

K955299

**510(k) Summary**

**This 510(k) summary was prepared on 11/17/95 and submitted by:**

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**Trade name: DPS 4 Dialyzer Preparation System**

**Common name: rinse machine**

**Classification name: none**

**Changes and amendments made 08/23/1996 by Brooks Rogers at the request of Gema Gonzalez (FDA).**

The Seratronics DPS 4 Dialyzer Preparation System is an automatic four-station rinsing machine for removing formaldehyde, glutaraldehyde or peracetic acid from reused dialyzers. Dialyzers are stored filled with the germicide and with the venous and arterial blood ports connected by a filled tubing segment that includes a sample site. This provides a blood side circuit that can be recirculated while the germicide is removed by the process of diffusion across the membrane.

The system removes the germicide from the dialyzer by delivering AAMI quality (RD5, -1992) water to the dialysate side of the dialyzer at a controlled temperature and flow rate while the blood side fluid is recirculated by a tubing pump. The germicide is diffused from the blood compartment of the dialyzer to a final concentration prescribed by the physician. The blood side of the dialysis circuit is never opened during the rinsing process on the DPS 4 rinse machine. At a predetermined time in the recirculation cycle (selected on the front panel), an alarm sounds, indicating that the rinse time has been completed. The blood and dialysate side flow continue when this end-of-cycle alarm occurs. A proprietary buffering agent, RINSE-QUICK<sup>™</sup> concentrate, can be added to the rinse solution to reduce rinse out times with formaldehyde only. This buffering agent does not introduce new chemicals or higher concentrations of chemicals normally used for dialysis.

The rinse times of individual dialyzers can vary significantly, depending on dialyzer type, size, germicide type, germicide concentration, number of uses, rinse technique used, etc. The germicide concentration may "rebound" if the rinsing process is interrupted due to (de)absorption from the solid components of the dialyzer. The dialyzer must undergo a final prime with sterile saline and flush of the dialysate side in order to bring the dialyzer up to temperature, pH, composition, and complete the final rinse of the dialyzer. It is necessary to test each dialyzer for residual germicide and pH just prior to connection to the patient. This is well known by medical professionals performing reuse and is described in the Operator's Manual.

The original 510(k) for this machine had an integrated analytical system that used a light and photosensor system to automatically determine the level of formaldehyde only in a sample ampule. At this time, we are not distributing the DPS 4 with this capability, and the operating instructions for the analytical capability have been removed (except for a description of the alarm codes, which have been retained for historical purposes). We have no plans at this time to include this feature in the future.

The Operator's manual has been updated from that submitted in the original 510(k).

This machine and accessories described in this submission are substantially equivalent to the device indicated in premarket notification K832230 and to any dialysis machine to the extent that it may be used to rinse germicide or manufacturing residuals from new or reused dialyzers.

There are many articles in the literature relating to germicide removal. The following technical literature is cited:

Man, N. K. Lebkiri, B., Polo, P., Et. Al.: *Prevention of Anti-N-Like Antibodies development with Non-formaldehyde Reuse Procedures*, Proc Dialy Transpl Forum 10, P 18 - 21, 1980.

Dean, N., Bemis, J. A.: *Multiple Use of Hemodialyzers, Final Report to National Institute of Arthritis, Diabetes and Digestive and Kidney Diseases*, June 1981.

Lewis, K. J., Dewar, P. J., Ward, M. K., Kerr, D. N. S.: *Formation of Anti-N-Like Antibodies in Dialysis Patients: Effect of Different Methods of Rinsing to Remove Formaldehyde*, Clin Neph 15 (1), P 85 -90, 1981.

Gotch, F. A., Keen, M.L.: *Formaldehyde Kinetics in Reused Dialyzers*, ASAIO Transactions, 29, p 396 - 401, 1983.

Hakim, R. M., Friedrich, R. A., Lowrie, E. G.: *Formaldehyde Kinetics and Bacteriology in Dialyzers*, Kidney Int 28, P 936 - 943, 1985.

Held, P. J., Pauly, M. V., Diamond, L.: *Survival analysis of patients undergoing dialysis*, Journal of the American Medical Association, 257: p 645 - 650, 1987.

