Renalin Residual Test Strips Directions for Use	50083-000
Renatron Service Manual	50101-000
Renalin 100 Cold Sterilant (without kit)	78397-844
Renalin 100 Cold Sterilant (1 test kit)	78397-845
Renalin 100 Cold Sterilant (3 test kits)	78397-846
Renalog RM Reprocessing Management Software	78398-192
Renalog III Dialyzer Reprocessing Data Management System	RS 8351
Renalin Residual Test Strips	78198-000
Perassay 500 Peracetic Acid Test Strips	78378-000
Dialyzer Dialysate Port Caps (Red)	78196-010 (100)
Ventable Dialyzer Dialysate Port Caps (2.25")	78208-000
Ventable Dialyzer Dialysate Port Caps (1.5")	78398-367
Dialyzer Blood Port Caps	78197-010 (100)
ISO Fitting Dialyzer Blood Port Caps	78397-704 (100)
Formula 409 Cleaner/Degreaser	93250-092
Renalog RM Label Kit	78398-179
Computer Form-Fed Labels	40080-025
Reprocessing Connectors	78397-699 (100)
On-Demand Autodilution System	78399-781
On-Demand Autodilution Water Hose	78399-901







**MINNTECH**®  
renal systems

Minntech Renal Systems  
14605 28th Avenue North  
Minneapolis, MN 55447 U.S.A.  
Phone: (763) 553-3300  
(800) 328-3340  
Fax: (763) 553-3387

Minntech B.V.  
6422 PC Heerlen  
The Netherlands  
Tel: (31) 45 5471471  
Fax: (31) 45 5429695