Fresenius

Optiflux® F200A F180A F200B F180B

Hemoflow™ F60A F80A F5 F6 F8

Hollow Fiber Dialyzer

GENERAL INFORMATION

Indications: Hemoflow/Optiflux dialyzers are designed for acute and chronic hemodialysis and are appropriate for single and multiple use when reprocessed utilizing the methods described or referenced in this package insert.

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

Contraindications: Specific contraindications for the dialyzer are unknown. Generally, the contraindications for hemodialysis are applicable. The dialyzer should only be used as directed by a physician.

Warning: Hypochlorite-based germicides should not be used for disinfection of the reprocessed dialyzer. Bleach should not be used as a blood path cleaning agent with F60A, F80A, F200A or F180A dialyzers unless Glutaraldehyde is used as the germicide.

Precautions: In the event of a blood leak during dialysis, the health care provider should respond according to the facility's established protocol.

Warning: Air entering the extracorporeal circuit during dialysis can result in serious injury or death. Check the integrity of all blood lines prior to the initiation of dialysis and periodically during the treatment. The venous return line or drip chamber should be continuously monitored with an air detector.

Warning: Due to the high water flux capability of dialyzer membrane with an ultrafiltration coefficient (Kuf) ≥ 8 mL/hr/mmhg, it is necessary to use such dialyzers only in conjunction with dialysis machines that are equipped with precise ultrafiltration control, such as the Fresenius 2008 series. Dialyzer models F6, F8, F60A, F80A, F200A, F180A, F200B, and F180B must only be used with such UF control machines. In any case, the safety instructions of the manufacturer of the hemodialysis machine must be followed.

The user is cautioned to regularly monitor the patient's chemistry values using quantitative measurements and analysis to insure that the expected therapy is delivered. The clinical parameters monitored should, at least, include: urea, hematocrit, and serum albumin.

Dialyzers may leak, resulting in patient blood loss or contamination with dialysate. Each reprocessed dialyzer should be subjected to an air pressure leak test prior to use on a patient. Significant blood loss may require blood transfusion at the discretion of the physician.

Dialysate: The dialysate must meet the Association for the Advancement of Medical Instrumentation's (AAMI) standards for dialysis. The use of bicarbonate dialysate is recommended for short dialysis.

Side effects: In rare cases hypersensitivity reactions may occur during hemodialysis treatment. A history of allergies is an indication for careful monitoring of hypersensitivity reactions. Dialyzers of this type should not be used again on any patient exhibiting a hypersensitivity reaction. With severe reactions, dialysis must be discontinued and aggressive, first line therapy for anaphylactic reactions must be initiated. The decision to return the blood to the patient must be made by a physician. The complete battery of tests necessary to demonstrate the carcinogenic potential of the material after reprocessing has not been performed. The AMES assay, for mutagenic potential was performed and it was negative (no indication of mutagenic potential). Biocompatibility tests on dialyzers reprocessed with formaldehyde were performed only on dialyzers reprocessed with 1.5% formaldehyde @ 40°C.

Heparinization: It is recommended that the patient be systemically heparinized by allowing the heparin to circulate for 3 to 5 minutes before beginning extracorporeal circulation. In addition, the extracorporeal circuit may be heparinized taking care that the total amount of heparin to be delivered does not exceed the prescription. During dialysis, the dosage of heparin and the mode of administration are the responsibility of the attending physician. The coagulation time should be checked regularly.

Sterile/Non-pyrogenic: The dialyzer blood pathway is sterile and non-pyrogenic if the blood port caps are in place and undamaged. The dialyzer is sterilized with ethylene oxide gas. Do not use if the dialyzer is damaged in any way. Use aseptic technique for all blood side connections. Structural integrity of the hemodialyzer is warranted for the first use only when prepared as directed.

- **Recommended storage:** Between 5 and 30 °C (41 and 86 °F).
- Dialyzers disinfected with 1.5% formaldehyde @ 40°C or with 4.0% formaldehyde may be stored for a maximum of 30 days. After 30 days the dialyzers must be reprocessed.
- Dialyzers disinfected with Diacide® shall be stored according to the germicide manufacturer's instructions.
- Dialyzers disinfected with Puristeril 340™ solution shall be stored according to the germicide manufacturer's instructions.
- Dialyzers disinfected with Renalin® shall be stored according to the germicide manufacturer's instructions.

- **Note:** Diacide®, Puristeril 340™ concentrate and Renalin® are commercial germicides intended for the disinfection of hemodialyzers, and the manufacturer's instructions should be followed when using any of these germicides. Diacide® is a Glutaraldehyde based germicide. Puristeril 340™ and Renalin® are both Peracetic acid based germicides.

Dialyzer reuse: Reuse of these devices is a clinical decision. The Medical Director is responsible for the choice to reuse dialyzers and the procedures and safety of the reuse program. If dialyzer reuse is chosen, dialyzers must be reused in a carefully monitored program that complies with the AAMI Recommended Practice for the Reuse of Hemodialyzers, Centers for Medicare and Medicaid Services (CMS) requirements and other applicable Federal, State and local laws and regulations. Reprocessed dialyzers should not be used on patients with sepsis, excessive clotting problems, or known hypersensitivity. Reprocessed dialyzers can be used by the same patient, only. Follow recommendations of the Centers for Disease Control regarding reuse practices and the reuse of dialyzers on patients with hepatitis or HIV.
Follow universal precautions when handling used dialyzers.

Warning: The choice of cleaning agents, germicides, processing conditions, and reprocessing protocol must be carefully selected to avoid significant degradation of the dialyzer components. Certain sanitizing agents used for exterior cleaning, such as quaternary ammonium compounds, phenol-containing compounds, bleach (≥0.06%), or Renalin® / Puristeril 340™ solution (> 1.0%) may damage the plastic components when exposed for extended periods of time.

Warning: Pyrogenic reactions may occur with reused dialyzers. The water used to reprocess the dialyzer must meet AAMI standards for water for dialyzer reprocessing.

Dialyzers may clot after a variable number of uses. Any dialyzer that does not retain at least 80% of its original total cell volume (TCV) should be discarded. It is recommended that the original TCV be determined for each dialyzer prior to use.

In rare cases, dialysate may channel, resulting in reduced clearance. This condition is not identified by the TCV test.

Follow AAMI standards and the germicide manufacturer's instructions to assure that the disinfection process was carried out as intended.

Warning: Any chemical germicide in the dialyzer must be rinsed out prior to clinical use of the dialyzer.