Vanholder, R. C., Noens, L., de Smet, R., Ringoir, S.: *Development of Anti-N-Like Antibodies during Formaldehyde Reuse in spite of Adequate Predialysis Rinsing*, Am J Kidney Dis 11 (6), P 477 - 480, 1988.

CDC: *Acute Allergic Reactions Associated with Reprocessed Hemodialyzers - Virginia*, MMWR 38 (50):873, 1989.

CDC: *Update: Acute Allergic Reactions Associated with Reprocessed Hemodialyzers*, MMWR 40 (9):147, 1991.

Alter, M. J., Favero, M. S., Moyer, L. A., Bland, L. A.: *National Surveillance of Dialysis-associated Diseases in the United States, 1989*. Transactions of the American Society for Artificial Internal Organs Vol. 37, p 97-109, 1991.

Held, P. J., Wolfe, R. A., Gaylin, D. S., Levin, N. W., Port, K. F., Turenne, M. N., Urban Institute: *A Brief Overview of Current Analyses of the Association of Dialyzer Reuse and Patient Outcomes, preliminary report, October 7, 1992*.

AAMI: *Recommended Practice for Reuse of Hemodialyzers*, Arlington VA, Association for Advancement of Medical instrumentation, RD47, 1993.

Tokars, J. L., Alter, M. J., Favero, M. S., et al.: *National Surveillance of Dialysis Associated Diseases in the United States, 1991*, ASAIO J, 1993 Oct - Dec, 39(4): p 966- 975.

Held, P. J., PhD, Wolfe, R. A., PhD, Gaylin, D. S., BA, Port, F. K., MD, MS, Levin, N. W., MD, Turenne, M. N., BA: *Analysis of the Association of Dialyzer Reuse Practices and Patient Outcomes*, American Journal of Kidney Diseases, Vol 23, No 5, May, 1994: p 692 - 708.

Straiger, A., Wendenckx, D., Jadoul, M.: *Rinsing Time and Disinfectant Release of Reused Dialyzers: Comparison of Formaldehyde, Hypochlorite, Warexin, and Renalin*, American Journal of Kidney Diseases, Vol 26, No 3, September, 1995: p 549 - 553.

*US Code of Federal Regulations*, 42 CFR part 405.2150, 1992, amended F.R., Vol 60, Vol 180, Sept. 18, 1995, p 48039 -48044.

A study was performed to demonstrate the effectiveness of Rinse-Quick concentrate in reducing the rinse times of formaldehyde filled dialyzers.

Following is a table showing the formaldehyde rinse out rate with various dialyzers. The rinse time is different for the various dialyzers, as expected. These data demonstrate that Rinse-Quick concentrate is effective in reducing the rinse time of formaldehyde filled dialyzers as compared to use of RO rinse water alone.

Dialyzer type	Approximate rinse time (min) to achieve indicated PPM			
	5 PPM		1 PPM	
	W/O R-Q	W/R-Q	W/O R-Q	W/R-Q
CDAK 90SCE	31	5	43	13
Renak RE-09	27	8	36	13
CDAK 4000	52	15	>70	35
Clirans C121	42	9	56	19
CF 12-11	40, est	9	64	18
Bax. C110G	7	<5	17	10

The following is safety and effectiveness information extracted from the product labeling:

Federal law restricts this device to use by or on the order of a physician.

This device is intended solely for processing (e.g., *in vitro* rinsing) of hemodialyzers. Any subsequent clinical use of the dialyzer processed by this machine is the sole responsibility of the patient's physician.

**Warning:** Failure to install, operate, or maintain this equipment in accordance with manufactures specifications and operating instructions may cause user or patient injury.

**Caution:** Care must be used to aseptically connect the blood lines to the blood ports of the dialyzer. The arterial blood line must be filled with sterile saline solution before attaching to the dialyzer. Care should be taken not to introduce air into the system during the connection.

**Warning:** A saline prime on the blood side and dialysate side flow is required at the bedside before connecting the patient to the extracorporeal circuit. It is necessary to assure that the blood circuit is at the proper dialyzing temperature, PH, and conductivity before initiating dialysis.

**Warning:** Adequate procedural steps must be followed to assure that rinsed dialyzers are not mixed with non-rinsed dialyzers. Test the blood circuit for residual disinfectant after the clinical prime of the dialyzer, before initiating dialysis.

