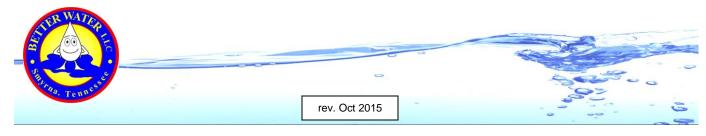
Better Water LLC

Deionization (DI) Tanks for Hemodialysis

Operator Manual





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Visit our website to see our complete product line of water purification products!

www.betterwater.com



Our Company

Better Water LLC is a leading integrated manufacturer of water treatment equipment and components for the industrial, commercial, and institutional markets.



Located in Smyrna, Tennessee, Better Water LLC continues its history of manufacturing and distribution of equipment specifically designed for the renal dialysis market.

Founded in 1971, Better Water LLC has built a reputation for solving our customers' toughest problems with high quality products and unmatched service.

Contact Us

Better Water LLC 698 Swan Dr Smyrna, TN 37167

Phone (615) 355-6063 Fax (615) 355-6065

Technical Support:

Phone (615) 355-6063, press "1" Email <u>support@betterwater.com</u>

Customer Service:

Phone (615) 355-6063, press "3"
Email customerservice@betterwater.com

Technical Phone Support

Support is available regarding all Better Water LLC systems, 24 hours a day, 7 days a week.

 Normal business hours are Monday through Friday from 8:00 am until 3:30 pm, Central Standard Time (excluding holidays)

Call (615) 355-6063, press "1" for Technical Support

Emergency assistance is available after normal business hours (including holidays) by calling (615) 708-8627.

BEFORE calling for emergency assistance:

- Check the Troubleshooting guide in this manual
- Check the electrical-power connections, fuses/circuit breakers (if applicable)
- Check all valves to ensure each is in the correct position (if applicable)

Technical Support Info Online

Our website, **www.betterwater.com**, which is updated frequently, contains a wealth of technical support information on the **SUPPORT** tab and includes:

- Operator and Service Manuals
- Interactive Frequently Asked Questions for Troubleshooting
- Consumables and Accessories Lists
- Technical Service Bulletins



For your convenience there are also online forms for placing **Orders** and requesting **Returned Goods Authorization**. These are Adobe forms that can be downloaded and either faxed or emailed to us.

Deionization (DI) Tanks for Hemodialysis Operator Manual Specific Technical Support Phone (615) 355-6063, option "1" Email support@betterwater.com **Contacts** To Place an Order Fax (615) 355-6065 (purchase orders) Email orders@betterwater.com Phone (615) 355-6063 **Customer Service** Phone (615) 355-6063, option "2" (returns) Fax (615) 355-6065 customerservice@betterwater.com Email Website www.betterwater.com Helpful information and forms that can be found on our website: - Operator & Service Manuals - Technical Service Bulletins

- Consumables and Replacement Parts List
- Brochures
- Order Form
- Return Goods Authorization Request Form

Introduction

This Operator Manual has been developed for the purpose of operating DI Tanks for hemodialysis. Current versions of this Operator Manual as well as other helpful information can be found on our website at www.betterwater.com/support.



WARNINGS



- **1.** It is unsafe to operate or service the Deionization System without first reading and understanding the <u>entire</u> Operator's Manual. Keep this manual and other associated documentation for future reference.
- **2.** Misuse, improper operation, and/or improper monitoring of this system could result in serious injury, death, or other serious reactions to patients undergoing hemodialysis treatment.
- **3.** During DI tank installation and/or replacement, serious injury can occur if the tank(s) are not depressurized, as well as the procedures outlined in this manual are not followed completely.
- **4.** If the DI Tank Fill Port is tampered with or opened while the tank is pressurized (in operation), serious injury can occur.

