

2008T BlueStar™ Hemodialysis Machine

Training Guide



Indication for Use:

2008T BlueStar Hemodialysis Machine: The 2008T BlueStar Hemodialysis Machine is indicated for acute and chronic dialysis therapy in a healthcare facility.

Additional therapy options for patients receiving hemodialysis include: Isolated Ultrafiltration, Sustained Low Efficiency Dialysis (SLED), and low volume hemodialysis (patients weighing \geq 20kg and \leq 40 kg). This machine accommodates the use of both low flux and high flux dialyzers. The SLED therapy option is not to be used for patients weighing \leq 40 kg. The 2008T BlueStar Hemodialysis Machine is not to be used for plasma replacement therapies, for patients weighing less than 20 kg, or for renal therapies using substitution fluid.

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

Note: Read the Instructions for Use for safe and proper use of this device. For a complete description of hazards, contraindications, side effects and precautions, see full package labeling at fmcna.com.



2008T BlueStar Hemodialysis Machine Training Guide

The 2008T BlueStar[™] Hemodialysis Machine Training Guide is designed for the training of skilled hemodialysis nurses and technical assistants in the use of the machine. Use this guide as a companion to the 2008T Hemodialysis Machine Operator's Manual, which contains detailed instructions for all machine functions, and the 2008T Hemodialysis Machine Quick Start Guide.

This Training Guide covers the basic instruction topics for the 2008T BlueStar Hemodialysis Machine. It is not intended to compromise or replace specific policies and procedures of individual hemodialysis providers. Fresenius Renal Technologies and its affiliates make no recommendations and assume no liability for the policies and procedures established in hemodialysis provider's clinics.

The guide is designed to be flexible. While approximate timeframes for training sessions are given, the actual time commitment required will depend on the size of the group and the prior experience of participants.

Similarly, the guide suggests topics where hands-on exercises will enhance your participant's experience. These demonstrations may occur at many different times during your facility's training, with the time and location dependent on the individual unit. We encourage you to tailor these hands-on experiences to the needs of the group and to pace the sessions accordingly.

In addition to this Training Guide, the following materials are integral to training in the proper use of the 2008T BlueStar Hemodialysis Machine:

- 2008T Hemodialysis Machine Operator's Manual (P/N 490122)
- 2008T Hemodialysis Machine Quick Start Guide (P/N 490161)
- 2008T Operator's Troubleshooting Guide with bibag (P/N 102297-01)
- 2008T BlueStar Hemodialysis Machine Participant Workbook (P/N 103324-01)

Icons and Descriptions:

The following icons are used within this Training Guide to provide direction and clarity:

Icons and Descriptions				
1	Trainer explanation and demonstration			
i	Facilitation tip and supplemental comments			
	Participant hands-on practice recommended			
	Information found in the <i>Quick Start Guide</i>			
T	Features unique to the 2008T BlueStar Hemodialysis Machine			

Training Timeline

3-4 weeks prior to training:

- Determine the number of participants.
- Order training supplies to be shipped directly to facility (2008T BlueStar Machine Getting Started Training Kit).

2 weeks prior to training:

• Confirm dialysis supplies are on hand or have been ordered.

1 week prior to training:

- · Ensure machines have arrived and are installed.
- Ensure cultures have been drawn.
- Ensure dialysis supplies are in the unit.
- · Confirm receipt of the training materials.

2008T BlueStar Machine Getting Started Training Kit, includes:

- 2008T Hemodialysis Machine Operator's Manual (P/N 490122)
- 2008T BlueStar Hemodialysis Machine Training Guide (P/N 103323-01)
- 2008T Hemodialysis Machine Quick Start Guide (P/N 490161), (one per participant)
- 2008T BlueStar Hemodialysis Machine Participant Workbook (P/N 103324-01), (one per participant)
- 2008T Operator's Troubleshooting Guide (P/N 102297-01)
- 2008T BlueStar In-Service Checklist (P/N 103322-01)



