# Core Curriculum for the Dialysis Technician

## A Comprehensive Review of Hemodialysis

SIXTH EDITION

MEDICAL EDUCATION INSTITUTE

# *Core Curriculum for the Dialysis Technician*

## SIXTH EDITION



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# 5 Dialyzer Reprocessing


*Stephen Jones lives with his family in Richmond VA. He started drawing at the age of 7. Art has been his passion for many years. He loves to draw and feels through his artwork he can escape to many places. Stephen can frequently be found drawing while at dialysis, and loves to share his artwork with others. He considers this a blessing and honor to share these drawings.*

*"I have been on reuse for about 3 years. I have had no side-effects. Prior to each dialysis run, the RN or technician runs a test in front of me, and we both have to agree that the test comes out clear. If not, the dialyzer is rinsed for another 15 minutes and re-tested."*

# Objectives


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After you complete this module, you will be able to:

1. Discuss the history of dialyzer reprocessing.
2. Explain why dialysis clinics may reprocess dialyzers.
3. List the steps, in order, for dialyzer reprocessing.
4. Discuss the hazards to patients and staff that can occur with dialyzer reprocessing.
5. Describe the documentation needed when dialyzers are reprocessed.

***An acronym list can be found in the Glossary.***

# Introduction

The hollow fiber dialyzer, or artificial kidney, is a feat of modern engineering. It is complex enough to do some of the work of a human kidney. Yet, a dialyzer is reliable enough to use many times. Dialyzers can be *reprocessed*: cleaned, tested, and disinfected to be used again by the same patient, instead of being thrown out after one treatment. This is called *reuse*.

Federal and some state laws and rules cover dialyzer reprocessing. The rules state what clinics must do to make reuse as safe and effective as it can be for both patients and staff. A reprocessing technician has the key job of reducing the risks of reuse. This is done by carefully following all of the laws, rules, and clinic procedures.

This module covers the history of reprocessing, the role of rules and guidelines, and the steps used to reprocess dialyzers.

# History of Dialyzer Reprocessing

Dialyzer reprocessing has been around since the late 1960s. At first, it was done manually. Today, reprocessing is most often done with an automated system. As dialyzer technology evolved, reuse equipment evolved as well.

In the mid-1960s, most patients were treated with Kiil dialyzers (see Figure 1). A Kiil was a "sandwich" made of layers of membrane sheets held apart by grooved plastic boards. Rubber gaskets and metal clamps held the sandwich together. The Kiil had to be assembled and pressure tested before each use—a slow and complex process. About 10%–20% of the time the Kiil would fail the pressure test and the whole process would have to start over with fresh sheets of membrane.

In 1967, Dr. Belding Scribner (who helped devise the arteriovenous fistula) reported that reuse of a Kiil was possible. The blood side of a Kiil could be filled with a *germicide* (germ killer), rinsed—and used again. This meant that a Kiil did *not* have to be taken apart and rebuilt for each use, which saved Dr. Scribner's home patients some of the need to "tear down" and rebuild the Kiil. At the time, most of his Seattle patients were doing home HD.[1]

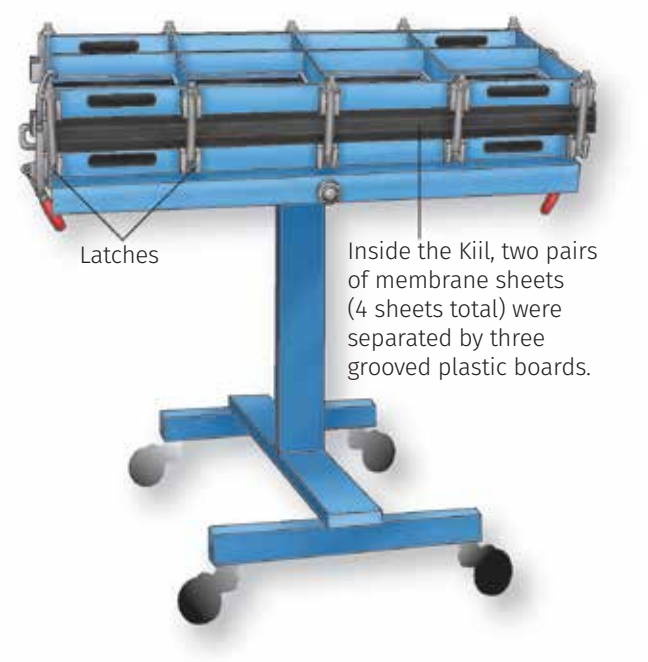



**Figure 1: Kiil Dialyzer**

By the late 1960s, coil dialyzers were preferred for reuse. Coils were easier to set up and prime (fill and rinse with normal saline) than Kiils. But, coils were too costly for many hospitals to use just once, as their manufacturers suggested. Before reuse, they were filled with a germicide and kept in a refrigerator.[2]

By the late 1970s, parallel plate dialyzers were in use and able to be reused. The dialyzer could be sealed off with germicide in the blood and dialysate sides, which reduced the chances that germs could grow inside.

## *Hollow Fiber Dialyzers and Reuse*

When hollow fiber dialyzers came on the market in 1970, they proved to be well-suited for reuse. They were strong, easy to rinse, and high water pressure could be used to wash fibrin and blood out of the fibers. *Total cell volume** (TCV), the total fluid volume of the blood compartment, was easy to measure, and when a dialyzer lost 20% of the baseline TCV, it was discarded. For these reasons, hollow fiber dialyzers became the leading choice for reuse.

* For most hollow fiber dialyzers, a 20% loss of TCV is approximately a 10% loss of clearance.