CAUTIONS



- 1. When used as a medical device, federal law restricts this device to sale by or on the authority of a physician. Per CFR 801.109 (b)(1).
- 2. DI Tanks or Systems will not remove microbiological contaminants (bacteria/endotoxins) from the water.
- **3.** Misuse or improper operation of this device will void any warranty, could result in financial charges if DI tanks damaged, and could result in the water not meeting the AAMI hemodialysis water quality standards.
- 4. Where water is mentioned, unless otherwise noted, it must be AAMI standard quality water.
- **5.** Electrical and plumbing connections must adhere to local statutes and any facility codes. Connect this device to a proper ground connection in accordance with the National Electrical Code. Do not remove the ground wire or ground plug. Do not use an extension cord with this device.
- 6. Do not remove any Caution, Warning, or any other descriptive labels from the device.
- **7.** Do not operate this device in an explosive environment or in the presence of flammable materials. Do not use this device to store, mix, or transfer flammable liquids.
- 8. Movement or vibrations during shipment may cause connections to loosen.
- **9.** Do not operate this unit in an environment where temperatures may be below 50° F or above 90° F.
- **10.** This device should not be used for purposes outside the device's stated applications, specifications, or limitations.

TANK SIZES

There are six primary tank sizes, each of which can be filled with one of three types of resins based on the requirements to produce deionized water. These three resin types are Anion, Cation, or Mixed (cation/anion).

Tank Size (Cubic Foot Capacity) 14" x 47" (3.5 Ft²) 9" x 42" (1.4 Ft²) 8" x 30" (.79 Ft²) 8" x 18" (.47 Ft²) 6" x 18" (.27 Ft²)	(M-5) 355-6043			18	6039
	14"x47"	9"x42"	8"x30"	8"x18"	6"x18"

IMPORTANT INFORMATION FOR SUPPORT

Each DI Tank has been assigned a specific identifying number. This can be found <u>stenciled</u> onto the side of the tank and/or be on an <u>attached tag</u> near the top of the tank. Please have this information available if you contact Better Water concerning issues with a specific tank.



PRODUCT DESCRIPTION

A deionizer (DI) system consists of proper pre-treatment, a minimum of two DI tanks connected in series with an appropriate resistivity alarms. The output water from DI tanks should be further treated with appropriate particulate filtration and microbiological contaminant controls.

DI tanks can last anywhere from a few hours to several months. The time to tank exhaustion is dependent upon the quality of the water entering the tank and the amount of water leaving the tank. DI tanks that polish RO water can produce greater than 1 megohm water for a considerable period of time. DI tanks without RO pre-treatment can exhaust in a very short period of time.

Using DI tanks as a component of a complete water treatment system requires very strict daily monitoring, policies and procedures to be performed by knowledgeable and trained personnel on how to respond when an alarm condition occurs.

The DI product water should be tested periodically for microbiological contaminants (bacteria and endotoxins), and for chemical contaminants, as often as dictated by the medical director and company policies.



RESISTIVITY ALARM

The resistivity alarms will alert when the output (product) water of the DI tank is less than one megohm-cm resistivity.

These have Green and Red Alarm lights as well as an audible alarm.

- A GREEN steady-light indicates the resistivity is greater than one (>1) megohm-cm.
- A **RED** flashing light indicates the resistivity is less than one megohm-cm, and the audible alarm will sound.

The alarm can be temporarily silenced by pressing the Alarm Silence Button. A remote alarm is also available. Once silenced manually, the alarm will not resound until the next Green to Red shift of the alarm lights.

A standard setup would have this resistivity alarm installed on the output (product) side of DI Tank#1.



GENERAL OPERATION

Before you start using this device, operators must read and understand this manual in its entirety. This manual of Operator's Instructions describes in considerable detail all of the steps and procedures required to **safely** operate DI tanks. The DI tanks and resins are of the utmost quality. With adequate pre-treatment, effective post-treatment, proper DI tank installation, monitoring and proper use, the DI tanks will provide you with water for hemodialysis that meets AAMI standards.

It is **unsafe** to operate DI tanks without a basic understanding of water treatment and a thorough understanding of the contents of this manual.