Training Topics and Agenda

	training time (minutes)
 Welcome/Getting Started Participant Workbook Distribution and Introduction 2008T Hemodialysis Machine Operator's Manual Introduction 2008T Hemodialysis Machine Quick Start Guide Introduction 	5
Review 2008T BlueStar Hemodialysis Machine • Review Key Machine Features	10-15
Demonstrate Daily Preparation for Treatment • Set Up Concentrate	45
Set Up the Bloodline	
 Prime the Extracorporeal Circuit, Manual, or Auto Prime 	
Test the 2008T BlueStar Hemodialysis Machine	
Recirculation	
Manual or Auto Prime	
Manual or Auto Start	
Review Screens	
Review Initiation of Treatment	10
Alarms and Troubleshooting Activity	15
Review Termination of Treatment	
Manual or Assisted Reinfusion	
Disinfection and Maintenance	10-15
Acid Clean and Heat Disinfect	
Acid Clean and Chemical Rinse	
DIASAFE® Plus Filter Replacement	
Manual or Assisted Reinfusion	
Appendix	

- HD Equipment and MIS Support
- In-Service Evaluation

Getting Started



Welcome Participants

Have all of your registered participants sign the In-Service Attendance Sheet. Solicit the cooperation of the group to ensure a good learning experience.

Set expectations:

- · No cell phone usage, including text messaging.
- Show respect for other participants.
- Share all comments and questions with the room. (i.e., no side conversations)
- Consider using a "parking lot" for questions, particularly if the group is large.

Distribute and introduce the 2008T BlueStar Hemodialysis Machine Participant Workbook (P/N 103324-01)

- Give participants a few minutes to familiarize themselves with the workbook. Encourage participants to take notes for future reference after the training.
- Introduce the In-Service Checklist, on page 4 of the Participant Workbook, and encourage participants to check topics off as they are covered during the training. Individual facilities may want to keep a copy of the Checklist in the employee's file.

Introduce the 2008T Hemodialysis Machine Operator's Manual (P/N 490122)

- Point out the Alarms/Troubleshooting Section and Glossary for future reference.
- Remind participants that the Operator's Manual is the most comprehensive reference guide for the 2008T BlueStar Machine.

Distribute a 2008T Hemodialysis Machine Quick Start Guide (P/N 490161) to each participant

- Share that many of the key demonstrations during this training are detailed in the Quick Start Guide (QSG); it is designed to be a ready job aid, but does not substitute for the Operator's Manual.
- Suggest that participants keep the QSG handy for easy reference as they become familiar with the 2008T BlueStar Hemodialysis Machine.

Notes:			



Review 2008T BlueStar Hemodialysis Machine



Review the physical features of the 2008T BlueStar machine, being sure to point out specific features as detailed below:

Back of the machine:

- Power switch
- Heater switch
- 9-volt battery
- USB
- RS232 port

- Incoming water line
- Drain line
- Fresh dialysate line
- Spent dialysate line
- DIASAFE® Plus filter/cover

Right side of the machine:

- · Adjustable IV pole height
- Priming bucket with line guides
- Shunt interlock
- · Cap holder
- PatientCard Reader
- Incoming dialysate line (BLUE): Sample port and flow meter
- Outgoing dialysate line (RED)
- Brake pedal

Left side of machine:

Blood pressure cuff basket

Front of machine:

- Display screen
- Status indicator light: Green normal; Yellow warning; Red alarm
- Control Panel Keys: Power; Mute; Reset; Stat Deflate; New Treatment Prime. UF On/Off

Note: Be sure to reinforce the proper sequence for pressing Control Panel keys, refer to the Overview and Setting Parameters sections of the Operator's Manual.

- Touchpad: Confirm; Escape
- Keyboard: Key placement; 10-key panel; Toggle switch for CDX Module
- Modules: Arterial Chamber Holder; Line Guides; Blood Pump; Speed Arrows; Blood Flow Rate (BFR) Display; Pump Segment Settings; Aterial TP Port; Heparin Pump; Air Foam Detector: Air Sensor Heads, Venous Line Clamp, Optical Detector, Line Guides, Venous TP Port.
- Acid connector: O-ring
- Bicarb connector: O-ring
- Ultrafiltration: Fluid sample port



• Encourage participants to take notes on the diagrams contained in the *Participant Workbook*.

