Reuse of dialyzers, tubings, and end caps is banned by law in many countries, but is widely practiced in India to reduce cost. An analysis of reuse practices by Galvao (2012) adjusted for covariates concluded that dialyzer reuse *per se* was not associated with increased mortality although the overall study quality was low. There are variations in the practice of reuse in terms of the method of reprocessing (manual vs. automated), the use of chemicals and disinfectants, and tests of performance. Although the main objective of reprocessing dialyzers is lowering cost, this should not compromise the quality of dialysis and safety of patients. Another concern is the relative environmental load of reprocessing chemicals versus that of discarded dialyzers.

1. We suggest that hollow fiber dialyzers may be reprocessed in order to reduce the cost of the HD procedure.
2. We recommend that units that practice reuse should have an adequate protocol of reprocessing and a reliable system of monitoring.
3. We recommend that only dialyzers that have been validated and are approved for reuse by the manufacturers [Table 1] should be reused.
4. We recommend that the following types of dialyzers not be reused:
   - Dialyzers with opaque nondetachable headers are impossible to check for clots in the headers. Should the header contain medium-sized friable clots, they may need to be detached in order to remove the clots.
5. We suggest manual method when the reprocessing machine is not available.
6. We recommend chemical disinfectant reprocessing.
7. We recommend heat reprocessing only for polysulfone dialyzers.
8. We suggest that dialyzers from HBV-positive and human immunodeficiency virus (HIV)-positive patients should not be reused.
9. We suggest that dialyzers from patients with acute hepatitis where the cause is unknown not be reused.
10. We recommend that dialyzers from patients with hepatitis C virus should be reprocessed in a separate reprocessing area and on dedicated reprocessing machines in the case of automated reprocessing, if they are reused.
11. We recommend performance testing for all reused dialyzers.
12. We recommend not using visual impressions as the sole criteria for continuing to reuse a dialyzer. Studies have demonstrated that dialyzers which appeared normal on inspection delivered an inadequate dose of dialysis.
13. We suggest that tubings, end caps, O rings, and dialyzer headers may be reused.
14. We suggest that an attempt should be made to treat end caps of both the blood and dialysate compartments along with the “O” rings of the dialyzer as a single unit and process them together in dedicated containers of disinfectant instead of randomly selecting from a common pool of end caps. Although the risk of transmitting viral infections is negligible with adequate exposure to formaldehyde, peracetic acid, and glutaraldehyde, we suggest extra caution to minimize the risk even further as it imposes no extra cost.
15. We suggest that venous or arterial transducer protectors should not be reused.
16. We recommend that operators should wear appropriate protective gear for all reprocessing procedures.
17. We recommend that the process of reusing dialyzers should be monitored for efficacy and safety.
18. We recommend that the process including the results of performance tests should be documented by the operator and verified by the dialysis doctor.

**Table 1: Dialyzers validated and approved for reuse**

| Manufacturer                  | Manufacturer models approved for multiple use |
|------------------------------|-----------------------------------------------|
| Asahi medical Co Ltd         | AM-R series, APS series                        |
| Baxter Healthcare Corp       | CA 90, CA 110, CA 130, CA 150, CA 170, CA 190, CA 210 |
|                              | CAHP 110, CAHP 130, CAHP 150, CAHP 170, CAHP 210 |
|                              | CT 190, CT 210                                 |
|                              | PSN 130, PSn 150, PSn 170, PSN 210              |
| Althin                       | AlthinAltraflux 200/Altra Nova 200             |
| Fresenius Medical Care       | F4, F5, F6, F7, F8                             |
|                              | F60M, F70M, F80M                               |
|                              | F60A, F70A, F80A                               |
|                              | F60B, F70B, F80B Optiflux 200A                 |
| Gambro Healthcare            | Polyflux 17R, Polyflux 21R                      |
| Minntech Corp                | Primus 100, Primus 1350, Primus 2000           |
| Terumo Medical Corp          | CLIRANS T-series                              |
19. We recommend that the decision to discard a dialyzer should be taken by the dialysis technician/nurse as per protocol. The dialysis doctor should make the decision in case of any protocol deviation.

