2008T BlueStar™ Software Update With Cybersecurity

2008T Hemodialysis Machine
to
2008T BlueStar Standard Software

Part Number 490443 Rev A

If there are any questions regarding these instructions, contact Fresenius Medical Care Technical Support at 800-227-2572.

PURPOSE:

The purpose of these instructions is to outline the process of updating a 2008T Hemodialysis machine to 2008T BlueStar software using a USB flash drive.

SCOPE:

The 2008T BlueStar Functional board software requires a two-step update process that is different from the past Functional board software updates. **During the first Functional board software update, a temporary software version will be installed, which will be a version that is different than noted on the Flash Drive label.** Once the temporary software is installed, the machine will be restarted. The Functional board software update will need to be performed again and the second installation will install the new Functional board software. Once Functional board has been updated, the Actuator-Test and UI-MICS board software can be updated. **The process of updating the Actuator-Test and UI-MICS board software has not changed.**

NOTE: The Low Volume feature included in the 2008T BlueStar software will not work with machines equipped with a SunTech Blood Pressure Module. This module will need to be replaced by contacting the Fresenius Medical Care Technical Services at 800-227-2572.

NOTE: After updating to 2008T BlueStar software, the first heat disinfection may take longer than normal. Do not interrupt the heat disinfection process. Subsequent heat disinfections will complete in a more typical time.

NOTE: **Before starting this update process, review the 2008T BlueStar Service Mode & Cybersecurity (P/N 490437) document included in the kit.**
2008T BlueStar Functional Board Software version 2.84 introduces Cybersecurity protection to Service Mode. Once the Functional board software is installed, login credentials are required to enter Service Mode. Be prepared to set up the Cybersecurity login credentials in order to complete this update process.

REFERENCE DOCUMENT:

- 2008T Hemodialysis Machine Operator's Manual – P/N 490122*

- 2008T Calibration Procedures – P/N 508032*

- 2008T BlueStar Service Mode & Cybersecurity - 490437* (included in kit)

*Electronic version available at: www.fmcna.com/frtmanuals

EQUIPMENT NEEDED:

- 2008T Software Update Flash Drive

  Note: The 2008T BlueStar Software Upgrade Flash Drive contains an update to 2008T BlueStar Functional, Actuator-Test and UI-MICS board software. Refer to the label attached to the Flash Drive for software versions and CRC values.

- Mesa 90XL Dialysate Meter (With Conductivity/Temperature Module)

- Mesa Serial Cable – P/N 368402-10

- Null Modem – P/N 190323

2008T BLUESTAR SOFTWARE UPDATE WITH CYBERSECURITY

PROCEDURES:

Important Note: Always update the Functional board software first.
The 2008T BlueStar Software Update Flash Drive contains a matched set of software which includes the Functional, Actuator-Test and UI-MICS board software.

Temporary Software Installation

1. Power on the machine and put it into Service Mode.

NOTE: The machine is placed into Service Mode by turning the machine power on and waiting for the message Press CONFIRM for Service Mode to appear. Once it appears, press the CONFIRM key and the message will change to Machine in Service Mode. After the System Initializing process is complete, the machine will be in Service Mode.

2. Plug in the 2008T Software Update Flash Drive into the USB port located on the right-hand side of the display/fascia assembly. The port is covered by a protective flap.

3. On the Service Mode screen, press the Update Software screen button and the screen will change.

NOTE: Even though the temporary software installation is the first part of the Functional board software update, the Functional Board button will be used in the next step.

4. On the new screen, press the Functional Board button and the screen will change.

5. Press the Start Update button on the new screen and then press the CONFIRM key. The process of analyzing the old and new software versions will start.

NOTE: **The displayed new CRC value and software version is for the temporary software not the Functional Board software. The new CRC value and software version shown will not match the Functional Board CRC or software version on the Flash Drive and will be lower than the current Functional Board software version.**

6. Press the CONFIRM key to install the temporary software.

7. After the machine displays "FLASH PROGRAMMED SUCCESSFUL" turn the power off.

NOTE: Leave the Flash Drive plugged into the USB port so the Software Update process can be completed in the next section.

Functional Board Software Update

8. Power the machine back on and the machine will automatically enter Service Mode.

9. On the Service Mode screen, press the Update Software screen button and the screen will change.

NOTE: Now that the temporary software has been installed, the next step will update the Functional board software using the Functional Board button in the next step.