The concentration of residual germicide must be measured and determined to be acceptable before clinical use. Use a test recommended by the germicide manufacturer or a test that is intended for measurement of residual levels of the germicide. Follow the instructions of the residual test manufacturer. Germicide concentration may increase (rebound) if the rinsing process is interrupted prior to connection to the patient. Additional rinsing and residual retesting are required in this event. Discard the prime solution when starting blood flow through the dialyzer. If the prime solution must be given to the patient for volume enhancement, replace the fluid in the circuit with fresh saline just before attachment to the patient. It is the responsibility of the medical director to assure that the residual levels of the germicide are acceptable.

Warning: These are suggested rinse procedures that contain many elements that are necessary in order to obtain fully rinsed dialyzers. However, Fresenius does not take responsibility for the rinsing procedures used at the dialysis facility. In addition, Fresenius makes no representations nor is assurance given that following these procedures will prevent patient reactions. It is necessary to follow AAMI guidelines, validate the rinse procedure, and be sure that it is followed, and properly test each dialyzer for residual chemical.

• PREPARATION FOR DIALYSIS - DRY PACK

- If the dialysate delivery system was chemically disinfected or sterilized prior to patient use, be sure to test the dialysis machine for the absence of germicide residuals with a test intended for this application, according to the manufacturers' instructions.
- Place the dry dialyzer in a vertical position, arterial end down.
- Install the arterial and venous bloodlines on the hemodialysis machine.

- **Note:** Refer to the manufacture's instructions for the dialysate delivery machine.

- Remove any dialyzer blood port caps and aseptically connect the arterial and venous blood lines to the dialyzer.
- Aseptically spike a 1 liter bag of 0.9% sterile normal saline with a clamped IV administration set. Attach the IV administration set to the patient end of the arterial bloodline.
- Open the clamp on the IV set. Prime the arterial bloodline, dialyzer, and venous bloodline using a blood pump speed of approximately 150 mL/min. Discard the first 500 mL of solution. The drip chambers should be maintained about 3/4 full.
- Stop the blood pump. Clamp the arterial and venous bloodlines. **Turn the dialyzer so that the venous end is downward.** Aseptically connect the patient ends of the arterial and venous lines together in preparation for recirculation. Open the clamps on the bloodlines.
- Verify that the dialysate is within the prescribed conductivity limits with a calibrated external conductivity meter. To identify situations where the acetate or acid and bicarbonate concentrates are not properly matched, use pH paper or a meter to verify that the approximate pH is in the physiologic range.
- Attach the dialysate lines to the dialyzer. Fill the dialysate compartment. In order to maximize the efficiency of the dialyzer, the dialysate flow must be countercurrent to the blood flow.
- Rotate the dialyzer so that the arterial end is downward. Recirculate the blood side at a flow rate of 300 - 400 mL/min and a dialysate flow of 500 mL/min for a minimum of ten to fifteen minutes. Recirculate until all the air has been purged from the system before connecting to the patient. Continue recirculation and dialysate flow until patient connection.
- Ultrafilter or flush an additional 500 mL of 0.9% sterile normal saline so that the extracorporeal circuit has been flushed with a minimum of 1 liter of saline to minimize sterilization residues.
- Discard the prime solution when starting blood flow through the dialyzer. If the prime solution must be given to the patient for volume enhancement, replace the fluid in the circuit with fresh saline just before attachment to the patient.
- It is the responsibility of the Medical Director to assure that the residual levels are acceptable.

• PREPARATION FOR DIALYSIS – FORMALDEHYDE OR GLUTARALDEHYDE FILLED DIALYZERS

- If the dialysate delivery system was chemically disinfected or sterilized prior to patient use, be sure to test the dialysis machine for the absence of germicide residuals with a test intended for this application, according to the manufacturers' instructions.
- Check the dialyzer and label. Verify that the dialyzer is properly capped and has been filled with the dialyzer disinfecting solution. **Verify that the correct dialyzer has been selected for the patient.**
- Place the dialyzer in a vertical position.
- Install the arterial and venous bloodlines on the hemodialysis machine.

- **Note:** Refer to the manufacturer's instructions for the dialysate delivery machine.

- Verify that the dialysate is at the conductivity required by the prescribing physician with a calibrated external conductivity meter. To identify situations where the acetate or acid and bicarbonate concentrates are not properly matched, use pH paper or a meter to verify that the approximate pH is in the physiologic range.
- Connect the dialysate lines to the dialyzer and establish dialysate flow (> 500 mL/min). Place the dialyzer so that the dialysate flow is upward and all the air bubbles are flushed from the dialysate compartment. This step must precede the attachment of the bloodlines and priming of the bloodside of the dialyzer. Verify that dialysate is flowing through the dialyzer.
- If a heparin pump is to be used, fill the heparin syringe with the prescribed medication and prime the heparin infusion line to the arterial line. Clamp the infusion line as close as possible to the arterial line.
- Spike a 1 liter bag of 0.9% sterile normal saline with a clamped IV administration set.
- Attach the IV administration set to the patient end of the arterial bloodline.
- Aseptically prime the arterial line with saline. If not already done, insert the blood pump segment into the blood pump. Connect the arterial and venous lines to the dialyzer only after the dialysate side has flushed for a couple of minutes. Connect the arterial and venous drip chamber monitor lines to the machine with new transducer protectors.
- Rotate the dialyzer so that the arterial end is down and the venous end is up. Flush 500 mL of sterile saline through the blood side of dialyzer at a flow rate of 150 mL/min. Adjust the fluid levels in the drip chambers. Insure the monitor lines are cleared of any fluid. Fluid contamination of the transducer protectors can cause false pressure readings.
- Clamp the saline administration line. Connect the arterial and venous blood lines together and recirculate the blood side at a high rate (400 - 500 mL/min). Alternately clamp and unclamp the venous line (below the drip chamber) to help remove air from the dialyzer. Do not exceed 500 mmHg venous pressure.
- Set an ultrafiltration rate of about 2 liters/hour and turn the UF on. When the TMP begins to rise, unclamp the saline administration line. Be sure there is sufficient sterile saline left in the bag to complete the rinsing process.
- **Note:** If there are TMP alarms, Air Fill programs, or similar programs where the UF control system is bypassed or the TMP is relieved, clamp the saline administration line until the condition is cleared.

- About half-way through the recirculation procedure, rotate the dialyzer so that the flow directions are reversed. At this point the arterial end should be up and the venous end down.
- After an appropriate rinse time, test for residual germicide solution. Aseptically remove a sample from the venous bloodline and test for the absence of germicide residuals with a test intended for this application, according to the manufacturer's instructions.

- **Note:** Acceptable residual levels for formaldehyde as stated in the AAMI guidelines for dialyzer reuse (RD47 1993) are less than 5 ppm.
  Acceptable residual levels for Diacide® are less than 3 ppm Glutaraldehyde as stated by the manufacturer.