20. We recommend that automated machines where used be capable of handling a one or two dialyzers simultaneously.

21. We recommend that the specifications of all the dialyzers used in a unit be entered into the automated reprocessing machines database at the time of the initial setup.

22. We recommend that prior manual inspection of a dialyzer for clots and discolored fibers be carried out before it is connected to the reprocessing machine.

23. We recommend that the machines’ rejection of the dialyzer not be overridden.

24. We recommend that daily disinfection or sanitization cycles of the machine be carried out with the specified chemicals, usually sodium hypochlorite.

25. We recommend that calibration of the machine be carried out at least weekly to ensure accurate tests of performance.

Automated techniques eliminate human error, making the process more reproducible; they provide an accurate estimation of fiber bundle volume and pressure leak testing. The number of reuses obtained by automated reprocessing may be consistently higher than that by manual reprocessing, however studies with the manual method have also shown similar reuse numbers where a protocol was rigidly adhered to and monitored.

Reuse procedure involves a high risk of mucosal splash with contaminated material/effluent. The risk of transmission of HBV is approximately 30% after a mucosal exposure, around 3% for HCV, and 0.3% for HIV.

We recommend the following for automated reprocessing:

a. The automated reprocessing machine should be capable of
   i. Performing the tests of performance, namely, estimation of fiber bundle volume and pressure leak testing. These should be recorded.
   ii. Carrying out a disinfection cycle of its hydraulics.

b. Automated reprocessing techniques usually follow the same sequence of steps or a slightly modified cycle as described below for manual reprocessing. These are specified by the manufacturer and should be carried out as advised.

c. The chemicals required for cleaning and disinfection cycles should be connected to the machines as specified by the manufacturer.

d. Periodic changing of the chemicals should be carried out with checks for exhaustion.

For manual reprocessing, we recommend the following procedure:

1. Return the blood using the machine’s blood pump and 0.9% normal saline. Air should not be allowed to enter the blood tubings or the dialyzer. It is advisable to then add around 1000 U of heparin to the saline bottle and further fill the circuit after disconnecting it completely from the patient. Following this step, the arterial and venous tubings are joined with a universal connector and heparinized saline is circulated in the extracorporeal circuit for about 5 min. The pressure leak test described below may be performed at this time.

2. Remove dialyzer and tubings from the machine and take to the reprocessing area in a covered tray to avoid blood spills. The tubings are disconnected and the blood compartment of the dialyzer is connected to the water source. The blood compartment is rinsed with water till the effluent is clear.

3. Clean by instilling 1% hypochlorite into the blood compartment till it is completely filled and allowed to stay for not more than 2 min. Immediately rinse out of the cleaning agent from the blood compartment is recommended. If hydrogen peroxide is used, it should be instilled in the dialysate compartment and backwashing or reverse UF should be started after 1–2 min. Peracetic acid-based agents (Renalin (Sandor) Hemoclean (HEMOCLEAN CO., LTD Busan, Korea), Rein plus (Sceptre Medical India Private Limited)) usually also contain hydrogen peroxide and should therefore also be instilled in the dialysate compartment.

4. Inspect the dialyzer for a large number (>20%) of discolored fibers, large clots in the header, generalized blackening, change in color, or esthetically unpleasing appearance. If the clots in the headers appear small and friable, the header may be removed from the dialyzer to be cleaned separately.

5. Rinse out the cleaning agents with water.

6. Backwashing or reverse UF – The one end of the blood compartment is connected to the water supply, which is turned off, whereas the other end is left open. The one end of the dialysate compartment is capped, whereas the other is connected to a water supply with a pressure of 1–1.3 bar through a Hansen’s connector. The water should enter the dialysate compartment and exit through the blood compartment. This step is the most critical and is carried out for at least 15 min with periodic 1–2 min rinsing of the blood compartment. The direction of flow should be reversed at 5-min intervals.

Requirements for Manual Reprocessing

Cleaning and disinfecting agents

These should be available online in the reprocessing areas. Overhead tanks containing the chemicals maybe of 25–50 L capacity and should be refilled with fresh solutions every week, after cleaning. All tanks and piping for sodium hypochlorite should be composed of medical-grade PVC, and those for formaldehyde, glutaraldehyde, and peracetic acid should be composed of 316 SS.
Sodium hypochlorite

1%–2%. Commercially available cans (10%) should be diluted.