10. On the new screen, press the Functional Board button again and the screen will change.

NOTE: This time the Functional board software will be updated.

11. Press the Start Update button on the new screen and then press the CONFIRM key. The process of analyzing the old and new software versions will start.

12. When the analysis process finishes, the current and new software versions along with their CRC values will be displayed.

13. Verify that the new Functional board software version is the desired version <u>and</u> the CRC value for the new software matches the software versions CRC value on the Flash Drive label.

NOTE: If the new version does not match the desired version <u>or</u> the CRC values do not match, **<u>DO NOT</u>** press the CONFIRM key. Power down the machine and locate the desired version or non-corrupted file, then start over at step 8.

14. If the new Functional software is the correct version and the CRC values match, press the CONFIRM key to start the software update.

15. After the machine displays "FLASH PROGRAMMED SUCCESSFUL" turn the power off.

Actuator-Test and UI-MICS board Software Update

NOTE: Since Functional Board Software version 2.84 introduces Cybersecurity protection to Service Mode, **the next step will require setting up Cybersecurity credentials**. Once the credentials have been created, Service Mode can be logged into and the Actuator-Test and UI-MICS board software can be updated. Refer to the 2008T BlueStar Service Mode & Cybersecurity (P/N 490437) document included in the kit for further details.

16. Power on the machine and log into Service Mode.

17. On the Service Mode screen, press the Update Software screen button and the screen will change.

NOTE: The Actuator-Test and UI-MICS board software still needs to be updated. After each board software update, the machine must be powered down and then powered back on.

18. On the new screen, press the correct button for the board software being updated and the screen will change.

19. Press the Start Update button on the new screen and then press the CONFIRM key. The process of analyzing the old and new software versions will start.

20. When the analysis process finishes, the current and new software versions along with their CRC values will be displayed.

21. Verify that the new software version is the desired version <u>and</u> the CRC value for the new software matches the software versions CRC value on the Flash Drive label.

NOTE: If the new version does not match the desired version <u>or</u> the CRC values do not match, **<u>DO NOT</u>** press the CONFIRM key. Power down the machine and locate the desired version or non-corrupted file, then start over at step 16.

22. If the new software is the correct version and the CRC values match, press the CONFIRM key to start the software update. If the current software and new software versions and CRC values match, this software update can be skipped.

23. After the machine displays "FLASH PROGRAMMED SUCCESSFUL" turn the power off.

Mandatory Time and Date Setting

24. Power the machine on and log into Service Mode. Follow the "Set Clock" section of the 2008T Calibration Procedures (P/N 508032) to set the Time Zone and Daylight Savings settings on the Set Time and Date screen.

25. **Important Step; Do Not Skip**
    Due to the software upgrade process, the time **must be** changed and then the CONFIRM key pressed even if the time is correct. Once the new time has been set, it can now be set back to the correct time.

Power Off After Heat Disinfection Setting

2008T BlueStar software has moved the Off after Heat Disinfection option from the Default Settings screen to the new Scheduler screen in Service Mode. The 2008T BlueStar software update sets this option to No. If needed, follow the next steps to set this option to Yes. If not, proceed to the CDX Option Setting section.

26. While still in Service Mode, locate the new Scheduler screen. On this screen, locate the Auto Heat Disinfect screen.

27. On the Auto Heat Disinfect screen locate the Off after Heat Disin button (see Figure 1).
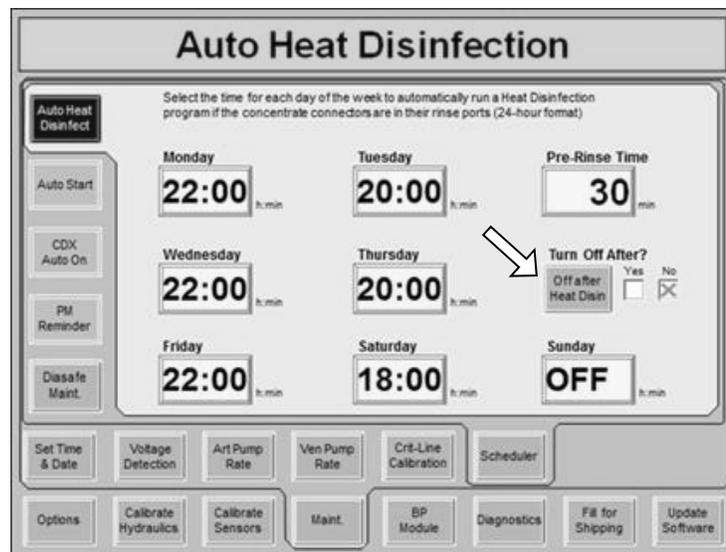
Figure 1