Over time, dialyzer reuse evolved. It was studied, tested, and practiced. Researchers looked at how dialyzers differed in how well they cleared small solutes. They

tried a number of different germicides, dwell times, concentrations, and temperatures. In time, they found the best ways to kill and prevent the growth of bacteria. Companies began to build automated systems for reprocessing. Some systems would process one dialyzer at a time, while others made multi-station systems.

## Dialyzer Reuse Numbers

In 1976, about 18% of U.S. HD patients were dialyzing with reused dialyzers.[3] In the 1980s, many studies reported that reuse with proper quality control was safe.[3] Automated reprocessing systems aided the growth of the practice.

In 1983, Medicare changed the way it paid for dialysis. Instead of fee for service, clinics were paid a fixed sum (a *composite rate*) per treatment to cover all of the equipment, labor, lab tests, and supplies.[4] This change may have been the largest reason for the fast growth of reuse—which peaked in 1997, with 82% of clinics using it.[3]

By 2002, reuse dropped to 63%,[3] because in 2001, the largest U.S. dialysis provider stopped the reuse of dialyzers in their clinics—since they also manufactured dialyzers.[5] Today, only 4 of the 10 largest dialysis providers reuse some of their dialyzers. Reuse data from 2010 to 2015 show that reuse of dialyzers in these companies dropped from 28% to just under 12%.[6]

# Why Dialyzers are Reused

Reasons for dialyzer reuse have changed over time. During HD treatments with a cellulose dialyzer, the inner membrane surface was coated with blood proteins. Reprocessing with some non-bleach germicides left these proteins in the dialyzer, which made it more biocompatible. This coating reduced the rate of *first-use syndrome*: symptoms of chest and back pain with new dialyzers.[7] Since newer synthetic membranes used in hollow fiber dialyzers tend to be more biocompatible, most patients do not have first-use syndrome.

Today, reuse is largely done to save money. Most clinicians believe it does not harm patients when it is done safely. In fact, preprocessing a dialyzer before the first use can rinse out plasticizers and manufacturing agents that could be lethal. In one case, 53 patients who were treated on new dialyzers died due to a chemical called PF-5070 used by a manufacturer.[8]

**Figure 2: Reuse Reduces Medical Waste in Landfills**

## Saving Dollars and Reducing Medical Waste

Dialyzer reuse may reduce the cost per dialysis treatment—or it may not when *all* of the costs are considered. If a dialyzer costs $9.00 and can be used 15 times, its per-treatment cost is $0.60, which would seem to be a savings of $8.40 per treatment. However, reprocessing itself may cost $3.00 to $5.50 per treatment, there is staff time as well, and extra saline must be used to rinse the dialyzer for the next treatment. Calculations like these may be why fewer clinics each year reprocess dialyzers.

Using dialyzers just once does have an impact on the planet. Each year, the U.S. generates an estimated 2.6 million tons of medical waste.[9] One large dialysis company notes that reuse could mean using 46 million fewer dialyzers a year—and keeping 62 million pounds of waste (31,000 tons) out of landfills (see Figure 2).[10] Reuse also lowers the costs of disposing of medical waste. Used dialyzers may be incinerated, and this can affect air quality as well.

# Safety of Reuse

How safe is dialyzer reuse? In a 2012 paper, researchers analyzed 14 studies that had both a reuse and a non-reuse group. They found about the same survival rates for both groups.[11] However, reuse may expose patients to pathogens or germicides if it is not done correctly. NOTE: CMS does not require written patient consent for reuse, but patient groups (AAKP and NKF) suggest it. CMS rules do state that patients must be told about reuse and how the process is done.[12] Patients have the

right to have a new dialyzer for each treatment—but a less costly dialyzer may be used.[13,14]

## Reuse and Exposure to Pathogens

Germs can enter a dialyzer from the water used to make dialysate. After a treatment, germs in the dialysate side may then stay in a dialyzer. If these germs multiply and enter the patient's blood, they could potentially cause lethal:

- ***Pyrogenic reactions*** (fever, chills, nausea, vomiting, low blood pressure, muscle pain)
- ***Sepsis*** (life-threatening blood infection)

A 2016 study tested to see if bacteria would grow after dialyzers were reprocessed—and they *did*.[15] Bacteria or endotoxin may survive reprocessing if:

- Dialysate water quality is poor
- The germicide is outdated, not mixed correctly, or not enough was used
- There was too little contact time between the dialyzer and germicide
- The dialyzer was not stored properly after reprocessing

Any bacteria or endotoxin in the reprocessed dialyzer could pose a risk to patients. It is important to check and record a patient's temperature at *least* pre- and post-treatment. This will give you baseline data just in case the patient develops any symptoms, such as chills, during treatment. A doctor will need to decide if the symptoms might be due to an adverse reaction to the dialyzer. If a patient has sudden symptoms, the team needs to take blood and dialysate cultures and assess for:

- Use of contaminated water
- Errors in treatment delivery
- Errors in dialyzer reprocessing

If a cluster of patients has pyrogenic reactions or sepsis *at the same time* due to reuse, the clinic must stop doing reuse. They may not restart until the whole reprocessing system has been checked.[16]

***Never reuse a dialyzer from a patient who tests positive for hepatitis B surface antigen (HBV+)***. Both the Association for the Advancement of Medical Instrumentation (AAMI)[17] and the CMS *Conditions for Coverage*[18] state this rule. We discard these dialyzers after use to keep staff and other patients safe.