**Caution:** Aseptic procedures are required to maintain sterility of dialyzers.

**Warning:** Do not use an adaptor to fit a 3-prong power plug to a 2-prong household outlet. The electrical circuit must be protected by a ground fault interrupter.

**Warning:** When replacing fuses in the Dialyzer Preparation System, replace only with the same type and rating of fuse to avoid overheating and short circuiting. A time-delay fuse must be used with this device if it is connected to a circuit that is protected by fuses.

**Danger:** Possible explosion hazard if used in the presence of flammable anesthetics.

**Caution:** Electric shock hazard. Do not remove cover or back. Refer servicing to qualified personnel.

**Caution:** Caution must be taken when handling human blood and blood components due to the possibility of exposure to hepatitis or other blood borne pathogens. It is recommended that gloves, masks, and appropriate protective clothing be worn.

**Warning:** When there is no cycle operating, periodically the 110 volt deaeration pump may periodically, automatically start and V-3 may close for a few seconds. This is normal.

**Caution:** During servicing, normal covers and panels are open, exposing 110 volts and rotating equipment. Service should only be performed by qualified personnel.

**Warning:** Following rinsing with the DPS 4 rinse machine, the concentration of disinfectant in the dialyzer may increase or "rebound" as disinfectant slowly diffuses out from the solid components of the dialyzer. A final rinse of the dialyzer and bloodline at the dialysis machine must be performed, and the solution tested for residual disinfectant.

The training of operators in the use of handling chemicals is the responsibility of the Medical Director. The handling of chemicals, such as formaldehyde, Glutaraldehyde, and Peracetic Acid should be carried out in a safe and careful manner, which includes proper protective clothing and equipment as set out by the Dialysis Center Procedures.

**Warning:** **FORMALDEHYDE** is an eye, skin, and respiratory irritant, and as such, caution should be used to prevent contact. This can be accomplished by wearing eye goggles and gloves in a well ventilated area when using open containers of concentrated solution.

**FIRST AID: CALL A PHYSICIAN.**

**IF INHALED:** Exposed people should remove themselves from exposure to fresh air, rest and keep warm. Give artificial respiration if breathing has stopped. Obtain medical attention.

**EYE CONTACT:** Immediately rinse thoroughly for 15 minutes. Lift eye lids occasionally while rinsing. This is of extreme importance to prevent coagulation of the surface of the cornea. Obtain medical attention.

**SKIN CONTACT:** rinse well with water and remove any contaminated clothing. These should be washed thoroughly before next use.

**IF SWALLOWED:** The mouth should be rinsed thoroughly with water followed by drinking milk. Induce vomiting. If the victim is unconscious, do not induce vomiting. Obtain medical attention.

### **Storage of Formaldehyde**

Protect against physical damage. Store in a cool, dry, well ventilated area separated from oxidizing or alkaline materials. Avoid exposure of containers to sources of heat.

### **Further Information**

For specific instructions on the safe handling of specified chemicals, refer to the Chemical Safety Data Sheet, SD-1, from the Manufacturing Chemists' Association, Inc.

**Warning:** **GLUTARALDEHYDE** is an eye and skin irritant, and as such, caution should be used to prevent contact. This can be accomplished by wearing eye goggles and gloves.

**FIRST AID:** CALL A PHYSICIAN.

**IF INHALED:** Exposed people should remove themselves from exposure to fresh air, rest and keep warm. Give artificial respiration if breathing has stopped. Obtain medical attention.

**EYE CONTACT:** Immediately rinse thoroughly for 15 minutes. Obtain medical attention.

**SKIN CONTACT:** Rinse well with water and remove any contaminated clothing. These should be washed thoroughly before next use.

**IF SWALLOWED:** The mouth should be rinsed thoroughly with water followed by drinking 2 glasses of water. Do not induce vomiting. Obtain medical attention.

### **Storage of Glutaraldehyde**

Protect against physical damage. Store in a cool, dry, well ventilated area separated from oxidizing or alkaline materials. Avoid exposure of containers to sources of heat.