28. Press the button to select Yes and then press the CONFIRM key.

CDX Option Setting

The 2008T BlueStar software update sets the CDX option to No on the Communication Options screen in Service Mode. If the CDX option is used, follow the next steps to set this option to Yes. If not, proceed to the Software Version Verification section.

29. While still in Service Mode, locate the Communication Options screen.

30. On the Communication Options screen, locate the CDX button.

31. Press the button to select Yes and then press the CONFIRM key.

Software Version Verification

32. From either a dialysis or rinse mode screen, enter debug by pressing and holding the CTRL key and then press the up and down arrow keys at the same time on the keyboard.

33. Use the up or down arrow keys to go to debug screen 3 ACTUATOR and verify that the new software versions are correct. See Figure 2 for software version locations on the debug screen.
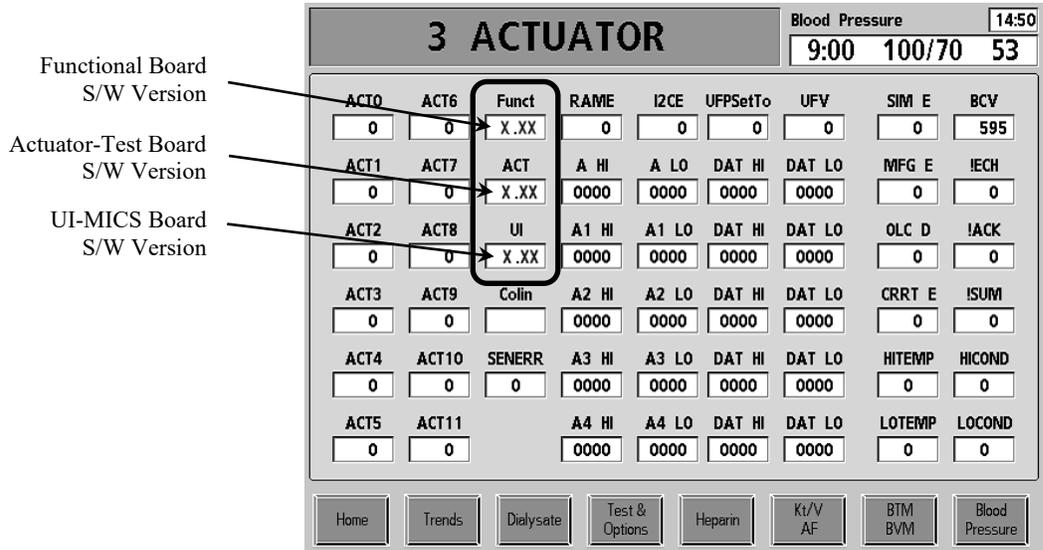
Figure 2

34. Once the software versions have been verified, power the machine off.

Calibrations

NOTE: The Temperature Control Calibration **must be** completed prior to performing the Conductivity Confirmation Cell Calibration

35. Power the machine on and log into Service Mode.

36. Refer to the 2008T Calibration Procedures (P/N 508032) to calibrate the following:

   ▪ Perform **one** of the following Temperature Control Calibrations:

   o If the SLED option **is not activated** and/or Idle Mode Flow Rate **is set to 300**, perform Temperature Control Calibration (Method 1) (Section 2.3.6.1) with Allow Slow Flow and Temp Comp options disabled.

   o If the SLED option **is activated** and/or Idle Mode Flow Rate **is set to 100**, perform Temperature Control Calibration (Method 2) (Section 2.3.6.2) with Allow Slow Flow and Temp Comp options enabled.

   ▪ Conductivity Confirmation Cell Calibration (Section 2.3.8.3)

37. Locate the Independent Cond Test option select Yes**. Press the CONFIRM key.

* Refer to the 2008T Operator's Manual for details.
** The Independent Cond Test option cannot be successfully enabled until the Conductivity Confirmation Cell Calibration has been calibrated.