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- The test used for determining residual levels of Formaldehyde and Diacide® should be performed according to the manufacturer's instructions.
- Adjust the level of fluid in the arterial and venous drip chambers. The arterial blood port of the dialyzer should be up for the dialysis treatment (blood flow down, dialysate flow up).
- 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 germicide. Inadequate rinsing of the dialyzer may cause the patient to experience reactions to the residual germicide.
- If dialysis is not to be initiated now, turn down the blood pump flow rate to about 100 mL/min. Turn down the UF rate to 70 - 300 mL/hr. The dialysate flow may be turned down to 300 mL/min.

• PREPARATION FOR DIALYSIS - Puristeril 340™ OR Renalin® SOLUTION FILLED DIALYZERS

- If the dialysate delivery system was chemically disinfected or sterilized prior to patient use, be sure to test the dialysis machine for the absence of germicide residuals with a test intended for this application, according to the manufacturers' instructions.
- Check the dialyzer and label. Verify that the dialyzer has been filled with germicide solution for the period specified by the manufacturer. **Verify that the correct dialyzer has been selected for the patient.**
- Place the dialyzer in a vertical position.
- Install the arterial and venous bloodlines on the hemodialysis machine.

- **Note:** Refer to the manufacturer's instructions for the dialysate delivery machine.

- Verify that the dialysate is at the conductivity required by the prescribing physician with a calibrated external conductivity meter. To identify situations where the acetate or acid and bicarbonate concentrates are not properly matched, use pH paper or a meter to verify that the approximate pH is in the physiologic range.
- Check the dialyzer for presence of germicide according to the germicide manufacturer's instructions.
- If a heparin pump is to be used, aseptically fill the heparin syringe with the prescribed medication and prime the heparin infusion line to the arterial line. Clamp the infusion line as close as possible to the arterial line.
- Aseptically prime the arterial line with saline. Connect the arterial and venous lines to the dialyzer. Clamp and connect the arterial and venous drip chamber monitor lines to the machine with new transducer protectors.
- With the arterial end down and the venous end up, flush about 500 mL of sterile saline through the blood side of dialyzer at a flow rate of about 150 mL/min.
- Clamp the saline administration line. Connect the dialysate lines to the dialyzer and establish dialysate flow (> 500 mL/min). Rotate the dialyzer so that the dialysate flow is upward and all the air bubbles are flushed from the dialysate compartment.
- When the dialysate side is filled, again, rotate the dialyzer so that the blood side flow will be upward (arterial blood port on the bottom).
- Connect the arterial and venous blood lines together and recirculate the blood side at a high rate (400 - 500 mL/min). Alternately clamp and unclamp the venous line (below the drip chamber) to flush all remaining bubbles from the fibers (do not exceed 500 mmHg venous pressure).
- Unclamp the arterial and venous monitor lines and set an ultrafiltration rate of about 2 liters/hour and turn the UF on. Be sure there is sufficient sterile saline left in the bag. When the TMP begins to rise, unclamp the saline administration line.

- **Note:** If there are TMP alarms, Air Fill programs, or similar programs where the UF control system is bypassed or the TMP is relieved, clamp the saline administration line until the condition is cleared.

- About half-way through the recirculation procedure, rotate the dialyzer so that the flow directions are reversed. At this point the arterial end should be up and the venous end down.
- After an appropriate rinse time, test for residual germicide. Aseptically remove a sample from the venous bloodline and check the dialyzer for an acceptable residual level of germicide according to the germicide manufacturer's instructions.

- **Note:** Acceptable residual levels for Puristeril 340™ solution and Renalin® are less than 3 ppm hydrogen peroxide as stated by the manufacturers.

- The test used for determining residual levels of both Puristeril 340™ solution and Renalin® should be performed according to the manufacturers' instructions.

- Adjust the level of fluid in the arterial and venous drip chambers. The arterial blood port of the dialyzer should be up for the dialysis treatment (blood flow down, dialysate flow up). Ensure the monitor lines are cleared of any fluid. Fluid contamination of the transducer protectors can cause false pressure readings.
- After an acceptable residual test has been obtained, the dialyzer should not be allowed to sit without recirculation unless the dialyzer is re-rinsed and tested again for residual germicide. Inadequate rinsing of the dialyzer may cause the patient to experience reactions to the residual germicide.
- If dialysis is not to be initiated at this time, turn down the blood pump flow rate to about 100 mL/min. Turn down the UF rate to 70 - 300 mL/hr. The dialysate flow may be turned down to 300 mL/min, if desired to conserve concentrate for the treatment.

• INITIATION OF DIALYSIS TREATMENT

- Turn the blood pump off. Clamp the saline line and the arterial and venous bloodlines.
- Do not infuse the recirculated saline prime into the patient. If saline is required for volume enhancement, discard the recirculated saline and fill the bloodlines with fresh saline.
- Aseptically attach the arterial bloodline to the patient's arterial access. Open the arterial bloodline clamp.
- Place the venous bloodline in a drain container, making sure not to contaminate the end of the bloodline. Open the clamp on the venous bloodline.
- Turn the blood pump speed up to 100 - 150 mL/min and fill the extracorporeal circuit with the patient's blood.

- **Warning: This step must be carefully monitored to prevent any possibility of blood loss.**

- Turn off the blood pump and clamp the venous bloodline.
- Aseptically attach the patient end of the venous bloodline to the patient's venous access. Open the clamp to the venous access.
- Unclamp the venous bloodline and set the blood flow to the prescribed rate. Rotate the dialyzer so that the venous end is downward.
- Set the prescribed ultrafiltration rate. A minimum ultrafiltration rate of 300 mL/hr during dialysis treatment is recommended with Fresenius Hemoflow/Optiflux High Flux dialyzers.

• DURING DIALYSIS TREATMENT

- If a blood leak should occur during the treatment, the decision to attempt to allow the leak to clot off by reducing the blood flow and ultrafiltration rate to minimum values is a clinical decision. The decision whether or not to return the blood to the patient must be made by a medical professional.
- Air entering the extracorporeal circuit during dialysis may be very serious and should be avoided. A routine check of all connections prior to initiation of dialysis and periodically throughout the treatment is recommended. Constant monitoring of the venous return line with an air detector is essential. Should air get into the venous line during treatment, the dialysis treatment must be discontinued without returning any of the patient's blood that is mixed with air.
- All blood tubing connections must be checked for security or obstruction to prevent damage or loss of blood or entry of air. Dialysate circuit leaks allowing air entry or fluid loss may cause significant ultrafiltration errors.