It is **unsafe** to operate this device without a basic understanding of water treatment and a thorough understanding of the contents of this manual. Inadequately treated water for hemodialysis poses a severe threat to the health and safety of hemodialysis patients. Education and training of the staff in these facilities is critical given the technically complex subject of water treatment. Guidelines and other related information are available from:

- Food and Drug Administration (FDA)
- National Association of Nephrology Technicians/Technologists (NANT)
- Association for the Advancement of Medical Instrumentation (AAMI)

Once the DI tanks have been delivered, it is the responsibility of the Medical Director to ensure that they are used, monitored, and maintained in such a manner so as to satisfy all applicable standards.

REPLACING EXHAUSTED DEIONIZATION TANKS

WARNING

Serious injury can occur if this procedure is not performed properly.

For these instructions DI Tank#1 designation is the FIRST of two tanks in series, while DI Tank#2 designation is the SECOND. This procedure assumes DI Tank#1 is exhausted, and details how to move Tank#1 out, move DI Tank#2 to the first position, and replace the second tank with a new tank.

- 1. Verify there is not requirement for treated water for hemodialysis.
- 2. **CLOSE** the **DI Water Inlet Valve** (on post-treatment device).
- 3. OPEN the Sample Port on DI Tank#1 to depressurize the entire deionization system.
- Pressure gauges both pre and post the DI tanks should read zero before proceeding.
- 4. Determine the location of the following DI tanks' ports

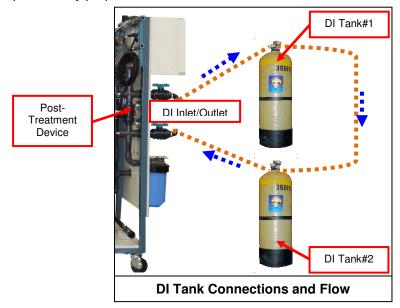
- INLET Water Inlet Port - OUTLET Water Outlet Port

- FILL Fill Port

* WARNING: Under no circumstances should the fill port cap be removed.

- 5. Disconnect the hoses between...
- DI Water Inlet Valve (on post-treatment device) and DI Tank#1 Inlet
- DI Tank#1 Outlet and DI Tank#2 Inlet
- DI Tank#2 Outlet and DI Water Outlet Valve (on post-treatment device)
- 6. Remove the Resistivity Alarm from DI Tank#1.

- 7. Move the DI Tanks as follows:
- Move the exhausted DI Tank#1 out of position
- Move DI Tank#2 to the first position to become DI Tank#1
- Move a new DI Tank#2 into the second position to become DI Tank#2
 - * NOTE: The freshly, regenerated tank must always go into the SECOND position in series to provide the greatest back-up capacity when DI Tank#1 becomes exhausted.
- 8. Remove the Port Caps on the new DI Tank#2's Inlet and Outlet ports and save.
- Reconnect the hoses between...
- DI Water Inlet Valve (on post-treatment device) and DI Tank#1 Inlet
- DI Tank#1 Outlet and DI Tank#2 Inlet
 - * NOTE: It does not matter which end of this "jumper" line goes into DI Tank#1 Outlet as long as the visual resistivity alarm light can be seen.
- DI Tank#2 Outlet and DI Water Outlet Valve (on post-treatment device)
- 10. Install the Resistivity Alarm onto DI Tank#1 Outlet.
- 11. Install the saved Port Caps onto the exhausted tank's Inlet and Outlet ports.
- 12. Stop and verify proper hose connections.



- 13. Remove trapped air in the DI Tanks Connection Loop:
- Partially **OPEN DI Inlet Valve** (on post-treatment device) prior to DI Tank#1.
- Slowly **OPEN** the **Sample Port on DI Tank#2** and allow the water to flow slowly through until no air is detected.
- Once no air is detected, fully **OPEN** the **DI Inlet Valve** (on post-treatment device).
- 14. Check for leaks.

The DI Tanks are now installed and free of trapped air. The following steps are required to insure the Outlet (product) water has a resistivity greater than one (>1) megohm-cm. Freshly regenerated DI tanks must be "pumped-up" to reach full capacity. This is accomplished by allowing output (product) water to drain until the resistivity alarm light changes from red to green.