### **Further Information**

For specific instructions on the safe handling of specified chemicals, refer to the Material Safety Data Sheet, from the Manufacturer Gulfstream Medical Inc. (617) 846-8545

**Warning:** **PERACETIC ACID** is an eye and skin irritant, and as such, caution should be used to prevent contact. This can be accomplished by wearing eye goggles and gloves.

**FIRST AID: CALL A PHYSICIAN.**

**IF INHALED:** Exposed people should remove themselves from exposure to fresh air, rest and keep warm. Give artificial respiration if breathing has stopped. Obtain medical attention.

**EYE CONTACT:** Immediately rinse thoroughly for 15 minutes. Obtain medical attention.

**SKIN CONTACT:** rinse well with water and remove any contaminated clothing.

**IF SWALLOWED:** The mouth should be rinsed thoroughly with water followed by drinking large quantities of water. Do not induce vomiting. Obtain medical attention.

### **Storage of Peracetic Acid**

Protect against physical damage. Store in a cool, dry, well ventilated area separated from oxidizing or other chemicals. Avoid exposure of containers to direct sunlight.

### **Further Information**

For specific instructions on the safe handling of specified chemicals, refer to the Material Safety Data Sheet, from the Fresenius USA INC. (800) 227-2572

**Caution:** **BLEACH (5.25% Sodium Hypochlorite)** is a strong oxidizing agent. Wear protective gloves and safety glasses when handling. Harmful if swallowed. Can cause severe eye irritation. Keep in a cool place.

**FIRST AID: CALL A PHYSICIAN.**

**IF SWALLOWED:** Feed milk; Do not induce vomiting.

**EYE CONTACT:** flood with water for at least 15 minutes.

**SKIN CONTACT:** Rinse thoroughly with water

**RINSE-QUICK** concentrate solution is a mixed bicarbonate buffer solution. In the diluted form it contains less sodium and bicarbonate than that used in bicarbonate dialysis.

**Warning:** Not for use as a bicarbonate concentrate for dialysis.

**Warning:** Not for injection or ingestion.

**Caution:** Do not contact with acid.

### **FIRST AID**

**EYE CONTACT:** Rinse thoroughly with water for 15 minutes. If irritation develops, obtain medical attention.

**SKIN CONTACT:** Rinse thoroughly with water

**IF SWALLOWED:** drink water to dilute.

**Warning:** Do not use an adaptor to fit a 3-prong power plug to a 2-prong household outlet.

**Warning:** Regardless of the test results that are obtained at the completion of the DPS 4 rinse cycle, a residual test and a PH test must be completed following the clinical prime of the complete blood circuit at the dialysis machine just prior to initiating dialysis.

**Warning:** After rinsing, the disinfectant has been removed from the dialyzer. Therefore, care must be used to aseptically connect the blood lines to the blood ports of the dialyzer. The arterial blood line must be filled with sterile saline solution before attaching to the dialyzer. Care should be taken not to introduce air into the system during the connection.

**Warning:** A saline prime on the blood side and dialysate flow is required before connecting the patient to the extracorporeal circuit. It is necessary to assure that the blood circuit is at the proper dialyzing temperature and conductivity (composition) and to test for disinfectant residual and PH before initiating dialysis.

After an acceptable residual test has been obtained, the dialyzer must not be allowed to sit without blood side recirculation and dialysate flow unless the dialyzer is re-rinsed and tested again for residual disinfectant. All disinfectants will absorb into all dialyzers and build up a "sink". Most of the rinsing time of a dialyzer is a result of this sink. The concentration of disinfectant in the dialyzer will "rebound" if rinsing/recirculation is discontinued. Of course, the amount of the rebound will be greater the larger the dialyzer.

Do not sample right after adding a quantity of fresh saline to the circuit. This can result in a false negative test. Allow the blood side to equilibrate before testing for residual.

These are suggested procedures that contain many elements that we have found necessary in order to obtain fully rinsed dialyzers. It is based on theory, experience, and testing at certain dialysis units. We have attempted to make sure that they are complete and correct. However, we cannot and do not take any responsibility for the rinsing procedures used at your dialysis unit due to the many variables. In addition, we can make no representations nor give you any assurances that following this procedure will prevent any patient reactions. In the final analysis, it is necessary for you to follow AAMI guidelines, validate your procedure, be sure that it is followed, and properly test each dialyzer for residual disinfectant.