

2008T BlueStar™ to 2008T BlueStar™ Software Update With Cybersecurity

2008T BlueStar Hemodialysis Machine
Functional Board Software Update
v2.71, v2.72, v2.74 or v2.75
to
v2.84

Part Number 490444 Rev A



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2008T BLUESTAR TO 2008T BLUESTAR SOFTWARE UPDATE WITH CYBERSECURITY

PURPOSE:

The purpose of these instructions is to outline the process of updating a 2008T BlueStar Hemodialysis machine from Functional board software v2.71, v2.72, 2.74 or 2.75 using a USB flash drive.

SCOPE:

Outline the software update process for 2008T BlueStar machines which already have Functional board software v2.71, v2.72, v2.74 or v2.75 installed. This includes the Functional, Actuator-Test and UI-MICS board software.

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 to complete this update process.

NOTE: Updating to Functional board software to version 2.84 varies based upon the current installed 2008T BlueStar Functional board software. The software update process is different from the past Functional board software update process.

- v2.71 to v2.84
 - Requires Functional board software update to be updated twice.
 - Automatic Service Mode entry after the first power cycle.
 - Uses temporary software version not listed on the USB Flash Drive.
- v2.72, v2.74 and v2.75 to v2.84
 - Requires Functional board software update to be updated twice.
 - Manual entry into Service mode is required after first power cycle in order to perform the second Functional board update process.
 - Doesn't use temporary software and will show v2.84 after power cycle. Second Functional software update is still required.

NOTE: Once the Functional board software 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, however, logging into Service Mode is required.**

NOTE: If needed, the 2008T BlueStar Functional board software will automatically update the Power Logic board software on 2008T BlueStar Premium equipped machines.

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 Fresenius Medical Care Technical Services at 800-227-2572.

NOTE: After updating the 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.

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REFERENCE DOCUMENT:

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

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

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.

If needed, the 2008T BlueStar Functional board software will automatically update the Power Logic board software on 2008T BlueStar Premium equipped machines.

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.

Machine Pre-Testing

The software update process requires the 9-volt battery on the back of the machine to be in good condition before starting the update process. During the Alarm Test on the Test & Option screen, this battery is tested. Perform at least the Alarm Test as outlined in the Testing the 2008T Hemodialysis Machine section in Chapter 2 of the 2008T Operator's Manual (P/N 490122). Once the testing is complete, confirm the Battery test passed before continuing the software upgrade.

Functional Board Software Update (First Update)

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.
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.
6. Press the CONFIRM key to install the temporary software.
7. After the machine displays "FLASH PROGRAMMED SUCCESSFUL" turn the power off.

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Functional Board Software Update (Second Update)

NOTE: Leave the Flash Drive plugged into the USB port so the Software Update process can be completed in step 8.

NOTE: In the next step, Service Mode **must be entered** to complete the required second update to the Functional board. Entry into Service Mode is based upon the current Functional board software version.

- If updating from v2.71, the machine **will** automatically enter Service Mode
- If updating from v2.72, v2.74 or v2.75, the machine **will not** automatically enter Service Mode so make sure to press the CONFIRM key when prompted during power up.

8. Power the machine on and make sure the machine enters Service Mode (see note above).
 9. On the Service Mode screen, press the Update Software screen button and the screen will change.
 10. On the Update Software screen, press the Functional Board button and the screen will change.
 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 and 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 or the CRC values do not match, **DO NOT** 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.

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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 and 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 or the CRC values do not match, **DO NOT** 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.

Software Version Verification

24. 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.
25. 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 1 for software version locations on the debug screen.

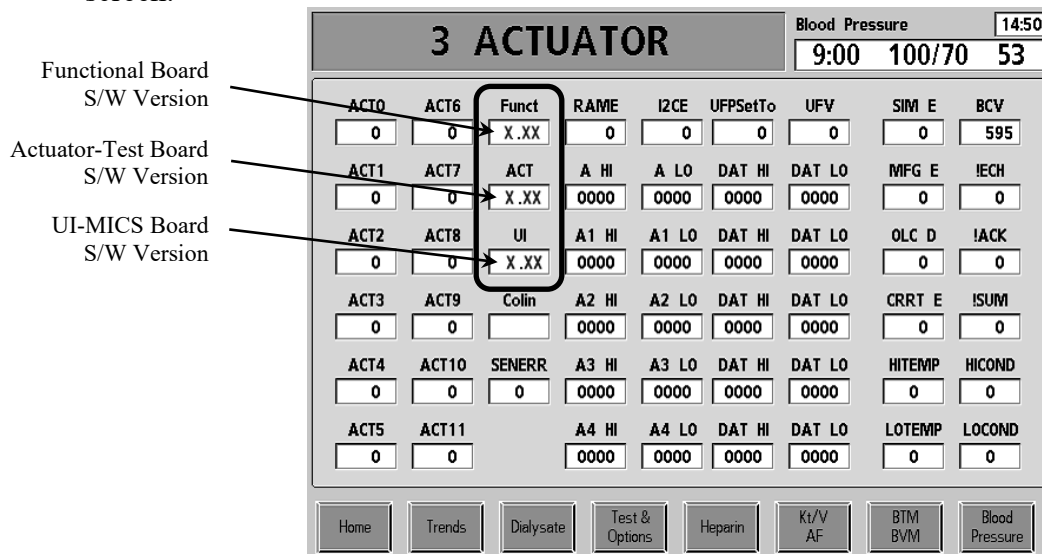


Figure 1

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