## Reuse and Exposure to Germicides

Germicides are toxic if they enter the patient's blood, even in small amounts (see Figure 3). If *all* of the germicide is not rinsed out before the treatment begins, the patient may:

- Have burning in the access limb
- Feel numbness in the lips
- Lose vision or hearing
- Die

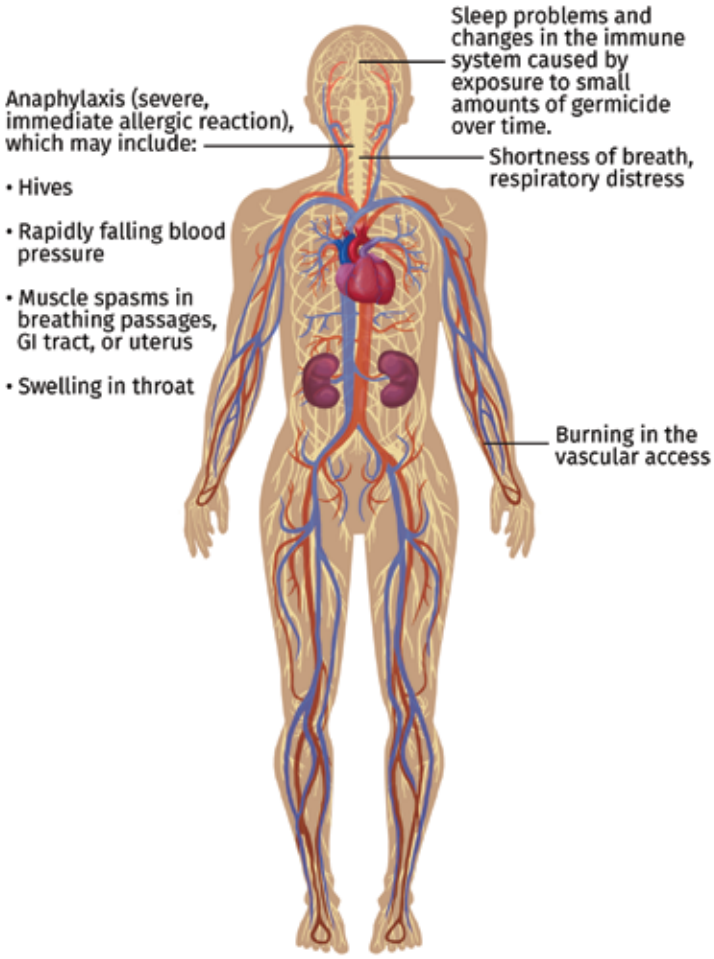



**Figure 3: Medical Risks of Incorrect Dialyzer Reprocessing**

*Acute* (sudden) toxicity can occur if dialysis does not start right after the germicide test is done. This may occur because there may be residual germicide in the dialysate side of the dialyzer. Waiting can let some of the germicide move to the blood side—where it can mix with the patient's blood.

Small amounts of some germicides may not cause acute symptoms, but may cause long-term problems, such as trouble sleeping and changes in the immune system.

Follow your clinic's policies and procedures for chemical use to avoid or minimize the risk of exposure. ***Test every dialyzer before use to make sure all of the chemical has been removed***.

## Reuse and Dialyzer Efficiency

Each reuse and reprocessing changes the dialyzer membrane and may reduce the TCV. The TCV tells us how well a dialyzer may work to remove solutes and water. Over time, a lower TCV can affect solute transport and ultrafiltration (UF). If this occurs, the patient does not receive the full dialysis dose, because:

- **Cleaning agents and germicide can harm the membrane**. Leaks and reduced clearance can occur.
- **Each time a dialyzer is used, fibers can clog with blood or other material**. These clogs reduce the surface area of the dialyzer. Having a smaller surface area reduces both clearance and the UF rate.

For most dialyzers, a 20% drop in TCV equals a 10% loss of urea clearance—and less waste removal for the patient.[19] When some fibers clot, the rest get a higher blood flow, so there is a higher diffusion rate in each unclotted fiber. This is why when TCV is 80% of baseline, urea, sodium, or ionic clearance only drops by about 10% and not the full 20%.

# Rules for Dialyzer Reprocessing

Dialyzers must be reprocessed using the ANSI/AAMI standards. Medicare adopted the ANSI/AAMI *Reuse of Hemodialyzers*, third edition, as a *Condition for Coverage* and as federal rules.[20]

The ANSI/AAMI standard covers:

- Equipment
- Cleaning and disinfecting
- Labeling and the reprocessing procedure
- Record keeping
- Reprocessing supplies
- Physical plant and environmental safety
- Patient considerations and staff qualifications
- Training
- Preparation for dialysis
- Testing for germicides
- Monitoring
- Quality assurance

As we cover the reprocessing steps (see Figure 4), we will tell you what the rules require you to do.

## Dialyzer Labeling for Reuse

Dialyzers must be FDA-cleared for reuse. In 1996, the FDA said that each dialyzer's label must say if it is for "single" or "multiple" use,[21] and this guidance is still in place today.[22] **We can only reuse dialyzers that say "multiple use" on the label.** Companies that sell dialyzers to clinics that reuse must include:[21]

- A method to reprocess the dialyzer
- *A list of approved cleaning agents and germicides.* (Not all dialyzers can be reprocessed with all germicides.)
- Scientific proof that reuse of the dialyzer is safe and effective.

Each dialyzer will have a manufacturer's "Directions for Use." Read this *before* you start to prepare it for reprocessing. Your clinic must set maximum use limits for dialyzers you reprocess.