Hydrogen peroxide

This is meant for instillation only in the dialysate compartment.

Formaldehyde 4%

Commercially available as 40%, this can be diluted with the water used for reprocessing to give a final strength of 4%. Formalin exists as a vapor at room temperature and hence dialyzer blood compartment and dialysate compartment ports should have airtight caps to prevent escape of the disinfectant. Chronic exposure to formalin fumes has been reported to result in anti-N antibody formation, carcinogenicity, and irritation of mucus membranes, hence we recommend that formalin be handled in an area equipped with an exhaust.

Glutaraldehyde 2%

This has to be freshly prepared and activated. The chemical potency of the solution may be tested with Schiffs reagent, which produces a magenta color similar to that seen with formaldehyde. Glutaraldehyde should be used for preserving the end caps, universal connectors, O rings, and dialyzer caps when not in use. The solution should be replaced at intervals of not less than 10 days. Small containers containing glutaraldehyde should be available both at the dialysis stations and at the reprocessing areas so that dedicated caps are maintained for each dialyzer rather than being selected from a general pool.

Peracetic acid (Renalin/Hemoclean, Rein Plus, etc.)

The undiluted solution should be diluted to prepare two solutions of 2% (as a cleaning agent and 3.5% as a disinfectant.)

Peracetic acid is formed from the reaction of acetic acid and hydrogen peroxide and tends to build up pressure in a closed space. This can result in a spray at high pressure when a dialyzer is uncapped or when the ports of the blood or dialysate compartments are removed from the machine. The caps on the dialyzer ports should be vented in order to allow dissipation of the pressure and prevent accidental burns. Undiluted peracetic acid can result in severe chemical burns and milder burns can occur even with a 2% solution, hence extreme care should be taken when handling this disinfectant.

Measuring cylinder

- Scientific laboratory grade with a capacity of 100, 200, and 1000 ml should have a least graduation of 2 ml (preferably 1 ml)
- Covered tray for transferring dialyzer and tubings to the reprocessing areas.

Carrying out tests of performance

The blood and dialysate compartment are filled with water and both openings of the dialysate compartment are capped. The dialyzer is placed over a scientific measuring cylinder and the water from the blood compartment is expelled into the cylinder with a sphygmomanometer bulb or a large syringe. This is the total cell volume (TCV) or the fiber bundle volume (FBV) of the dialyzer. The dialyzer should be discarded if the TCV is <80% of its initial value.

A better examination of the fibers is possible when the headers are removed. The headers and the O rings should be placed in glutaraldehyde while the dialyzer is being reprocessed. If the dialyzer or the header cannot be made free of clots or too many fibers appear blackened, it should be discarded.

If the header is removed, special care should be taken to check the O ring and replace it properly. Improper placement of the O ring or failure to replace it will result in a blood leak when the dialyzer is next used.

We suggest that all dialyzers should be tested before the first use and overreliance should not be placed on the stated values.

Pressure leak testing can be performed at the time of priming the dialyzer using the dialysis monitor or by using a vacuum gauge. The venous bubble trap is filled with saline up to 2/3rd of its volume and connected to the venous pressure transducer.

The venous outflow line is clamped and the blood pump is run at a speed of 100–150 mL/min, until the venous pressure rises to 400 mmHg. The blood pump is then turned off. The pressure should decrease slowly by around 1 mm/s. If the pressure drops abruptly, there is likely to be a leak due to rupture of some of the fibers and the dialyzer should be discarded.

Filling with disinfectant

1. Air from the blood compartment is once again rinsed out with water, and the dialyzer is filled with the disinfectant from the other direction, allowing the disinfectant to displace water
2. Both the blood and the dialysate compartment should be completely filled with disinfectant.