Notes:	



Daily Preparation for Treatment

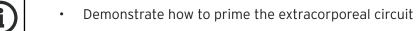


Refer participants to the detailed instructions found in the Quick Start Guide (QSG). The QSG will be a good resource for participants following the training, so encourage participants to watch the demonstration and use their Participant Workbook to take any additional notes.



Using the Step-by-Step Instructions Found in the Quick Start Guide:

- Demonstrate how to set up the concentrate
- Demonstrate how to set up the bloodline
 - o Proper loading and unloading of the blood pump segment
 - o Verify blood pump segment millimeter size



- o Manual or Auto Prime
- o Remind participants to ensure all air is out of the blood pump segment prior to connecting the arterial line to the dialyzer
- Demonstrate how to test the machine
 - o Manual or Auto Start
 - o Remind participants of the criteria for testing: TPs off the machine, stable conductivity, dialysate connector on machine, and no alarms
- Demonstrate the recirculation procedure

	 Return demonstration is recommended for each of the above steps, depending on the level of experience of the participants. Return demonstrations may be done in either the training area or the treatment setting, at the discretion of the unit.
i	Point out topics in the Quick Start Guide to encourage participants to become familiar with using the it as a reference.
Notes:	

Review Screens



Review each screen, providing appropriate detail regarding the selections and actions that are available for each screen.

Select Program Screen

- Dialysis
- Rinse
- Acid Clean
- Heat Disinfect
- Chemical Rinse

- Chemical Dwell
- Last Disinfection Cycle and Time
- Software Version
- SLED
- Disinfect Log

- Serial Number
- Apps Installed
- Hour Meter
- PM Due
- DIASAFE Plus
 Maintenance Due

Dialysate Screen

- Changing Concentrate
- Na+ Level
- Bicarb Level
- Acid/Bicarb Alert
- Alarm Width

- Alarm Position
- Lock/Unlock
- Actual vs. Theoretical Conductivity (TCD)
- Granuflo® Option
- Citrasate Option

Home Screen

- Arterial Pressure Display
- Venous Pressure Display
- TMP Display
- Treatment Clock
- BFR
- Ultrafiltration (UF) Goal
- UF Time

- UF Rate
- UF Removed
- UF Profiles: 1-8
- Dialysate Flow: Auto Flow (All 3) Idle Mode, Sequential
- Temperature
- Conductivity

- Remaining Time of Dialysis (RTD)
- Alarm Volume Control
- Sodium Variation System (SVS) Profiles:

Step, Linear, Exponential, None, Starting Na+, Ending Na+, SVS Time

Trends Screen

- Arterial, Venous, and TMP Readings
- Adequacy Monitoring
- SVS/Ultrafiltration Graphics

- Blood Pressure Graphic
- Current vs. Previous
- Patient Data

Test/Options Screen

- Test: Both Test
- Alarm Test (including 9V battery)
- Pressure Test
- DIASAFE Plus Test
- Time Stamp
- Names of Tests Blue vs. Red "x" as Test Completes
- Independent Conductivity

• Options:

Patient ID Recirculate

High Flux Single Needle Recirculate

Arterial Alarm Limits

Venous Alarm Limits

(Locked vs.

Changeable Limits)
Verify Crit-Line
Low Volume
Auto Prime

Assisted Reinfusion



Review Screens (continued)



Heparin Screen

- Syringe Type
- Hourly Rate Infusion Time
- Total Infusion
- Bolus Amount
- Infuse Bolus

- Heparin Prime
- Load Syringe
- Heparin Dwell (if Selected)

Delivered (sp Kt/V)

• Delivered (E Kt/V)

Delivered Kt/V

· Access Flow

Kt/V/AF Screen

- Online Clearance (OLC) Volume OLC Data Sub-screen:
- Number of Tests
- Blood Volume Processed (BVP)
- Target Kt/V
- Delivered Kt/V
- Projected Kt/V
- Red vs. Blue Line

- Volume
- Actual Time
- Plasma Na+
- Yes/No
- BVP
- Target Kt/V
- Graphic Display:
 - Clearance Effective of Conductivity (Kecn) Table and notations when tests are completed (M=Manual, AF=Access Flow, Nothing=Machine automatically generated test)