- 15. Check the resistivity alarm on DI Tank#1 Outlet. This light should be GREEN.
- If it is **RED**, open the Sample Port on DI Tank#2 and allow the water to flow to drain until the light turns **GREEN**.

The DI tanks are now installed, free of trapped air, and producing water with a resistivity greater than one (>1) megohm-cm. It is highly recommended that the following be performed:

- a. Collect a water sample from the DI Tank#2 Outlet and test for microbiological contaminants (bacteria and endotoxins) to insure the water quality meets the AAMI standard for water used for hemodialysis.
- b. Collect a water sample from the DI Tank#2 Outlet and test for chemical contaminants to insure the water quality meets the AAMI standard for water used for hemodialysis.
- c. An accurate record should be maintained on all tank exchanges which should include the following:
 - Vendor (tank provider) information
 - DI tank serial numbers
 - Date DI tank received
 - The DI tank resistivity rating, noted on the vendor's quality label
 - Date/time the DI tank was installed into the system
 - Water quality assurance data at the conclusion of the tank exchange
 - Identification of who performed the tank exchange
 - Date DI tank returned to vendor

MONITORING DEIONIZATION (DI) TANKS

This is a mandatory procedure that must be performed by trained personnel who fully understand the water treatment system and actions required when tank exhaustion occurs. This procedure does not replace any requirement to monitor other components and/or devices used in the water treatment system for pre-treatment, chlorine/chloramines removal, and controlling microbiological contaminants.

Water must be flowing through the water treatment system for the quality monitoring devices to work properly.

WARNING

Failure to properly monitor the Deionization System could result in serious injury, death or other serious reactions to hemodialysis patients.

WARNING

If the resistivity alarm on either DI Tank alerts, IMMEDIATELY DISCONTINUE ALL HEMODIALYSIS TREATMENTS using water from this Deionization System.

- 1. Daily and before each hemodialysis treatment or shift of treatments and with water flowing through the water treatment system, check the resistivity alarms on the output of each of the DI tanks.
- If no problems, the light should be GREEN and no audible alarm sounding.

NOTE: If the resistivity alarm light on DI Tank#1 is RED and the resistivity alarm light on DI Tank#2 is GREEN, the Output (product) water is great than one (>1) megohm-cm and considered to be safe for hemodialysis. However, if DI Tank#1 is exhausted, the time remaining before DI Tank#2 becomes exhausted is unknown but nearing and requires close monitoring. DI Tank#1 should be replaced before DI Tank#2 becomes exhausted.

- 2. If the water treatment system has a Resistivity Meter, the resistivity must be great than on (>1) megohm-cm and there must be no alarm warnings.
- 3. Record the data including date/time checked, results, and identification of who performed the quality assurance checks.

STORAGE of DEIONIZATION (DI) TANKS

During the regeneration process, Better Water LLC disinfects the DI tanks, and they are delivered with dry resin.

When new DI tanks are stored for immediate back-up for the water-treatment system, they...

- ... must be stored dry
- ... cannot be stored for longer than 90 days from the date of delivery
- ... should not be exposed to temperatures below 35 °F or above 110 °F.

NOTE

Deionization tanks should never be stored after the resin has been wetted, or after any temporary use, but should be returned for regeneration.

LIMITED WARRANTY TERMS and CONDITIONS

- a. This limited warranty is given only to the original buyer and covers the equipment delivered with this limited warranty.
- b. The buyer shall be barred from any recovery on this limited warranty or otherwise for damages due in whole or in part to...
 - ... unreasonable use
 - ... improper operation
 - ... use beyond normal fashion
 - ... failure to follow instructions
 - ... failure to maintain the product in good condition and repair
 - ... or the like.
- c. If the buyer discovers or should have discovered a defect in which it is reasonable to conclude that damage, either personal, property, or economic, may result, the buyer's continued use of the product shall constitute any assumption of risk by the buyer and a bar to any recovery for breach of this limited warranty or otherwise.
- d. No oral or written representation, information, or advice given by Better Water LLC or any of its representatives shall create a warranty or in any way increase the scope of this express limited warranty and shall not form a part of the basis for bargain.