Labeling and storage

Patients’ name, hospital number, the TCV, the reuse number, and the date should be marked in indelible ink and affixed to the dialyzer. The dialyzer should be placed in a sealed polyethylene bag and stored in a rack with separate compartments for each dialyzer. The minimum period of storage at ambient temperature should be 24 h, for complete action of the disinfectant. If the dialyzer is not used for 7 days, it should be refilled with disinfectant at this point in time.
**Priming and checking for residual disinfectant**

The dialyzer should be primed with at least 2000 ml of 0.9% normal saline using the dialysis machine blood pump at a speed of 150 ml/min. The dialysate lines should be connected and the dialysate compartment should be filled with dialysate flowing at 500 ml/min prior to starting the priming procedure. Failure to “dialyze” the disinfectant out may result in inadequate removal and reactions after starting dialysis. The pressure leak test may also be performed at this time.

After 2000 ml of saline priming, effluent from the venous line should be checked for the presence of residual disinfectant. This should be done using a commercial (Formacure) test strip or Schiff reagent, which gives a magenta color if the concentration of formalin is >5 ppm.

Peracetic acid testing requires two steps: the presence of adequate disinfectant in the dialyzer prior to priming and the absence after adequate priming. The caps of the blood and dialysate compartment should be removed before removing the dialyzer from the polythene bag to avoid splash.

The dialyzer is held parallel to the ground and the meniscus of disinfectant fluid in the header is inspected. It should be greater than two-thirds of the header. The cap from the dialysate compartment with a few milliliters of disinfectant is tested with a specific test strip for peracetic acid (Hemocheck or other). A dark brown or black color should be obtained showing the concentration of disinfectant to be >2000 mg/L (3.5% is 35,000 mg/L). After priming the saline, effluent from the venous line should be tested for residual hydrogen peroxide which lasts longer than peracetic acid with a peroxide 25 strip (Hemocheck, Allied health Sciences Pvt Ltd). The strip is white in the absence of H₂O₂ and detects concentrations from 0.5 to 25 mg/L with various shades of blue.

Absence of citric acid should be documented by absence of color change with litmus or pH papers. A pH of 6–8 confirms the absence of citric acid.

We recommend the following procedure for heated citric acid reprocessing. (This method has only been validated for polysulfone dialyzers.)

a) Preparation of the citric acid solution – 1.5% citric acid solution is prepared by dissolving 150 g of anhydrous citric acid in 10 L of water of AAMI or purer standard. The concentration of the citric acid solution can be verified by testing its conductivity (f 2875 μS/cm) at 21°C.

b) The steps of prerinsing, cleaning, inspection, backwashing, and performance testing are carried out as described earlier. The dialyzer is wiped dry with a sterile gauze pad and the blood compartment is filled with citric acid. The dialysate compartment is filled 4/5th with citric acid and capped. The dialyzer is placed in a hot air oven at 95°C for 20 h. The dialyzer is removed from the oven, checked for any leak, and exposed to heat by confirming change in color of the heat-sensitive paper. The presence of citric acid in the dialyzer is confirmed by a pH of 2.2 on a pH meter or pH paper strips.

d) Performing a pressure leak test is mandatory for dialyzer reprocessed by heat.

e) Although there is no evidence to support the reuse of dialyzers after single use.

As tubing costs have decreased in proportion to the total cost of dialysis, we suggest that individual centers may choose to reprocess or discard dialyzers after single use.

We recommend the following steps for reprocessing of tubings:

1. The tubings are washed free of blood by treated water of AAMI or EU standard, and then with a 1.6% solution of sodium hypochlorite.

2. The arterial and venous bubble chambers should be gently tapped to release clots.

3. The side tubings are all cleared by clamping the outlets to dislodge any adherent material.

4. Tubings are again rinsed with water and then connected to a supply of 4% formaldehyde, which is allowed to completely displace water and air from the tubings. Alternatively, the tubings can be filled with a 3.5% solution of peracetic acid.

Tubings may be dried after washing with pressurized air and sterilized with EtO gas. The dried tubing is placed in specific polythene bags, an indicator strip is placed alongside the tubing, and the ends of the bag are heat sealed. The gas should be at a temperature of 65°C–70°C and with an exposure time of 8–12 h. Adequate exposure to EtO gas is indicated by a color change of the test strip. Following EtO exposure, the tubings should remain in sealed packing for a period of 48 h for degassing.