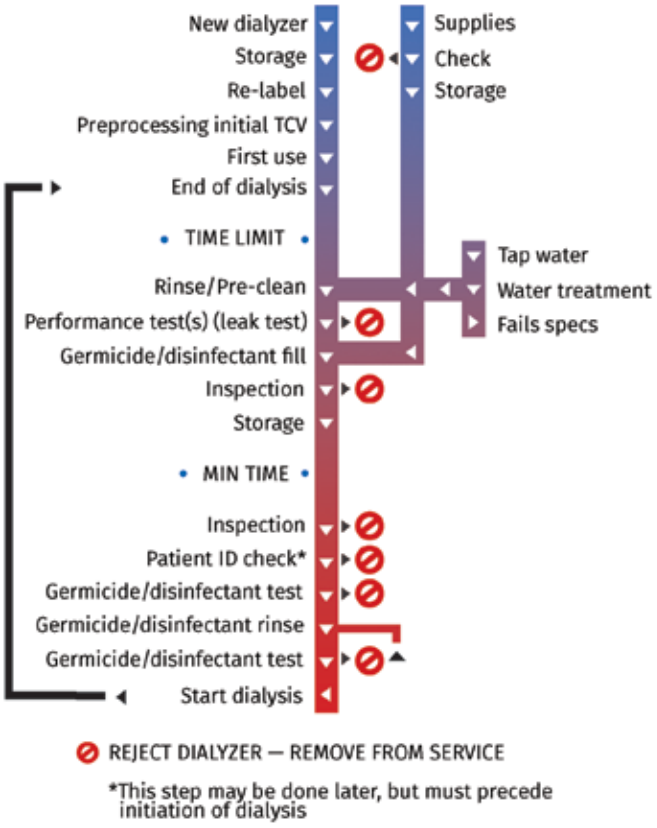



**Figure 4: Systems Diagram for Reprocessing Dialyzers**

## *Automated Versus Manual Reprocessing*

Dialyzers *can* be reprocessed manually. But, using an automated system (see Figure 5):[23]

- Is more efficient
- Is more consistent
- Tracks the process
- May be safer

Since reprocessing tasks are repetitive, it can be easy to become bored and make errors that could harm patients. And, automated systems use consistent standards, print proper labels, and keep records.

**Figure 5: Automated Reprocessing System**

Photo used with permission from Medivators Inc.

Automated systems can self-test the dialyzer. Follow the manufacturer's instructions to use them. If you reprocess dialyzers manually, you must test the tools you are using to be sure they are working. You will follow your clinic's procedures, and use:

- A graduated cylinder to collect and measure the fluid from the blood compartment of the dialyzer to find the TCV
- A stopwatch and a hand-held pressure bulb and manometer so you can apply pressure to the blood compartment to determine the timed pressure drop across the membrane

These tests can show whether the TCV measurement of a dialyzer is within 80% of its initial volume and the membrane is intact.

# Preparing a Dialyzer for First Use

The CMS *Conditions for Coverage* state the rules for dialyzer labeling:[24]

- ***The dialyzer must be labeled and have the patient's name on it before the first use.***
- ***If patients have the same (or similar) last names, the dialyzer must have a warning or alert*** (see Figure 6). The label should also have extra information to prevent mix-ups, such as:
  - The patient's first name and middle initial
  - A color code
  - Medical record number
- ***The label will need space for***:
  - The number of uses
  - Date and time the dialyzer was last reprocessed
  - An identifier for the reprocessing staff member
  - Results of tests done on the dialyzer


**Figure 6: Example of a Reprocessing Label and Same Name Alert**

CMS also says that you still need to be able to *read* the labels after reprocessing. The label should *not* cover up:

- The model or lot numbers
- Arrows for blood and/or dialysate flow
- Other key data

On dialyzers with clear casings, place labels so you can see some of the fibers all the way from one end of the dialyzer to the other.

## Preprocessing

Before you use a new dialyzer for the first time, you will *preprocess* it. This means that you complete all of the reprocessing steps, which tells you the baseline TCV. Then, *after* each use, you will recheck a dialyzer against its *own* TCV value. **If the TCV is less than 80% of the baseline, it is time to discard the dialyzer**.

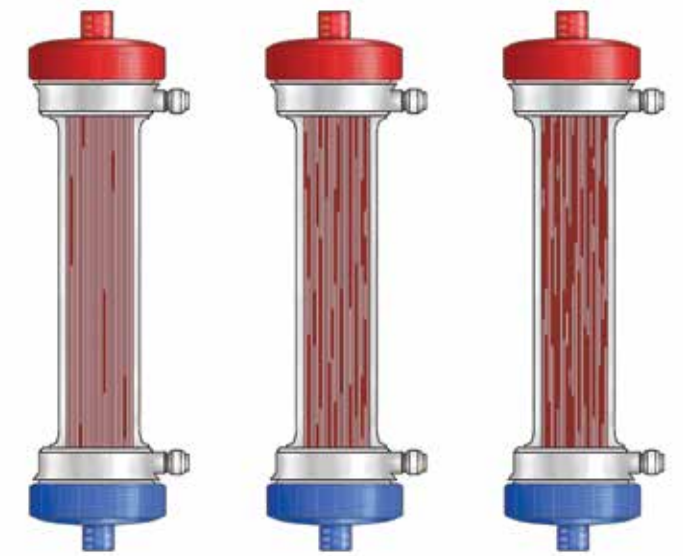
**Clinics must preprocess *all* new dialyzers that will be reused.**[19] If a "dry pack" (a dialyzer right out of the box) is used without preprocessing, you must throw it out after a treatment. Some manufacturers make dialyzers that cannot be preprocessed. These are single use only.

