

Reopening Dialysis Clinics

FDA Advice to Follow when Reopening Hemodialysis Clinics after Restoration of Power and Water

This document gives recommendations to follow before reopening dialysis clinics after a period of time without power or water.

NOTE: If you perform dialysis at home, and you have lost power or water, see V. Home Hemodialysis Systems.

Before you reopen your dialysis clinic, check each component using the guidelines in each section below.

- I. Water Treatment Systems
- II. Dialysis Machines
- III. Filters (Dialyzers) and Tubing
- IV. Dialysate and Dialysate Mixing Systems
- V. Home Hemodialysis Systems
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I. Water Treatment Systems

All dialysis units require purified, dialysis-quality water. Most dialysis units use on-site water treatment systems to purify the municipal water supply. Note that the loss of power to a water treatment system is just as serious as the loss of a potable water supply. Both can result in the potential contamination of water.

WARNING! Upon resumption of power and a potable water supply, **DO NOT attempt to use water from your water treatment system for treating dialysis patients until you have fully assessed your water treatment system, replaced any contaminated system components, and disinfected and thoroughly rinsed the entire system.**

Flooded Facilities:

If your facility flooded, even for a short time, the water treatment system and distribution loops may be contaminated. Flooding can lead to electrical shorting of your power supply and loss of power, which compounds the problem.

- **Contact the company that services your water treatment system to determine what you may need to do to make it suitable for use.** For more information and recommendations for facilities that have been flooded, see www.bt.cdc.gov/disasters/floods.

Contaminated Water Supply:

If either your municipal water supply or your water treatment system is or was contaminated, it may be difficult to produce dialysis-quality water. Follow the steps below to determine whether or not you may resume producing water for dialysis.

- **Determine whether or not the municipal water supply meets current EPA standards for drinking (potable) water, taking into account normal local variations.** Do not use your water treatment system until you have a safe supply of water. Contact the municipal water authority to determine the present status of water in your community. You may need to make adjustments to your water treatment system if additional chemicals, such as chlorine or chloramines, have been added by the municipal water authority.

Why? If the municipal water supply does not meet EPA standards, you may not be able to purify it for dialysis and should consider it unsafe. In addition, pollutants or other toxins in the municipal water supply could damage or destroy components of the water treatment system.

- **Under a “boil water” alert, attempt to purify water for dialysis ONLY if you HAVE a working reverse osmosis (RO) system.** For more information about treating water when you are under a “boil water” alert, see http://www.cdc.gov/ncidod/hip/dialysis/boilwater_advisory.htm.

- **Contact the company that services your water treatment system for information on how to flush and test system components.** Do not use the water treatment system until it has been fully assessed, adjustments have been made, and all contaminated components have been replaced. For more information, see <http://www.bt.cdc.gov/disasters/watersystemrepair.asp>.

Why? Bacteria may grow on any component of a water treatment system that has been wet for an extended period of time, particularly if water has not been flowing through the system. Water passing through that component would be contaminated by the bacteria rather than being properly purified.

- **Disinfect the system and rinse system thoroughly.** Make sure to test disinfectant residuals to ensure proper rinsing.
- **Upon resumption of normal operation of the water treatment system, test the water output to make sure it meets AAMI standard RD62:2001 – *Water Treatment Equipment for Hemodialysis Applications*.** Send a sample of product water for a AAMI analysis (chemical analysis, chlorine and chloramines, total microbial count, and endotoxin) as soon as is practical. Store your water samples at 4-6°C and have them analyzed within 24 hours.

Why? AAMI RD62:2001 gives FDA-recognized maximal allowable chemical and microbial levels in water used to prepare dialysate and reprocess dialyzers.

- If possible, test for endotoxin on site before you run patients. While waiting for test results, confirm water quality by monitoring water conductivity frequently.

II. Dialysis Machines

Dialysis machines must be clean, dry, and disinfected prior to use.

WARNING! Do NOT use your dialysis machine if the outside or any internal components are wet, if your facility flooded, or if your facility was exposed to corrosive chemicals or excessive heat (above the limits listed in the manufacturer's specifications).

Flooded Facilities:

If your facility flooded, even for a short time, the dialysis machines may be contaminated.

- **Contact your manufacturer or service company to determine if your dialysis machines are suitable for use.** For more information and recommendations for facilities that have been flooded, see www.bt.cdc.gov/disasters/floods.

Power Loss:

If your clinic lost power, your dialysis machines could be contaminated. Follow the steps below before using your dialysis machines.

- **Check the transducers and the transducer protectors (if present) to make sure they are completely dry and clean.** If they are damp, wet, or dirty, do not use the machine. Do not use the machine until a trained and qualified service technician has replaced the transducer and transducer protector. Contact your manufacturer or service technician if you are not able to do this repair yourself.

Why? If the transducers or internal transducer protectors are damp, wet, or dirty, they will not work properly. This could make the dialysis machine unsafe.

- **Perform all tests and self-checks to verify proper working condition.** If a self-test fails, repair indicated problems, or contact your manufacturer or service company technician to inspect and repair the machine before using it on patients.

Why? If the machines were not shut off properly, or if they were not in operation for an extended period of time, they could malfunction or present an electrical hazard.