• TERMINATION OF DIALYSIS TREATMENT

- When the dialysis treatment is completed, turn the blood flow rate to zero and UF rate to recommended minimum.
- Clamp arterial bloodline and aseptically disconnect from the patient's arterial access.
- Using the blood pump, rinse the patient's blood back using sterile 0.9% saline solution at a slow rate. **Do not allow air to enter the extracorporeal circuit.**
- Once the blood has been returned, turn the blood pump flow rate to zero.
- Clamp the venous bloodline.
- Clamp the patient's venous access and aseptically disconnect the venous bloodline from the patient's access.

- **If the dialyzer is to be discarded, place the extracorporeal circuit in an appropriate biohazard waste receptacle.** References: 29CFR 1910.145, 1910.1030 (Code of Federal Regulations) and appropriate state or local codes.

- If the dialyzer is to be reused, infuse any remaining heparin and recirculate for 1 to 2 minutes. After recirculation cap the blood and dialysate ports being sure to keep both compartments full of fluid. **Insure that the dialyzer is marked in indelible ink with the patient's name.** Pre-clean and reprocess the dialyzer as soon as possible or refrigerate.

• DIALYZER PRE-CLEANING

- The water used to pre-clean dialyzers must meet AAMI standards for water for dialyzer reprocessing.

- **Warning: Header caps and O-rings must remain with their respective dialyzers.**

- Wear protective clothing, gloves, goggles, and mask.
- Step 1: Unscrew the header on dialyzers with substantial clots.
- Step 2: Clean all residual blood and protein from the header and tubesheet surface under running (AAMI quality) water.
- Step 3: Disinfect the header, header cap, and O-ring, prior to reassembly.

- If Renalin® or Puristeril 340™ solution is used as the dialyzer germicide, dip the header, header cap, and O-ring in 1% Renalin® or Puristeril 340™ solution.
- If Formaldehyde or Glutaraldehyde is used as the dialyzer germicide, dip the header, header cap, and O-ring in a 100 to 1 diluted solution of 5.25% bleach.
- Some germicides may attack the plastic used in dialyzers, so if cracking of the dialyzer occurs with extended use, this procedure must be evaluated.

- Step 4: Carefully reseat the header O-ring and hand tighten the header cap. If too loose, the header may leak when tested and if over-tightened the header, header cap, or O-ring may be damaged.
- Step 5: Rinse the blood compartment of the dialyzer with treated water until the effluent is clear.
- Step 6: The dialyzer may also be pre-cleaned by applying a reverse UF flush using AAMI quality water. If a vacuum is used on the blood side, the vacuum should not exceed 725 mmHg. If a positive pressure is used on the dialysate side, the pressure should not exceed 750 mmHg.

• REPROCESSING PROCEDURES

- Reprocessing of hemodialyzers should be performed according to the AAMI guidelines for Reprocessing of Hemodialyzers..

Warning: The only reuse methods tested for these dialyzers were 4% Formaldehyde, 1.5% Formaldehyde @ 40°C, 3.5% Renalin® / Puristeril 340™ solution, and Diacide® / 0.8% Glutaraldehyde as germicides. The only cleaning agents tested were bleach and Renalin® / Puristeril 340™ solution. All dialyzers reprocessed in the *in vitro* testing were reprocessed using the Seratronics® DRS-4 machine. Refer to the Operator's Manual for these complete instructions for use.

- **Warning: CMS regulations require that once a dialyzer has been reprocessed with one type of chemical germicide, it may not be reprocessed using any other method.**

- **Warning: Dialyzers which will be disinfected using 4% Formaldehyde and 0.8% Glutaraldehyde should be reprocessed with the Seratronics® DRS-4 machine. Dialyzers which will be disinfected using Peracetic acid should be reprocessed with the Renatron® or the Seratronics® DRS-4 machine. Dialyzers which will be disinfected using 1.5% formaldehyde should be reprocessed with the Seratronics® DRS-4 machine and heated to 40°C in an incubator with the following characteristics:**

- **Renal Scientific Dialyzer Incubator (Model # 20000-1) and follow the Renal Scientific Incubator Operator's Manual (153-020-000) or use an alternate incubator capable of delivering 45°C +/- 4°C for 24 hours.**
- As much residual blood as possible should be removed during the reprocessing procedure. When cleaning the dialyzer, pressures should not exceed 750 mmHg.
- Reverse ultrafiltration may also be used to aid in the removal of residual blood from the dialyzer. If reverse ultrafiltration is used, positive pressures should not exceed 750 mmHg and negative pressures should not exceed 725 mmHg.
- Reprocessed dialyzers must always be tested according to the AAMI guidelines for performance and membrane integrity prior to disinfection.
- *In vitro* Ultrafiltration test results may not be used to establish TMP treatment parameters.
- A total cell volume (TCV) test must be performed each time the dialyzer is reprocessed to insure it has at least 80% of its original volume. Dialyzers with less than 80% of original volume should not be used. For dialyzers with a high coefficient of ultrafiltration (Kuf > 8), when performing the TCV test by blowing out the blood compartment, the dialysate compartment must be filled with water and sealed to prevent fluid transfer from the blood to dialysate compartment.
- A membrane integrity test must be performed each time the dialyzer is reprocessed prior to disinfection.

- Bleach, Puristeril 340™ solution, and Renalin®, may be used as cleaning agents during reprocessing. If cleaning agents are used, dialyzer performance may be altered. See dialyzer performance characteristic information.

- If bleach is used as the cleaning agent, the concentration in the dialyzer should not exceed 1.0%.

- If Puristeril 340™ solution or Renalin® are used as cleaning agents the concentration in the dialyzer should not exceed 2.0%. Puristeril 340™ solution may only be used as a cleaning agent if Puristeril 340™ solution is used as the dialyzer germicide. Renalin® may only be used as a cleaning agent if Renalin® is used as the dialyzer germicide.

• REUSE DIALYZER LABELING

- All reused dialyzers must be labeled according to the AAMI guidelines, each time they are reprocessed. These reprocessing labels must not obscure the manufacturer's label.

TECHNICAL DATA: These data represent typical *in vitro* performance. Actual *in vivo* performance may differ.

	F5	F6, 60A	F8, 80A	F180A, F180B	F200A, F200B	
Priming volume blood	63	82	110	99	113	mL
Maximum TMP	600 80	600 80	600 80	600 80	600 80	mmHg kPa
Maximum blood flow	400	400	600	600	600	mL/min
Maximum dialysate flow	1000	1000	1000	1000	1000	mL/min
Surface area	1.0	1.3	1.8	1.8	2.0	m^2

Membrane material:	Fresenius Polysulfone® polymer
Inner diameter (nominal):	200 μm
Wall thickness (nominal):	40 μm
Housing	Polycarbonate
Potting compound:	Polyurethane
O-ring:	Silicone
Blood connectors:	DIN 13090 Part 3
Dialysis fluid connectors:	DIN 58352 Part 2

The Kuf and clearance characteristics of the dialyzers may change after repeated exposure to the reprocessing procedure. For example, the *in vitro* Kuf will usually rise with exposure to reuse processes. The use of volume ultrafiltration control dialysis equipment is mandatory when these dialyzers are reused.