# After Dialysis

At the end of a treatment, blood in the dialyzer is *rinsed back* (returned to the patient). Rinse as much blood as you can back to the patient to reduce blood loss. A rinseback that is fair or poor leaves too much blood in the dialyzer. Any blood left may clot in the fibers, so the dialyzer is harder to clean and does not perform as well (see Figure 7). After rinseback:

- *Recirculate* (send through the loop) the saline in the extracorporeal circuit before you remove the dialyzer from the machine. To do this, you will connect the bloodlines together and turn on the blood pump. The continuous saline movement will decrease clotting.
- Disconnect the bloodlines from the dialyzer. Place disinfected caps—made for dialyzer reuse—on each of the ports.
- Bring the capped dialyzer to the reprocessing room. Or, bag the dialyzer to prevent cross-contamination and place it in a tub with others to be moved to the reprocessing room.

**All water used to rinse, preprocess, reprocess dialyzers, and dilute germicide must meet ANSI/AAMI standards.**[25]



**Good rinseback** a few streaks of blood

**Fair rinseback** several streaks, possibly in different places

**Poor rinseback** many streaks

**Figure 7: Good, Fair, and Poor Rinsebacks**

Dialyzers that will not be reprocessed within 2 hours must be refrigerated—but not frozen. Keeping dialyzers cold slows the growth of bacteria. Dialyzers that are reprocessed off-site must be kept cold during transport. The temperature range and maximum refrigeration time will be set by your clinic.

## Pre-clean the Dialyzer

Pre-cleaning is optional. A clinic may choose to pre-clean all, some, or none of the dialyzers before reprocessing. When pre-cleaning is done, it removes some blood from the blood compartment. **You must use ANSI/AAMI-quality water.***[26]

All product water used to make dialysate or concentrates or for reuse, must have a total viable microbe count lower than 200 CFU/mL. The endotoxin level must be lower than 2 EU/mL.

- The action level for the total viable microbial count in the product water is 50 CFU/mL.
- The action level for the endotoxin concentration shall be 1 EU/mL.[27]

*ANSI/AAMI RD47 standard is used as accepted practice for dialyzer reuse. Much of the RD47:2008 standard has been adopted by CMS as a requirement in the *Conditions for Coverage*.

Pre-cleaning may use *reverse ultrafiltration (UF)*. If so, you will:[28]

- Purge all air from the dialysate compartment. Air left in the dialyzer will be forced across the membrane.
- Place a cap on one of the dialysate ports.
- Send a supply of ANSI/AAMI-quality water into the other dialysate port at a pressure (*maximum transmembrane pressure*, or max TMP) suggested by the manufacturer.
- Monitor the pressure if you use a manual system. Too-high pressures may break fibers and cause blood leaks. Automated systems monitor and regulate internal pressure.

## Clean and Disinfect the Header

Dialyzer housings, supports, and membranes can adsorb endotoxin. If this occurs, they may be released into the blood at the next treatment. Endotoxin is very hard to rinse out. This is why bacteria levels in water used to make dialysate and to dilute germicide must be kept as low as possible.[25] Cleaning and disinfecting the header can also help reduce the level of endotoxin. For some dialyzers, you may need to take off the header caps to remove clotted blood from the headers (see Figure 8). If so, learn and follow your clinic's policy for removing dialyzer header caps. Once the caps are off:[29]

- Use *only* a free-flowing stream of ANSI/AAMI-quality water to clean the header, header cap and O-ring—not a paper clip, 4x4, or rag.
- Once the header, header cap, and O-ring are clean, dip them in disinfectant before you put them back on the dialyzer.
- **Keep the header caps and O-rings with the dialyzer they came from**. Putting the wrong part on a dialyzer could expose a patient to someone else's blood. For this reason, it is safest to clean one dialyzer at a time.

## Test Dialyzer Performance

After you rinse and clean a dialyzer, you will need to test it. NOTE: dialyzer testing is a built-in process in automated systems.

- Since dialyzer performance is linked to TCV, federal and state rules require you to check TCV after each reuse.
- You will also need to do a leak test. This measures how well the dialyzer can withstand a pressure load and protects the patient from a blood leak.
- Inspect the dialyzer for cracks, chips, or defects in the plastic housing.