Blood Volume Monitor (BVM)/Blood Temperature Monitor (BTM) Screen

• BVM: Relative Blood Volume • BTM: Thermal Energy vs. Temperature Control

(RBV), Arrow Direction Relative Hemoglobin

(Hgb)/Hematocrit (Hct) Alert Level, Graphic Display

Biofeedback

Recirculation Value **Graphic Display**

Crit-Line®

- Elapsed Time
- Initial Hct
- Estimated Hgb
- Profile; Letter
- Current Hct
- Current Hgb

- · Blood Volume %
- Oxygen Saturation
- Oxygen Minimum Saturation
- Treatment Clock; BV Alert Level
- O₂ Alert Level
- Print/Markers Button

- BV Graph
- 0₂/BP Graph
- Home Screen
- Treatment Information

Blood Pressure Screen

• Systolic, Diastolic, Pulse Upper and Lower Limits

Inflation Pressure Setting

- Clock/Interval Setting
- Machine Time Setting/Change
- Graphic Display During Treatment
- Treatment Start Time

Time permitting, ask participants to demonstrate entering treatment parameters and confirming settings after the training is complete. Otherwise, this can be done in the treatment area.



Many of these screens may be discussed during the Daily Preparation for Treatment, depending on the trainer. Ensure that all screens have been covered during the In-service.

Initiation of Treatment



• Using the step-by-step instructions found in the Quick Start Guide (Starting Dialysis), review the procedure for initiating dialysis treatment.



• Return demonstration may be conducted after the initial In-service or in the treatment area during first initiation. All return demonstrations conducted in the treatment area require close supervision.



• Time permitting, ask participants to review their facility's Policy and Procedures before reviewing the steps for initiating treatment

Notes:	



Review Alarms: Troubleshooting Activity



Since it is often difficult to simulate alarms and troubleshooting during a demonstration, the following activity has been designed to engage participants in a discussion of alarms. It also helps to reinforce the use of the Troubleshooting Guide and the Operator's Manual to troubleshoot common issues that may occur during treatment.

- Review the reset button; Demonstrate how to reset or hold to completely clear an alarm.
- Introduce the 2008T Troubleshooting Guide and briefly review the topics.
- Run Troubleshooting Activity:
 - o Distribute the guide to the participants. Each participant may have several guides, depending on the size of the group.
 - o Call out an alarm and ask the participant with the guide that matches that alarm to read the information on the guide for the group.
 - o Check to ensure that the answer was clear before moving on to the next alarm.
 - o Address 4-5 key alarms in the same manner, and cover at least one:
 - Blood-related alarm
 - Dialysate-related alarm
 - Warning message
- To close the activity, reinforce that the *Troubleshooting Guide* is designed to be a quick reference, but the Operator's Manual is the most comprehensive resource for troubleshooting.



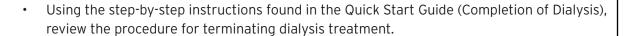
- Collect the Troubleshooting Guide and leave it with the unit.
- Continue working with alarms and Troubleshooting Guide in treatment area as alarms are encountered (i.e., during return demonstrations).



- This is an excellent opportunity to engage participants; try to select alarms to troubleshoot such that several participants have an opportunity to share with the group.
- Leave the Troubleshooting Guide with the unit. If a facility would like additional sets, they may be ordered through the parts department, or the original guide may be copied and laminated by the unit.

Termination of Treatment







· Manual or Assisted Reinfusion procedure



• Return demonstration may be conducted after the initial In-service or in the treatment area during the first termination. All return demonstrations conducted in the treatment area require close supervision.



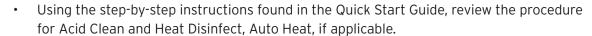
• Time permitting, ask participants to review the facility Policy and Procedures before reviewing the steps for terminating treatment.

Notes:	



Disinfection and Maintenance







o Acid clean is only recommended when closing down the machine for the day. It does not need to be done when bleaching in between patients.



o Acid clean does not need to occur if bicarbonate was not introduced into the machine. Performing Heat Disinfect and/or Chemical Rinse on spare machines or machines not used, is all that is recommended.