Note: All dialyzers reprocessed using Formaldehyde (4% and 1.5%), and 0.8% Glutaraldehyde in the *in vivo* testing were reprocessed using the Seratronics® DRS-4 machine. Dialyzers tested with Peracetic acid were reprocessed with the Renatron® or Seratronics® DRS-4 machine. All dialyzers reprocessed using Puristeril 340™ solution in the *in vivo* testing were reprocessed using the Renatron®. All *in vitro* testing was performed at a dialysate flow rate of 500 mL/min @ 37°C.

Note: The methodology used to generate all of the *in vitro* and *in vivo* data presented below, is based on testing requirements outlined in the FDA "Guidance for Hemodialyzer Reuse Labeling". Clearance tests were performed using aqueous solutions of urea, creatinine, phosphate and Vitamin B_{12}.

SUMMARY OF *IN VITRO* TESTING METHODS 4.0% FORMALDEHYDE

In vitro testing of Fresenius Hemoflow/Optiflux Dialyzers was performed according to the "Guidance for Hemodialyzer Reuse Labeling" testing protocol. Where possible, three dialyzers from each of three different manufacturing lots were tested. Dialyzers were reprocessed a total of 15 times with the 0.75% Bleach / 4.0% Formaldehyde reprocessing procedure. Dialyzers were not exposed to blood between reprocessings. Dialyzers were stored for 24 hours before the subsequent reprocessing. Dialyzers were tested for *in vitro* Kuf using fresh whole beef blood and aqueous solute clearance using urea, creatinine and Vitamin B_{12} as the solute markers.

***In vitro* Ultrafiltration Coefficient, Kuf of Dialyzers Reprocessed with 0.75% Bleach / 4.0% Formaldehyde Using Fresh Whole Beef Blood (Kuf=mL/hr/mmHg)**

	0	1 use	5 use	15 use
F6	7	9	11	11
F8	11	14	15	18
F180B	56	56	57	87
F200B	62	64	83	101

Aqueous *In vitro* Urea Clearance of Dialyzers Reprocessed with 0.75% Bleach / 4.0% Formaldehyde (mL/min)

	QB	0	1 use	5 use	15 use
F6	200	171	171	168	171
	300	222	222	222	222
	400	252	249	251	249
F8	200	177	180	182	179
	300	241	244	245	244
	400	280	284	286	288
	500	302	307	310	317
F180B	200	194	193	191	195
	300	269	260	264	272
	400	314	300	306	321
	500	337	324	333	353
F200B	200	194	194	195	195
	300	271	273	273	277
	400	320	320	321	329
	500	346	348	350	360

Aqueous *In vitro* Creatinine Clearance of Dialyzers Reprocessed with 0.75% Bleach / 4.0% Formaldehyde (mL/min)

	QB	0	1 use	5 use	15 use
F6	200	154	157	156	157
	300	192	194	195	194
	400	211	212	214	212
F8	200	167	170	171	170
	300	215	220	222	221
	400	240	248	250	253
	500	255	262	253	275
F180B	200	188	187	186	191
	300	247	239	242	254
	400	280	267	275	291
	500	300	290	300	320
F200B	200	191	191	191	194
	300	251	253	254	260
	400	289	290	291	303
	500	309	313	318	327

Aqueous *In vitro* Vitamin B_{12} Clearance of Dialyzers Reprocessed with 0.75% Bleach / 4.0% Formaldehyde (mL/min)

	QB	0	1 use	5 use	15 use
F6	200	60	83	83	81
	300	61	88	91	96
	400	60	85	80	80
F8	200	70	103	94	113
	300	76	113	105	131
	400	77	115	120	140
	500	73	113	112	146
F180B	200	138	138	138	150
	300	161	157	163	178
	400	171	168	178	195
	500	181	177	189	211
F200B	200	146	145	151	157
	300	169	171	178	189
	400	185	189	194	211
	500	191	198	207	224

IN VITRO RESULTS 4.0% FORMALDEHYDE

In vitro Kuf increased by multiple exposures to 0.75% Bleach / 4.0% Formaldehyde reprocessing. Urea and creatinine clearance were unaffected by multiple exposures to the reuse process. Vitamin B_{12} clearances did increase with multiple exposures.

SUMMARY OF *IN VIVO* TESTING METHODS 4.0% FORMALDEHYDE

In vivo testing of Fresenius Hemoflow Dialyzers was performed according to the "Guidance for Hemodialyzer Reuse Labeling" testing protocol. Clinical testing of the F8 dialyzer was performed with 14 patients (4 males, 10 females), average age 64, average blood flow of 400 mL/min and average dialysis time of 2.93 hours. *In vivo* Kuf for the different hemodialyzers were calculated from pressure determinations available from the Fresenius 2008H hemodialysis machine. Blood samples were taken at predetermined times pre and post dialysis session on the 0, 1, 5 and 15th reuse. Blood samples were analyzed for urea, albumin and Beta2-Microglobulin (B2M for high flux hemodialyzers only). Equilibrated single pool Kt/V urea (spKt/V), urea reduction ratio, (URR = %) and pre/post serum albumin values were calculated.

Note: *In vivo* reuse testing was not performed on the Optiflux dialyzers. However, the reuse performance of the Optiflux dialyzers will be similar to the Fresenius Hemoflow dialyzers.

***In vivo* Ultrafiltration Coefficient, Kuf of Dialyzers Reprocessed with 0.75% Bleach / 4.0% Foraldehyde (Kuf=mL/hr/mmHg)**

	0	1 use	5 use	15 use
F8	14	15	18	21

***In vivo* spKt/V and URR of Dialyzers Reprocessed with 0.75% Bleach / 4.0% Formaldehyde (URR=%)**

	0	1 use	5 use	15 use
F8				
spKt/V	1.81	1.78	1.79	1.81
URR	75	76	76	76

***In vivo* Pre and Post Serum Albumin Levels of Dialyzers Reprocessed with 0.75% Bleach / 4.0% Formaldehyde (Albumin=g/dl)**

	0	1 use	5 use	15 use
F8				
Pre Serum	3.75	4.01	3.92	3.76
Post Serum	4.30	4.14	4.31	4.20

IN VIVO RESULTS 4.0% FORMALDEHYDE

In vivo Kuf increased when exposed to multiple reprocessing with 0.75% Bleach / 4.0% Formaldehyde. The use of volume ultrafiltration control dialysis equipment is mandatory when these dialyzers are reused.