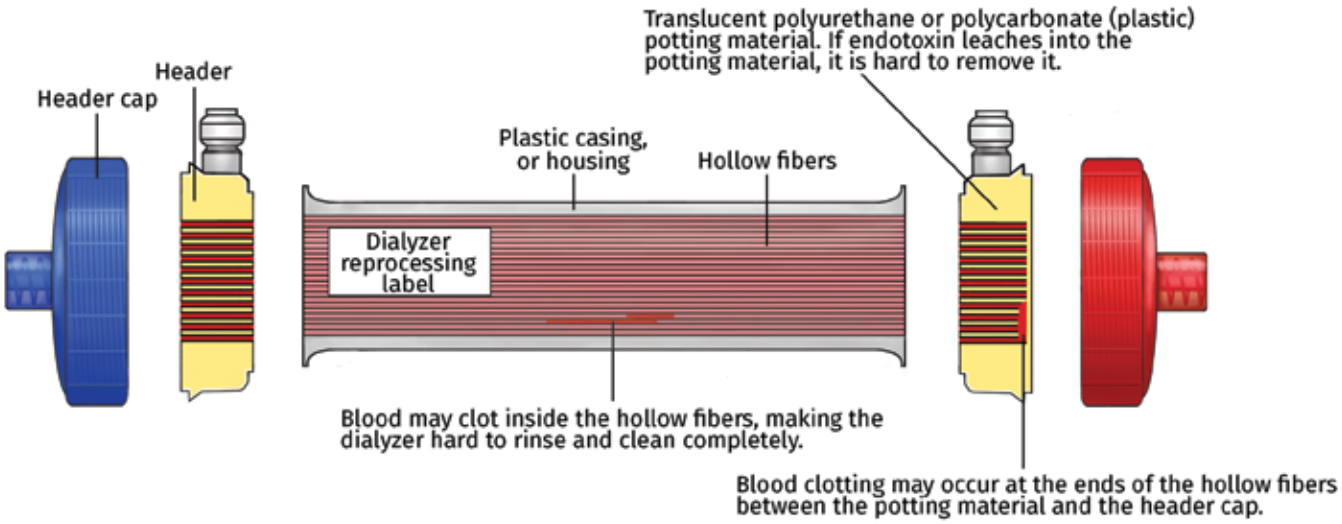



**Figure 8: Parts of a Hollow Fiber Dialyzer**

## Rejecting a Dialyzer

Before you go any further in reprocessing, discard dialyzers that:[30]

- Have reached their maximum number of uses (per your clinic's policy)
- Fail performance tests
- Have cracks or leaks in the plastic housing
- Have been exposed to more than one germicide
- Have large clots or other deposits in the headers
- Have more than a "few" discolored fibers - the dialyzer needs to look good to patients and staff
- Have labels that cannot be read
- Have less than 80% of the baseline TCV[19]

## Disinfect the Dialyzer

Dialyzers that pass inspection will next need to be disinfected. Automated systems will fill dialyzers with a germicide when you connect them. **Medicare allows dialyzers to be exposed to only *one* reprocessing germicide**.[31] So, if your clinic switches to a new germicide, all dialyzers must be discarded before the new one is used.

Each germicide has pros and cons (see Table 1). The four main types of germicides that have been used in the U.S. are:

- **Peracetic acid**
- **Heat and citric acid**
- **Formaldehyde**
- **Glutaraldehyde**

When you use an automated system that mixes germicide on-line, you need to check it at least once a month.[17] Some germicides come premixed at their dialyzer use concentration. These are verified by the manufacturer, but it is good practice to check them before you use them.

Germicide must stay in a dialyzer for a certain amount of time to kill germs. This *contact time* differs for each germicide. Your clinic will have a policy for the contact time, based on what the manufacturer says. CMS requires your clinic to keep detailed records of all of this information.

# Handling Hazardous Materials

Used dialyzers are *hazardous materials*. They contain blood. Handle them with Standard Precautions, until the inside and outside are disinfected. Wear personal protective equipment (PPE) to touch used dialyzers.[32]

Germicides kill germs, but ***they can also harm you and your patients***. The use of germicides requires protective gear and routine monitoring of vapors in and around the reprocessing area.

OSHA standards require clinics to tell staff about all hazardous chemicals in the workplace. OSHA has also set exposure limits for germicides used in reprocessing. See Table 2 for OHSA environment exposure limits. Clinics must keep a file of results of the health exams of reuse staff who are exposed to hazardous chemicals.[33]

**Table 1: Germicide Pros and Cons[23]**

| Germicide | Pros | Cons |
|---|---|---|
| **Peracetic acid** | When diluted, breaks down into biodegradable acetic acid (vinegar), oxygen, and water | ■ Higher cost |
| **Heat and citric acid** | Safe for staff and the environment | ■ Not all dialyzers can be heat disinfected |
| **Formaldehyde*** | Low cost | ■ Technician must wear a respirator<br>■ Clinic must have a quick drench shower<br>■ May cause cancer<br>■ Higher disposal costs |
| **Glutaraldehyde*** | Low cost | ■ Linked with skin and breathing problems<br>■ Higher disposal costs |

*Used only with manual reprocessing and rarely seen in current practice

***Your clinic must provide a list of all chemicals and keep it up to date:***

- One copy of the Safety Data Sheet (SDS) for each substance must be kept in a file that staff can access.[34]
- One copy must be posted near where a chemical is used, so you can find it quickly in an emergency.
- All containers must be clearly labeled, to avoid mix-ups.

## Safety Training

Your clinic must train you in its procedures for handling hazardous materials.[35] They must have spill kits for the chemicals you will use and train you in their use. The clinic must encourage you to read its written policies. You should know where to find policies, emergency procedures, and training materials. A clinic with more than 10 staff must also keep records of occupational illnesses and injuries. It is the employer's job to comply with safety practices and rules.

Procedures alone cannot keep you safe from toxic substances. YOU must learn the steps and follow them. Taking shortcuts does not save time if it causes an accident. *Protect yourself, your coworkers, and your patients: learn how to handle hazardous materials safely*.

## Peracetic Acid Safety

Air quality is tested for acetic acid and hydrogen peroxide to ensure safety.