We suggest that a dummy load be placed in the EtO chamber for each cycle and cultured to verify the quality of the disinfection. We suggest that centers choosing to use EtO gas for sterilization be aware of the role of EtO gas in first-use reactions and abandon it switching to single use of heat or gamma ray sterilized tubings in case of a suspected first-use reaction.

5. Tests of performance: No objective tests of performance are available for blood tubings.

6. The tubings should be discarded if:

   a) The normal elasticity appears to be lost

   b) There are visible cracks

   c) Change from the normal transparent appearance

   d) Damage to any of the hubs

   e) Damage to the sampling ports.
A test sometimes useful is to compare the elasticity of the pump segment with that of new tubing on a blood pump.

Failure to give 90% of the flow obtained with a new tubing segment, or “slipping” of the tubing or a “slapping sound” from the rollers may indicate a malfunction of the pump segment of the tubing and require it to be discarded.

**Procedure of automated reprocessing**

The initial steps of returning the blood and prerinsing with heparinized saline should be carried out as for the manual procedure. The dialyzer should be carefully inspected at the reprocessing station for discolored fibers and especially for friable clots in the headers. If present, these may need to be removed after detaching the headers or by rinsing with a jet injector.

The reprocessing machine is unable to carry out this step.

The dialyzer is placed on the holder and the blood compartment and dialysate compartment are connected to the respective connections. As the machine injection lines to the blood compartment have screw-type connections, care should be taken to ensure they do not get kinked during connection. Kinking of the lines from the machine to the blood compartment can result in faulty cleaning or injection of disinfectant, improper measurement of TVC, or pressure leak or even fiber rupture.

In units using multiple sized dialyzers from more than one manufacturer, ensure that the dialyzer being reprocessed matches the option chosen on the machine as the machine manufacturer, ensure that the dialyzer being reprocessed following steps or a slight modification:

- **Rinsing** – The dialyzer is rinsed with the treated water of ISN standards and supplied to the reprocessing machine at the specified pressure. This step usually lasts around 2 min.
- **Cleaning** – The dialyzer blood and dialysate compartments are exposed to cleaning chemicals in a prespecified program. For most commercially available machines, this is 2% peracetic acid (see section on chemical disinfectants).
- **Backwashing** – The dialysate compartment is pressurized at a pressure of 1 to 1.3 kg/m² with ISN standard water.
- **Tests of performance** – The machine tests the TCV/FBV of the dialyzer and compares it with the corresponding value entered in the database. The reprocessing uses an indirect gravimetric assessment of TCV rather than a direct volumetric measurement, in which the volume of water from the blood compartment is expelled into a load cell. This is based on the assumption that the density of water is 1, and that 1 ml of water weighs 1 g.

The leak test for pressure is also performed at the same time.

At this point, the machine will indicate that the dialyzer is fit to continue being used if both the tests are passed. If the dialyzer fails the test of performance, the machine will indicate this on the screen and should not proceed to inject disinfectant. Unfortunately, this step can be easily bypassed and the machine will proceed to inject disinfectant.

We recommend that the TCV be verified manually if a doubt exists about the value obtained by the machine.

The disinfectant is usually 3.5% peracetic acid, the strength of which is verified by the machine by an online conductivity measurement. As this measurement is indirect, we recommend that the concentration of disinfectant be verified prior to using the dialyzer (see section on testing for residual disinfectant).

Once the machine has filled the dialyzer with disinfectant, it will display the results of the TCV and pressure leak test on the screen. The printer of the machine will also provide a printout of the same values with the date, and this should be affixed to the dialyzer or entered into the patients’ file or dialyzer log. The dialyzer is then removed from the machine and the blood and dialysate compartment ports are closed with vented caps. Attendants should wear protective gear to avoid splash with disinfectant and chemical burns during this step. The dialyzer should then be labeled with a label in indelible ink, placed in a polythene ziplock bag and stored till the next use.

We recommend a minimum time of 11 h of storage at room temperature for 3.5% peracetic acid.

The subsequent steps of use of the dialyzer are manual and as described above in the section on manual reprocessing.