In vivo spKt/V and URR were unchanged with multiple exposure to the reprocessing procedure. There was no change in serum albumin levels for any of the hemodialyzers tested.

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SUMMARY OF *IN VITRO* TESTING METHODS
1.5% FORMALDEHYDE @ 40°C

In vitro testing of Fresenius Hemoflow/Optiflux Dialyzers was performed according to the "Guidance for Hemodialyzer Reuse Labeling" testing protocol. Where possible, three dialyzers from each of three different manufacturing lots were tested. Dialyzers were reprocessed a total of 15 times with the 0.75% Bleach / 1.5% Formaldehyde @ 40°C reprocessing procedure. Dialyzers were not exposed to blood between reprocessings. Dialyzers were stored for 24 hours before the subsequent reprocessing. Dialyzers were tested for *in vitro* Kuf using fresh whole beef blood and aqueous solute clearance using urea, creatinine and Vitamin B_{12} as the solute markers.

***In vitro* Ultrafiltration Coefficient, Kuf of Dialyzers Reprocessed with 0.75% Bleach / 1.5% Formaldehyde @ 40°C Using Fresh Whole Beef Blood (Kuf=mL/hr/mmHg)**

	0	1 use	5 use	15 use
F6	9	11	13	16
F8	11	12	15	19
F180B	46	54	61	72
F200B	58	62	74	91

Aqueous *In vitro* Urea Clearance of Dialyzers Reprocessed with 0.75% Bleach / 1.5% Formaldehyde @ 40°C (mL/min)

	QB	0	1 use	5 use	15 use
F6	200	175	179	175	179
	300	222	223	227	230
	400	250	252	254	259
F8	200	180	185	189	188
	300	240	247	247	247
	400	280	284	283	286
	500	304	307	304	309
F180B	200	192	195	192	195
	300	262	268	260	267
	400	305	312	300	309
	500	328	334	330	337
F200B	200	193	195	199	198
	300	271	270	274	273
	400	318	314	321	321
	500	349	342	352	349

Aqueous *In vitro* Creatinine Clearance of Dialyzers Reprocessed with 0.75% Bleach / 1.5% Formaldehyde @ 40°C (mL/min)

	QB	0	1 use	5 use	15 use
F6	200	158	161	162	162
	300	190	192	197	200
	400	210	213	218	221
F8	200	168	171	175	175
	300	214	217	216	217
	400	243	247	246	248
	500	260	265	261	267
F180B	200	184	188	185	190
	300	241	244	241	246
	400	273	276	273	276
	500	292	300	295	298
F200B	200	191	191	191	191
	300	249	250	251	252
	400	285	283	285	287
	500	313	308	313	312

Aqueous *In vitro* Vitamin B_{12} Clearance of Dialyzers Reprocessed with 0.75% Bleach / 1.5% Formaldehyde @ 40°C (mL/min)

	QB	0	1 use	5 use	15 use
F6	200	63	70	80	88
	300	64	74	85	95
	400	64	75	85	96
F8	200	74	84	93	102
	300	80	94	105	117
	400	83	99	110	124
	500	83	100	107	125
F180B	200	131	138	134	142
	300	154	158	158	164
	400	167	170	172	177
	500	176	180	181	185
F200B	200	144	145	146	149
	300	166	167	170	174
	400	180	178	185	189
	500	190	188	198	200

IN VITRO RESULTS 1.5% FORMALDEHYDE @ 40°C

In vitro Kuf increased by multiple exposures to 0.75% Bleach / 1.5% Formaldehyde @ 40°C reprocessing. Urea and creatinine clearance were unaffected by multiple exposures to the reuse process. Vitamin B_{12} clearances did increase with multiple exposures.

SUMMARY OF *IN VIVO* TESTING METHODS
1.5% FORMALDEHYDE @ 40°C

In vivo testing of Fresenius Hemoflow Dialyzers was performed according to the "Guidance for Hemodialyzer Reuse Labeling" testing protocol. Clinical testing of the F8 dialyzer was performed with 15 patients (5 males, 10 females), average age 58, average blood flow of 327 mL/min and average dialysis time of 2.48 hours. *In vivo* Kuf for the different hemodialyzers were calculated from pressure determinations available from the Fresenius 2008H hemodialysis machine. Blood samples were taken at predetermined times pre and post dialysis session on the 0, 1, 5 and 15th reuse. Blood samples were analyzed for urea, albumin and Beta2-Microglobulin (B2M for high flux hemodialyzers only). Equilibrated single pool Kt/V urea (spKt/V), urea reduction ratio, (URR = %) and pre/post serum albumin values were calculated.

Note: *In vivo* reuse testing was not performed on the Optiflux dialyzers. However, the reuse performance of the Optiflux dialyzers will be similar to the Fresenius Hemoflow dialyzers.

***In vivo* Ultrafiltration Coefficient, Kuf of Dialyzers Reprocessed with 0.75% Bleach / 1.5% Formaldehyde @ 40°C (Kuf=mL/hr/mmHg)**

	0	1 use	5 use	15 use
F8	9	11	14	18

***In vivo* spKt/V and URR of Dialyzers Reprocessed with 0.75% Bleach / 1.5% Formaldehyde @ 40°C (URR=%)**

	0	1 use	5 use	15 use
F8				
spKt/V	1.34	1.30	1.29	1.31
URR	67	66	66	65

***In vivo* Pre and Post Serum Albumin Levels of Dialyzers Reprocessed with 0.75% Bleach / 1.5% Formaldehyde (Albumin=g/dL)**

	0	1 use	5 use	15 use
F8				
Pre Serum	3.46	3.55	3.46	3.40
Post Serum	4.19	4.24	3.96	4.23

IN VIVO RESULTS 1.5% FORMALDEHYDE @ 40°C

In vivo Kuf increased when exposed to multiple reprocessing with 0.75% Bleach / 1.5% Formaldehyde @ 40°C. The use of volume ultrafiltration control dialysis equipment is mandatory when these dialyzers are reused.

In vivo spKt/V and URR were unchanged with multiple exposure to the reprocessing procedure. There was no change in serum albumin levels for any of the hemodialyzers tested.

SUMMARY OF *IN VITRO* TESTING METHODS
GLUTARALDEHYDE

In vitro testing of Fresenius Hemoflow/Optiflux Dialyzers was performed according to the "Guidance for Hemodialyzer Reuse Labeling" testing protocol. Where possible, three dialyzers from each of three different manufacturing lots were tested. Dialyzers were reprocessed a total of 15 times with the 0.75% Bleach / 0.8% Glutaraldehyde reprocessing procedure. Dialyzers were not exposed to blood between reprocessings. Dialyzers were stored for 24 hours before the subsequent reprocessing. Dialyzers were tested for *in vitro* Kuf using fresh whole beef blood and aqueous solute clearance using urea, creatinine and Vitamin B_{12} as the solute markers.