## Formaldehyde Safety

Formaldehyde is a strong irritant of the eyes, nose, and throat.[36] Because of this, it can:

- Cause coughing or wheezing
- Trigger severe allergic reactions of the skin, eyes, and breathing tract
- Possibly cause cancer

**Table 2: OSHA Environmental Exposure Limits**

| Substance | Permissible Exposure Limit (PEL) |
|---|---|
| Acetic Acid | 10 ppm TWA* |
| Chlorine Dioxide (syn.: chlorine oxide) | 0.1 ppm TWA<br>0.3 STEL** |
| Citric Acid | None set |
| Formaldehyde | 0.75 ppm TWA<br>2 ppm STEL (15 min)<br>0.5 ppm action level |
| Glutaraldehyde | 0.2 ppm ceiling NIOSH/OSHA |
| Hydrogen Peroxide | 1 ppm TWA |
| Peracetic Acid | See limits for acetic acid and hydrogen peroxide, the two main ingredients |
| Phenol (may be used to disinfect the inside of header caps or the casing) | 5 ppm TWA |

ppm = parts per million
NIOSH = National Institute for Occupational Safety and Health
OSHA = Occupational Safety and Health Administration
PEL – can be TWAs or STELs (below)
*Time-weighted average – how much an employee can be exposed to in an 8-hour period
**Short-term exposure limit – how much you can be exposed to in any 15-minute period

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## Glutaraldehyde Safety

Glutaraldehyde is also a strong irritant. It can:[37]

- Irritate or burn eyes and skin
- Cause itching or rash
- Irritate the nose or throat, causing coughing, wheezing, or sudden asthma attacks
- Lead to headaches, feeling drowsy or dizzy, or nosebleeds

# Storage of Reprocessed Dialyzers

Store dialyzers so they do not deteriorate, become contaminated, or break. Wall racks or carts can be used, as long as they are easy to clean. Your clinic should follow the germicide maker's guidance for the maximum storage time for a reprocessed dialyzer. After that time, a dialyzer must be reprocessed or discarded. Follow your clinic's policies and procedures to store dialyzers. These may include:

- Before storage, wipe off the outside of a dialyzer or soak it with a disinfectant.
- Before you label a dialyzer, look to see if it is clean and the ports are capped tightly.
- ***Never store reprocessed dialyzers with new ones or dirty dialyzers with clean ones***.[38]

# Prepare for the Next Use

## *Inspect the Dialyzer*

The first step in getting a dialyzer ready for its next use is to look at it (see Figure 9) to be sure that:

- It is labeled properly.
- No structural damage or tampering has occurred.
- The ports are capped, and there is no leakage from the ports or other parts of the dialyzer.
- It was stored long enough for the germicide to work—but not so long that it exceeds the shelf life.
- The cosmetic appearance is good— it *looks* clean with no visible damage.

***After you look at the dialyzer, use a potency test strip or ampule to confirm that germicide is present and strong enough to work***. Just looking at the dialyzer cannot tell you how strong the germicide is. Some germicides, like peracetic acid, are clear. A dialyzer may accidentally be filled only with water. Germicides can also degrade over time. You *must* test the fluid to confirm the presence and strength of germicide.[39] How you test will depend on which germicide your clinic uses.

## *Remove the Germicide*

The next step is to ***thoroughly rinse the germicide out of the dialyzer before use***, following your clinic's procedure. Germicide can "hide" in a dialyzer. The steps in Table 3 can help you ensure that it is *all* out so the patient is safe.

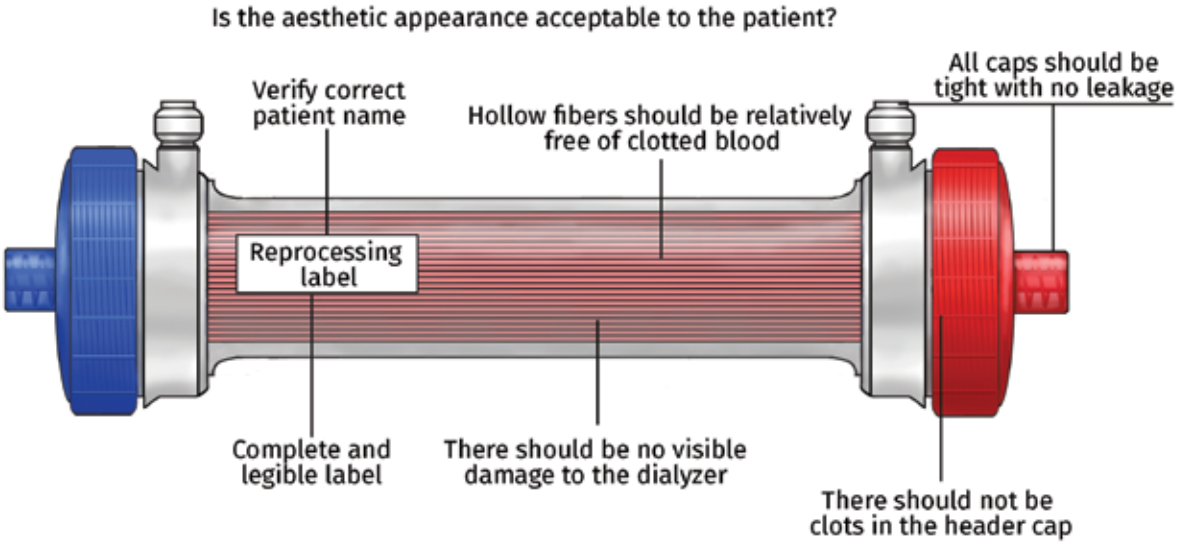


**Figure 9: Reprocessed Dialyzer**

**Table 3: How to Rinse a Reprocessed Dialyzer[17]**

| Problem | Solution |
|---|---|
| Air bubbles in fibers can trap germicide inside. | ***Fully prime the arterial line before you connect it to the dialyzer***. Flush the blood side before you start dialysate flow if you use a peracetic acid germicide. |
| Air in the dialysate side can trap germicide. | ***Rotate the dialyzer while you rinse it*** to release trapped air. |
| Germicide may back up into the heparin or monitor lines. | ***Clamp the heparin line*** so fluid cannot be forced in. |
| Germicide may back up into the saline bag. | ***Do not force fluid from the dialysis circuit into the saline bag***. Follow your clinic's procedures. |
| Sampling too quickly after rinsing may lead to a false negative germicide test. | ***Flush the dialyzer before testing***. Follow your clinic's procedure for the amount of time to continue flushing or rinsing. |
| The saline prime could contain some germicide. | ***Always replace the saline prime with fresh saline*** before you start blood flow to the dialyzer. |

Rinse/prime and recirculate the extracorporeal circuit per your clinic's procedure.