**Maintenance of the reprocessing machine**

We recommend that all reprocessing machines be used only with those chemicals recommended by the manufacturer. Like dialysis machines configured for a particular concentrate, reprocessing machines dilute peracetic acid or hypochlorite with water to produce different concentrations for the cleaning step, the disinfection step, and for machine sanitization. As various concentrations of the undiluted disinfectant are available [Table 2], it is essential to ensure that the machine receives the concentration it is configured for. Use of preparation B in a machine configured for preparation A [Table 2] will result in a suboptimal concentration of chemical disinfectant in the dialyzer.

We recommend that the machine be checked for its TCV measurement using the correction lumens provided by the manufacturer in each shift of the unit. The cylinders
provided by the manufacturer have a predetermined volume measured volumetrically or this can be determined with a scientific measuring cylinder. If the machine obtains a value >2 ml from the stated value, the TCV measurements will be erroneous. In such cases, the TCV of individual dialyzers may have to be checked manually while the machine blood volume and load cell may require calibration.

We recommend that the reprocessing machine receives a sanitization cycle at least once a day with sodium hypochlorite. Small blood clots, fibrin, and other proteinaceous material from the blood compartment are washed out of the dialyzer during reprocessing. These materials enter the machines’ hydraulic cycle and then are washed to drain. The machines’ solenoid valves, constrictions in the hydraulics, or the load cell can be blocked by protein residues and malfunction. This results in inaccurate measurements during the tests of performance. Sodium hypochlorite strips these residues from the hydraulics and restores patency if performed regularly. If not performed for long intervals, mechanical cleaning or replacement may be required.

We recommend that the blood volume calibration using the correction lumens be done at least once a month or whenever the machine readings are erroneous. As mentioned above, this malfunction can result in faulty TCV measurements.

We recommend that a qualified service engineer do the load cell calibration at least once in 6 months or if calibration of the blood volume with the correction lumens fails. The measurement of TCV is gravimetric and not volumetric and hence its accuracy is dependent on the performance of the load cell. This calibration is, therefore, essential for proper performance.

| Table 2: Preparations of peracetic acid and use for disinfection |
|---------------------------------------------------------------|
| Peracetic acid concentration (%) | Disinfectant A Rein Plus | Disinfectant B Hemoclean RP |
|---------------------------------|---------------------------|----------------------------|
| Hydrogen peroxide (%)           | 4.5                       | 1.73                       |
| 2% solution for dialyzer cleaning | 38.5 mL disinfectant + 4961.5 ml water | 100 ml disinfectant + 4900 ml water |
| 3.5% solution for dialyzer disinfection | 67.375 ml disinfectant + 4932.65 ml water | 175 ml disinfectant + 4825 ml water |
| 1% solution for accessory disinfection | 19.75 ml disinfectant + 4980.25 ml water | 50 ml disinfectant + 4950 ml water |

**Reuse of dialyzers and tubings of patients with acute kidney injury**

- No separate procedure is required to be followed for reprocessing dialyzers or tubings in patients with acute kidney injury (AKI)
- We suggest single use of dialyzers in AKI
- A lower rate of reuse is expected in patients undergoing slow extended daily dialysis, extended sessions, and anticoagulant-free dialysis sessions.

**Monitoring of outcomes and quality control of dialyzer reprocessing**

We recommend that the efficacy and safety of reused dialyzers be monitored regularly

1. The single-pool kinetic modeling (spKt/V) with new and reused dialyzers should be monitored at least once a month, where $K$ is the dialyzer urea clearance, $t$ is the total treatment time, and $V$ is the total volume within the body that urea is distributed.

2. Rigors, fever, and hypotension on dialysis suggest the possibility of infection caused by failure of the reprocessing technique and hemolysis caused by the chemical disinfectants

3. In case of rigors, fever, and hypotension or a visible change in the color of the blood in the tubing, the dialysis should be stopped. Blood should not be returned to the patient

4. Samples should be sent for culture, lactate dehydrogenase (LDH), and smear examination

5. The dialyzer should be rinsed with sterile normal saline and the effluent should be tested for:
   a. Residual disinfectants as described above.
   b. Cultured on Tryptic Soy Agar and Reasoner’s 2A Agar at 25°C and 37°C.
   c. Endotoxin by Gel-Clot LAL assay.