***In vitro* Ultrafiltration Coefficient, Kuf of Dialyzers Reprocessed with 0.75% Bleach / 0.8% Glutaraldehyde Using Fresh Whole Beef Blood (Kuf=mL/hr/mmHg)**

	0	1 use	5 use	15 use
F6	6	11	10	13
F8	10	16	15	20
F80A	50	47	36	33
F180A	43	46	38	38
F200A	57	53	48	50

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Aqueous *In vitro* Urea Clearance of Dialyzers Reprocessed with 0.75% Bleach / 0.8% Glutaraldehyde (mL/min)

	QB	0	1 use	5 use	15 use
F6	200	171	173	170	169
	300	221	223	223	223
	400	250	256	253	254
F8	200	173	181	182	180
	300	243	244	245	242
	400	281	283	281	278
	500	305	295	299	299
F80A	200	183	180	180	185
	300	246	251	249	248
	400	284	295	292	293
	500	306	321	322	319
F180A	200	194	195	193	194
	300	268	268	267	264
	400	313	312	309	309
	500	337	339	336	332
F200A	200	192	193	195	172
	300	270	265	268	265
	400	309	312	315	309
	500	341	345	344	338

Aqueous *In vitro* Creatinine Clearance of Dialyzers Reprocessed with 0.75% Bleach / 0.8% Glutaraldehyde (mL/min)

	QB	0	1 use	5 use	15 use
F6	200	154	159	157	156
	300	189	196	195	195
	400	210	219	215	215
F8	200	164	171	171	170
	300	216	220	219	218
	400	242	247	244	242
	500	261	253	256	256
F80A	200	175	173	173	173
	300	225	229	228	226
	400	254	263	261	258
	500	269	283	282	278
F180A	200	189	188	185	186
	300	247	245	244	241
	400	281	280	275	274
	500	301	304	300	295
F200A	200	187	188	189	188
	300	249	249	249	246
	400	281	288	286	284
	500	298	304	302	299

Aqueous *In vitro* Vitamin B_{12} Clearance of Dialyzers Reprocessed with 0.75% Bleach / 0.8% Glutaraldehyde (mL/min)

	QB	0	1 use	5 use	15 use
F6	200	52	91	91	94
	300	57	104	100	101
	400	60	109	100	102
F8	200	78	125	114	117
	300	87	137	130	129
	400	83	136	131	129
	500	82	132	123	130
F80A	200	136	145	129	118
	300	161	177	156	144
	400	170	188	167	153
	500	176	194	175	158
F180A	200	139	135	129	125
	300	160	156	148	141
	400	173	170	160	155
	500	179	178	167	162
F200A	200	138	138	136	132
	300	165	163	158	152
	400	178	179	171	166
	500	185	185	177	172

IN VITRO RESULTS GLUTARALDEHYDE

In vitro Kuf decreased with multiple exposures 0.75% Bleach / 0.8% Glutaraldehyde reprocessing. Urea and creatinine clearance were unaffected by multiple exposures to the reuse process. Vitamin B_{12} decreased reflecting the same effect as that observed with *in vitro* ultrafiltration.

SUMMARY OF *IN VIVO* TESTING METHODS GLUTARALDEHYDE

In vivo testing of Fresenius Hemoflow Dialyzers was performed according to the "Guidance for Hemodialyzer Reuse Labeling" testing protocol. Clinical testing of the F6 dialyzer was performed with 12 patients (4 males, 8 females), average age 66, average blood flow of 304 mL/min and average dialysis time of 3.07 hours. Clinical testing of the F80A dialyzer was performed with 15 patients (14 males, 1 female), average age 57, average blood flow of 373 mL/min and average dialysis time of 3.3 hours. *In vivo* Kuf for the different hemodialyzers were calculated from pressure determinations available from the Fresenius 2008H hemodialysis machine. Blood samples were taken at predetermined times pre and post dialysis session on the 0, 1, 5 and 15th reuse. Blood samples were analyzed for urea, albumin and Beta2-Microglobulin (B2M for high flux hemodialyzers only). Equilibrated single pool Kt/V urea (spKt/V), urea reduction ratio, (URR = %) and pre/post serum albumin values were calculated.

Note: *In vivo* reuse testing was not performed on the Optiflux dialyzers. However, the reuse performance of the Optiflux dialyzers will be similar to the Fresenius Hemoflow dialyzers.

***In vivo* ultrafiltration Coefficient, Kuf of Dialyzers Reprocessed with 0.75% Bleach / 0.8% Glutaraldehyde (Kuf=mL/hr/mmHg)**

	0	1 use	5 use	15 use
F6	9	12	12	15
F80A	73	69	67	71

***In vivo* spKt/V and URR of Dialyzers Reprocessed with 0.75% Bleach / 0.8% Glutaraldehyde (URR=%)**

	0	1 use	5 use	15 use
F6				
spKt/V	1.19	1.14	1.19	1.22
URR	62	61	61	61
F80A				
spKt/V	1.31	1.33	1.26	1.20
URR	66	67	64	63

***In vivo* Beta2-Microglobulin Clearance of Dialyzers Reprocessed with 0.75% Bleach / 0.8% Glutaraldehyde (B2M=mL/min)**

	0	1 use	5 use	15use
F80A	39	36	45	47

***In vivo* Pre and Post Serum Albumin Levels of Dialyzers Reprocessed with 0.75% Bleach / 0.8% Glutaraldehyde (Albumin=g/dL)**

	0	1 use	5 use	15 use
F6				
Pre Serum	3.75	3.90	3.74	3.68
Post Serum	4.15	4.06	4.15	4.46
F80A				
Pre Serum	3.80	3.72	3.66	3.74
Post Serum	4.30	4.11	4.25	4.28

IN VIVO RESULTS GLUTARALDEHYDE

In vivo Kuf (mL/hr/mmHg) increased for low flux F6 hemodialyzers and was unchanged in high flux hemodialyzers when exposed to multiple reprocessing with 0.75% Bleach / 0.8% Glutaraldehyde.

In vivo spKt/V and URR were unchanged with multiple exposure to the reprocessing procedure. Beta2-Microglobulin increased significantly with the F80A dialyzers with multiple exposure to the 0.75% Bleach / 0.8% Glutaraldehyde reprocessing procedure. There was no change in serum albumin levels for any of the hemodialyzers tested.