- **Disinfect the machines using the most rigorous method of disinfection recommended in the product labeling.**
- **Rinse the systems thoroughly; make sure to test for disinfectant residuals.**
- **Schedule dialysis machines for preventative maintenance as soon as possible, even if returned to patient use, to ensure all aspects of operation are adequate.**

III. Filters (Dialyzers) and Tubing

Hemodialysis systems use disposable dialyzers and tubing. Some dialyzers can be reused for the same patient.

WARNING! Do NOT reuse a dialyzer that is intended for single use. Follow instructions on dialyzer label to determine if it can be reprocessed for reuse.

Flooded Facilities:

If your facility flooded, even for a short time, the seals and packaging on disposable components may be compromised.

- ▶ **Check dialyzer and tubing packages to make sure that the seals and packaging are intact.** If the device packaging is open or wet, do not use the device and discard it.

Why? If there is any water damage or breaks in the package seal, there is a chance that the product is no longer sterile.

Power Loss:

If your clinic lost power, your supplies may be compromised. Follow the steps below to make sure your dialyzers and tubing are safe to use.

- ▶ **Use only new dialyzers and tubing.** Discard any used dialyzers that you reprocessed or dialyzers you refrigerated waiting to be reprocessed before you lost power.

Why? The dialyzers may be contaminated because of loss of refrigeration or elevated room temperatures. Even if you reprocessed the dialyzers before you lost power, the disinfectant solution may have leaked, preventing proper disinfection throughout the storage period.

- ▶ **Follow manufacturer's recommendations for rinsing and priming the dialyzer.**

- ▶ **If your dialyzers are labeled for re-use, check to make sure that you have the facilities and supplies to reprocess or refrigerate them immediately after use.** If you have lost your reprocessing or refrigeration facilities, you should not reuse the dialyzers. Instead, discard the dialyzers after each use.

Why? If you cannot reprocess or refrigerate dialyzers immediately after use, they may become contaminated and unsafe to use.

IV. Dialysate and Dialysate Mixing Systems

Dialysate powder must be kept dry before mixing with purified water.

WARNING! Do NOT use dialysate concentrate that is standing in water, even if the container appears to be sealed, because it is difficult to determine if there has been seepage into the container.

Flooded Facilities:

If your facility flooded, even for a short time, the dialysate may have become wet.

- ▶ **Check your dialysate powder to make sure it is dry.** Do not use concentrate if the packaging is wet.

Power Loss:

If your clinic lost power, your dialysate or dialysate mixing system may have been compromised. Follow the steps below before using your dialysate.

- ▶ **Disinfect the dialysate mixing system and test it for bacterial contamination.** Do not use if the system has been contaminated.
- ▶ **Consider whether the storage temperatures listed on the dialysate packaging have been exceeded.** If so, discard the dialysate.

V. Home Hemodialysis Systems

If you use a home hemodialysis system, and you lost power or water, your dialysis machine may not work properly. Check with your clinic or kidney doctor (nephrologist) if you are unsure about resuming treatment.

WARNING! Do NOT do home dialysis if you are unsure whether or not your water supply is clean or if your dialysis machine was in a room that flooded.

- ▶ **Check your equipment and supplies carefully for water damage or possible contamination.**

Why? Your equipment and supplies may be damaged or contaminated, so it may not be safe for you to use them.

- ▶ **Discard any disposable supplies that have gotten wet or that have breaks in the seals or packaging.**
- ▶ **Disinfect your machine using your normal procedures.**

- ▶ **Run all checks and self-tests. If your dialysis machine passes all tests, it is probably safe for use.** If your machine does not pass one or more self-tests, you should not use it because it may be unsafe or not working properly.

- ▶ **If you need regular dialysis treatments, contact your clinic or kidney doctor (nephrologist) right away.** If you cannot reach your clinic or nephrologist, get to a hospital or another dialysis clinic immediately. Contact the Red Cross (www.redcross.org) (202-303-4498) if you do not know where to go.

VI. Additional Information

Q. Can you use your water treatment system on water that has been trucked in from another location instead of using the municipal water supply?

A. Yes, if the water complies with EPA standards for potable water. For more information on trucked water considerations, see: <http://www.cdc.gov/ncidod/hip/Dialysis/dialysis.htm>.

Q. Can you do dialysis with sterile, bagged dialysate?

A. Yes, if you have a dialysis system that uses sterile bagged dialysate that does not require dilution, and you have all necessary components.

Q. Does FDA need to inspect my dialysis machines before I am ready to restart them?

A. No.

Q. Can you use a reverse osmosis water treatment system that FDA has not cleared for dialysis if that is your only way to get purified water?

A. Yes, if an unapproved reverse osmosis water treatment system is the only device you have available, you may use it to prepare dialysis-quality water. Under Section 561(a) of the Food, Drug, and Cosmetic Act, (21 U.S.C. 360bbb), and FDA's Guidance on Investigational Device Exemption (IDE) Policies and Procedures, devices not yet approved or cleared for marketing may be used in an emergency situation. As with any water treatment system, you must first test the water output to make sure it complies with AAMI RD62:2001.

Within 5 days of using the system or learning of its use, you should send the following information to the FDA address below

- a summary of the conditions constituting the emergency
- the patient protection measures that were followed
- patient outcome information

The Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
IDE Program
9200 Corporate Blvd. (HFZ-403)
Rockville, MD 20850