- Using the step-by-step instructions found in the Quick Start Guide, review the procedure for Acid Clean and Chemical Rinse (bleach).
 - o Introduce DIASAFE Plus Filter testing.
- DIASAFE Plus filter replacement
 - Determine appropriate unit personnel with responsibility for changing filter, DIASAFE Plus Maintenance Reminder, maintenance interval, and DIASAFE Plus reset.
 - o Demonstrate removing and replacing the filter per the Operator's Manual.
 - The filter should be disposed of per the unit's policy.
 - Heat Disinfect should be run after replacing the filter to disinfect the machine.
 - o Demonstrate testing the DIASAFE Plus filter.
 - Note: The DIASAFE Plus filter test shows a red "X" when setting up the machine, the operator should perform a test before moving forward to ensure that the filter is functioning.
 - Remind participants that machines should never be used for patients if there are red "X"'s in the test and option screen.



• Return demonstration is recommended either at the end of the In-Service, or in the treatment area at the end of the day.



• Because responsibility for cleaning and maintenance varies by facility, be sure to check with each unit to determine appropriate personnel to train, as well as policies and procedures.

Wrapping Up: CSS



- Ask participants to complete the In-Service Evaluation, located in the Participant Workbook.
 - o Completing the evaluation is optional.
 - o Provide the fax number of your manager so that participants can return the evaluation directly. A blank space is provided on the form for the fax number.
 - o If the form is returned to the trainer, review and distribute it internally as directed by your manager.
- Complete the *In-Service Training Checklist*, sign, and return to the facility contact.
- Conduct return demonstrations per training arrangements with the facility.
- · Conduct an exit interview with facility manager.
 - o Determine if any additional follow up and support is needed for the unit, place on the call list as needed.
 - o Explain to staff what to expect during follow up calls and record any additional information.
- Reinforce 24 hour, 7 days per week technical and clinical support at 800-227-2572.
 - o Direct participants to the support info, located on page 17 in the *Participant Workbook*.

Notes:			



2008T BlueStar Hemodialysis Machine In-Service Training Checklist



Facility:		Date of In-Service Training:	
Address:			_ Contact:
City:	State:	Zip:	Phone:
Presented by:			. RN

Training Topics

Topics may be modified to accommodate the specific policies and procedures of the unit being trained. Check marks indicate topics reviewed during the In-Service training; no representation is made regarding the participant competence or expertise.

Training Topics	1
1, 2008T BlueStar Features	√
Familiarize Physical Features	
Review of Screen Attributes	
Review of Alarms/Troubleshooting	
Disinfection & Maintenance	
Auto Start/Testing	
Sustained Low Efficiency Dialysis (SLED)	
Low Volume Mode	
Disinfect Log	
Auto Prime	
 Assisted Reinfusion 	
 Independent Conductivity/pH Testing 	
PatientCard System	
 Entering Patient Information 	
– Default Parameters	
– Dialysate/Heparin/BP/UF Settings	
– Prescription	
Alarm Volume Controls	
Select Program Screen Changes	
- DIASAFE® Plus Reminder	
- PM Reminder	
- Digital Hour Meter	
- Digital Serial Number	
New Heparin Syringe Choices	
Conductivity Alarm Position Lock (if clinic is using)	
New Treatment Prescription Warnings	

	1
 Low Power Mode 	
 Idle Mode Option of 100 mL/min. Dialysate Rate 	
 New 150 mL/min. Dialysate Rate 	
 Isolated UF 	
 Alarm Volume Control, includes: Difference Between Low and High Priority Sounds, Acute vs. Standard (Chronic), How to Adjust Volume, Mute Symbol, and Volume Control Limits. 	
2. Service Mode Options	
 Default Dialysate Flow 500/600/700/800 mL/min. 	
Plasma Sodium — Hide/Show	
 Sodium Variation System (SVS) On — Yes/No 	
Idle Mode Dialysate Flow Rate — 100/300 mL/min.	
 Conductivity Alarm Position — Lock/Unlock 	
New Treatment Prescription Warning	
Default Rx Screen	
 Low Volume Max UF Rate — 500 – 1,000 mL 	
Maximum UF Per Treatment vs. Per Hour	
 Alarm Type — Acute/Chronic 	
 Maintenance Scheduler Options 	

2008T BlueStar In-Service Checklist: P/N 103322-01 Rev A 05/2018

2008T BlueStar Hemodialysis In-Service Sign In



Print Name	Signature	Title







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