SUMMARY OF *IN VITRO* TESTING METHODS PERACETIC ACID

In vitro testing of Fresenius Hemoflow/Optiflux Dialyzers was performed according to the "Guidance for Hemodialyzer Reuse Labeling" testing protocol. Where possible, three dialyzers from each of three different manufacturing lots were tested. Dialyzers were reprocessed a total of 15 times with the Peracetic Acid reprocessing procedure. Dialyzers were not exposed to blood between reprocessings. Dialyzers were stored for 24 hours before the subsequent reprocessing. Low flux F6, and F8, and high flux F80A, and 200A dialyzers were used in the *in vitro* testing. Dialyzers were tested for *in vitro* Kuf using fresh whole beef blood and aqueous solute clearance using urea, creatinine and Vitamin B_{12} as the solute markers.

***In vitro* Ultrafiltration Coefficient, Kuf of Dialyzers Reprocessed with 3.5% Peracetic Acid Using Fresh Whole Beef Blood (Kuf=mL/hr/mmHg)**

	0	1 use	5 use	15 use
F6	6	11	10	13
F8	10	16	15	20
F80A	50	47	36	33
F180A	55	56	61	54
F200A	61	62	60	56

Aqueous *In vitro* Urea Clearance of Dialyzers Reprocessed with 3.5% Peracetic Acid (mL/min)

	QB	0	1 use	5 use	15 use
F6	200	175	177	178	179
	300	224	223	228	226
	400	247	249	257	257
F8	200	185	185	183	184
	300	246	247	244	246
	400	283	287	285	283
	500	308	311	310	311
F80A	200	183	186	188	187
	300	238	243	251	252
	400	278	285	288	293
	500	308	302	316	319
F180A	200	194	194	195	194
	300	269	264	270	269
	400	314	316	318	316
	500	338	344	342	344
F200A	200	196	196	196	195
	300	270	272	272	267
	400	322	327	328	310
	500	363	371	373	337

Aqueous *In vitro* Creatinine Clearance of Dialyzers Reprocessed with 3.5% Peracetic Acid (mL/min)

	QB	0	1 use	5 use	15 use
F6	200	156	159	160	160
	300	192	193	195	191
	400	207	208	216	216
F8	200	172	173	173	172
	300	215	219	218	217
	400	241	247	245	244
	500	259	267	265	264
F80A	200	169	177	177	177
	300	214	223	226	229
	400	246	254	257	260
	500	272	276	280	280
F180A	200	188	188	189	188
	300	248	247	248	247
	400	283	280	283	280
	500	306	309	307	308
F200A	200	188	189	190	191
	300	245	246	247	248
	400	278	279	283	281
	500	293	310	294	298

Aqueous *In vitro* Vitamin B_{12} Clearance of Dialyzers Reprocessed with 3.5% Peracetic Acid (mL/min)

	QB	0	1 use	5 use	15 use
F6	200	61	63	65	64
	300	64	65	68	67
	400	64	62	70	68
F8	200	56	77	76	74
	300	60	82	81	77
	400	61	84	84	80
	500	65	87	86	83
F80A	200	116	124	125	135
	300	134	141	144	159
	400	148	153	156	169
	500	159	163	165	176
F180A	200	139	140	142	140
	300	163	161	166	163
	400	177	177	179	176
	500	184	185	190	188
F200A	200	141	139	140	144
	300	163	162	163	162
	400	176	173	176	176
	500	182	179	182	182

IN VITRO RESULTS PERACETIC ACID

In vitro Kuf was unchanged in low flux hemodialyzers and decreased in mid flux and high flux hemodialyzers with multiple exposures to Peracetic acid reprocessing. Urea, creatinine, and Vitamin B_{12} increased for some study hemodialyzers.

SUMMARY OF *IN VIVO* TESTING METHODS PERACETIC ACID

Note: *In vivo* reuse testing was not performed on the Optiflux dialyzers. However, the reuse performance of the Optiflux dialyzers will be similar to the Fresenius Hemoflow high flux dialyzers. The *in vivo* reuse data for the Hemoflow dialyzers is provided for reference.

In vivo testing of Fresenius Hemoflow Dialyzers was performed according to the "Guidance for Hemodialyzer Reuse Labeling" testing protocol. Clinical testing of the F8 dialyzer was performed with 12 patients (6 males, 6 females), average age 57, average blood flow of 372 mL/min and average dialysis time of 3.02 hours. Clinical testing of the F80A dialyzer was performed with 16 patients (9 males, 7 females), average age 50, average blood flow of 378 mL/min and average dialysis time of 3.04 hours. *In vivo* Kuf for the different hemodialyzers were calculated from pressure determinations available from the Fresenius 2008H hemodialysis machine. Blood samples were taken at predetermined times pre and post dialysis session on the 0, 1, 5 and 15th reuse. Blood samples were analyzed for urea, albumin and Beta2-Microglobulin (B2M for high flux hemodialyzers only). Equilibrated single pool Kt/V urea (spKt/V), urea reduction ratio, (URR = %) and pre/post serum albumin values were calculated.

***In vivo* Ultrafiltration Coefficient, Kuf of Dialyzers Reprocessed with 3.5% Peracetic Acid (Kuf=mL/hr/mmHg)**

	0	1 use	5 use	15 use
F8	9	9	10	10
F80A	51	47	47	44

***In vivo* spKt/V and URR of Dialyzers Reprocessed with 3.5% Peracetic Acid (URR=%)**

	0	1 use	5 use	15 use
F8				
spKt/V	1.58	1.46	1.50	1.57
URR	70	69	69	70
F80A				
spKt/V	1.62	1.56	1.54	1.69
URR	70	70	70	66

***In vivo* Beta2-Microglobulin Clearance of Dialyzers Reprocessed with Minimum 0.1% Peracetic Acid (B2M=mL/min)**

	0	1 use	5 use	15 use
F80A	43	57	50	38

***In vivo* Pre and Post Serum Albumin Levels of Dialyzers Reprocessed with 3.5% Peracetic Acid (Albumin=g/dL)**

	0	1 use	5 use	15 use
F8				
Pre Serum	3.92	4.00	3.91	4.07
Post Serum	4.58	4.35	4.22	4.78
F80A				
Pre Serum	4.02	4.06	4.09	4.11
Post Serum	4.86	4.67	4.57	5.20

IN VIVO RESULTS PERACETIC ACID

In vivo Kuf was unchanged for low flux hemodialyzers and decreased for high flux hemodialyzers when exposed to multiple reprocessing with Peracetic acid.

In vivo spKt/V and URR were unchanged with multiple exposure to the reprocessing procedure. Beta2-Microglobulin decreased with the F80A dialyzers with multiple exposure to the Peracetic acid reprocessing procedure. There was no change in serum albumin levels for any of the hemodialyzers tested.

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