WHAT IS WARRANTED AND FOR HOW LONG?

- a. All equipment, excluding ion exchange and filtration media and cartridges, are warranted to be free from factory defects in materials, and workmanship under normal use for a period of one (1) year from the date of shipment.
- b. It is a condition precedent to recovery on this limited warranty that the buyer strictly comply with all operating and maintenance guidelines established by Better Water LLC and that the serial number (*if applicable*) is intact and legible on the equipment.
- c. It is a condition precedent to recovery on this limited warranty for damage to the external finish of the equipment that the buyer notifies Better Water LLC at the time of the installation that the finish is damaged.

WHAT IS REMEDY FOR BREACH OF THIS LIMITED WARRANTY or NEGLIGENCE BY BETTER WATER LLC

- a. Buyer's sole and exclusive remedy for any breach of this limited warranty or negligence by Better Water LLC shall be repair or replacement of the defective part, at the option of Better Water LLC, provided such defective part is returned to Better Water LLC for inspection.
- b. Better Water LLC shall not be obligated to supply an exact replacement of the defective part and reserves the right to substitute new and improved parts.
- c. Better Water LLC shall provide at no cost to buyer, labor to remove and/or replace defective parts covered by this limited warranty for a period of ninety (90) days from the date of installation by Better Water LLC of the equipment.
- d. After such ninety (90) day period, buyer shall be responsible for any labor or service charge for the removal and/or replacement of any defective parts.
- e. Buyer shall be responsible for all travel expenses and freight charges at all times.
- f. Better Water LLC shall have no obligation to repair or replace any defective part if buyer fails to follow the procedure set forth in "HOW TO OBTAIN A REPLACEMENT PART UNDER LIMITED WARRANTY".

IN NO EVENT SHALL THIS LIMITED WARRANTY BE CONSTRUED TO COVER, NOR SHALL BETTER WATER LLC BE LIABLE TO BUYER AS ANY OTHER PERSON FOR, ANY CONSEQUENTIAL, INCEDENTAL, ECONOMIC, DIRECT, INDIRECT, GENERAL OR SPECIAL DAMAGES, WHICH ARE HEREBY EXPRESSLY DISCLAIMED.

HOW TO OBTAIN A REPLACEMENT PART UNDER LIMITED WARRANTY

- a. Buyer should contact the Customer Service or Technical Support Departments and request a Return Goods Authorization.
- b. Described part(s) will be sent with a purchase order.
- c. The returned part(s) will be returned to the factory for limited warranty consideration. If part(s) are not covered under the limited warranty, part(s) will be considered billable against the purchase order supplied.

WHAT IS NOT COVERED BY THIS LIMITED WARRANTY:

By way of example and not limitation, this limited warranty does not cover:

- Damage to or replacement of any ion exchange resin of filter media
- Labor or service charges for the removal and/or replacement of any defective parts after the ninety (90) day period from the date of installation or sale by Better Water LLC
- · Freight charges and travel expenses
- Damage from inadequate or defective wiring, improper voltage, improper connections or electrical service, inadequate or defective plumbing, water supply, or water pressure, or in violation of applicable building, plumbing or electrical codes, laws, ordinances or regulations.
- Damage from improper installation or operation, including but not limited to, abuse, accident, neglect, improper maintenance, freezing and fires, or abnormal use.
- Damage caused by contaminants in Buyer's water supply, including hardness, chlorine, chloramines, sulfur, bacterial iron, tannin, algae, oil, organic matter or other unusual substances, if special equipment has not been installed by Better Water LLC to remove such contaminants
- Damage to or caused by filters/membranes or other replacement parts not purchased from Better Water LLC or damage caused by modification, alteration, repair or service of the equipment or any of its parts by anyone other than Better Water LLC or its expressly authorized representatives.