- Priming forces air and germicide out of the dialyzer and bloodlines.
- Recirculation helps the germicide move from the blood side of the dialyzer to the dialysate side, and then down the drain.

Just before you start a treatment, ***test the dialysis circuit for residual germicide***. Make sure the germicide is at or below the manufacturer's and clinic's accepted levels.[40]

**If you do not rinse the dialyzer well, the germicide could be infused into the patient.**

## Check the Dialyzer Prior to Treatment

Staff members must ensure that the dialyzer has been prepared for use. ***Doing dialyzer reprocessing incorrectly can harm patients***. The dialyzer must be labeled correctly, structurally sound (no cracks or leaks, all caps in place, etc.), free of germicide, and clean.

Just before the start of a treatment, ***two people must check the dialyzer label to be sure it matches the patient***. It is best if the patient can be one of these two people. Record this step on the reprocessing record or dialysis flow sheet, and sign it to show who did the check.

## Documentation

Reuse is part of a medical treatment. But, reprocessing is a type of manufacturing process. Clinics that reuse should follow the same "good manufacturing practice" standards used by companies that make dialyzers. Keep a record of all complaints and reactions to reused dialyzers in a Complaint Investigation File. Log blood leaks, changes in dialyzer performance, and other issues into the file. Include any corrective action. Review the file for trends to help make your clinic safer for staff and patients.

A large amount of documentation is required (see Table 4) for dialyzer reprocessing.[41] The staff person who completes the forms must be diligent, precise, and thorough.

## Quality Assurance (QA) and Quality Control (QC)

A clinic must prove it can safely and effectively reprocess dialyzers. Federal (CMS) rules require clinics that reuse dialyzers to have a program to check their systems.[20] QA and QC are the two parts of the program.

QA shows that a clinic has written, used, and tested its reuse policies and procedures. All standards as well as state and federal rules must be included. Each person who reprocesses dialyzers must pass the clinic's training course, prove competence, and be certified by the

**Table 4: Dialyzer Reprocessing Documents**

| Document | Description |
|---|---|
| **Dialyzer Reprocessing Manual** | A summary of all reuse specifications, policies, procedures, training materials, manuals, methods, and samples of forms and labels |
| **Reprocessing Log** | Record of each step in dialyzer use—from entry in the clinic, to all testing, to disposal |
| **Water Quality** | Record of water treatment system maintenance and operation to meet ANSI/AAMI standards and the clinic's policies and procedures. Includes cultures, endotoxin, and chemical analysis. |
| **Complaint Investigation Files and Special Incident Report** | Record of all complaints by patients and staff about dialyzer failures or possible harmful reactions. Include results from complaints and actions taken to fix a problem. Complaints should be reviewed for trends. |
| **Environmental Testing** | Record of testing required by regulatory agencies on germicides or cleaning agents used in dialyzer reprocessing |
| **Equipment Maintenance** | Log of the dates of preventive maintenance, repairs, and results of scheduled testing on all reprocessing and safety equipment |
| **Incoming Materials Log/ Material Quality Records** | Log of incoming materials such as dialyzers, port caps, disinfectants, other supplies, results of any quality control tests, first-in/first-out inventory control, and expiration dates |
| **Personnel Health Monitoring Records** | Record of staff medical exam results to monitor exposure to substances that may be toxic, as required by regulatory agencies |
| **Training Records** | Record of staff's completion of a training course in dialyzer reprocessing, proven ability to do reuse correctly, and certification by the Medical Director |
| **Quality Assurance and Quality Control** | Record of the dates and results of all quality assurance and quality control evaluations |

**Table 5: Quality Assurance Audit Schedule**

| | Monthly | Quarterly | Semi-annually | Annually |
|---|---|---|---|---|
| Patient information policy (14.3) | | | | ✓ |
| Equipment manuals and procedures (14.4) | | | | ✓ |
| Equipment maintenance and repair policies (14.4) | | | | ✓ |
| Environmental safety (8.1) | | | | ✓ |
| Environmental safety (8.2) | | ✓ | | |
| Environmental safety (8.4) | | ✓ | | |
| Reprocessing supplies (9) | | | ✓ | |
| Water treatment* (11.4.1.5) | ✓ | | | |
| Hemodialyzer labeling (10) | | ✓ | | |
| Reprocessing procedures** (14.8) | ✓ | | ✓ | |
| Procedures for preparation for dialysis (14.9) | | ✓ | | |

*More frequent monitoring may be required at first as described in 11.4.1.5
**These functions may allow for the less frequent review period indicated according to the circumstances specified in their respective sections
(Numbers in parentheses refer to AAMI sections)

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Medical Director. Each must pass a competency review once a year. The clinic should review all procedures and manuals each year *and* any time problems occur that could be due to equipment failure. ANSI/AAMI RD47:2008[17] has details on all parts of a reuse QA program (see Table 5).

QC shows that the materials, processes, and final product meet set standards. QC for reprocessing includes TCV, tests for bacteria and endotoxin, and tests for germicide.

# Conclusion

Dialyzer reprocessing, performed properly, can be safe for patients. However, done incorrectly, it can pose a hazard to patients *and* staff. As a dialysis technician, your role is to follow the clinic's policies and procedures to ensure patient and staff safety.

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