MEDICAL DEVICE CORRECTION
NxStage Cartridge Express, CAR-125-B IFU

April 20, 2022

Dear NxStage Customer,

NxStage Medical, Inc. is issuing this notice to alert you of missing steps in the troubleshooting section of NxView Software Version 1.3/2.0 specifically with use of CAR-125-B. The NxView troubleshooting instructions are missing steps to effectively remove air and resume treatment.

You are receiving this notice because our records indicate that NxStage Medical, Inc. has shipped CAR-125-B to you.

Potential Risk
There is no risk to patient health or safety if the instructions in NxView Software Version 1.3/2.0 are followed. If air cannot be completely removed during treatment, it may result in ending treatment without rinsing back the patient’s blood.

NxStage has not received any complaints or adverse events attributed to this issue.

Adverse reactions or quality problems experienced with the use of this product may be reported to qacomplaints@fmc-na.com or to the FDA’s MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

What should I do?
1. NxView Version 2.0 Users: Save or print Appendix A of this notice (below) to replace the NxView troubleshooting information for CAR-125-B.
2. NxView Version 1.3 Users: Save or print Appendix B of this notice (below) to replace the NxView troubleshooting information for CAR-125-B.
3. Ensure all users of CAR-125-B at your facility are informed of this Field Safety Notice.
4. Follow the instructions on the attached reply form or click on the following link to respond electronically, www.nxstage.com/carifunotice to acknowledge your receipt of this notice.

What is NxStage doing?
We are providing this notice to all NxStage CAR-125-B users. It contains the corrected steps for removing air from the bloodline during treatment.
We will be issuing a Service Bulletin for NxStage to upgrade the NxView software with the updated troubleshooting steps.

We are committed to continuous improvement to provide you and your patients with the best products available. We apologize for any inconvenience that this issue may have caused. If you have any questions or concerns, please contact NxStage Customer Service at 1-866-NXSTAGE (1-866-697-8243).

Regards,

Todd Snell
Senior Vice President
Quality Assurance, Regulatory, Clinical Affairs
# Appendix A

## NxView 2.0 Troubleshooting Instructions

### 10 - Check for Venous Air (Red Alarm)

1. Press **MUTE**.
2. Press **STOP**.
3. Using line-occluding forceps (not included with the Cartridge), clamp the *venous line* between the filter and the *Post-Filter “T”*.
4. If running Post-dilution Hemofiltration, close the clamp on the Therapy Fluid Outlet (green clamp).
5. Attach a 20cc syringe to the *Post-Filter “T”*. Open the blue clamp on *Post-Filter “T”*.
6. Slowly pull back on the syringe until all the air enters the syringe.
7. Inject the blood (not the air) back through the *Post-Filter “T”*.
8. Remove the line-occluding forceps and reclamp the venous line just after the *Post-Filter “T”*.
9. Unclamp the Therapy Fluid Outlet (green clamp).
10. Remove the filter from the holder and allow the filter to be suspended (blue end up).
11. Press **TREATMENT**. The *Yellow CAUTION “12”* displays and allows the blood and air to pump into the syringe. Gently tap on filter if necessary.

   **NOTE:** If the syringe gets close to its maximum filling point, press **STOP** twice, remove forceps, and inject blood (not the air) back to the patient. Replace forceps. Press **TREATMENT** and continue again.

12. When all of the air is in the syringe, remove the clamp and observe the *Venous Patient Line (blue clamp)* for air.
13. If air is seen in the *Venous Blood Line (blue clamp)*, press **STOP** twice and repeat steps 3 through 12.
14. If no air is seen, press **TREATMENT** again and inject the blood (not the air) back to the patient. Close the blue clamp on *Post-Filter “T”*.
15. Flush the *Post-Filter “T”* with 3 ml of saline to clear blood, then clamp the port securely. Continue to observe the *Post-Filter cap* for air.

### 11 – Check for Arterial Air (Red Alarm)

Perform arterial air recovery.

1. Press **MUTE**.
2. Check the arterial/access pressure reading to determine if this is a catheter issue or actual air.
   - a. Catheter issue = a large negative number indicating a vacuum, for example (AP -500 mm/Hg).
   - b. Actual Air = a pressure of 0 or within normal limits (-50 to -200).
3. Press **STOP**.
4. If it is a catheter issue follow your facilities policies for catheter issues and continue with step 7.
5. If it is air, identify and correct the source of air in the *arterial (access) patient line (red clamp)*.
6. To remove the air through the *Pre-filter “T”* follow these steps.
   - a. Attach a 20mL syringe to the *Pre-filter “T”* and unclamp.
   - b. Press **TREATMENT**. The *Yellow Caution Window* will display “12.”
c. The Blood Pump is running at 100 (or slower) so that you can remove the air moving toward the filter (air may not be clearly visible).

d. Slowly pull back on the syringe when air is visible.

e. When air is removed, inject blood but not air back through the Pre-filter "T" and re-clamp securely.

f. Verify that the source of air is corrected by observing the arterial (access) patient line (red clamp) for air (5 to 10 seconds).

g. If air is seen, open the red clamp and repeat steps d though f.

h. Press TREATMENT  to return to ordered flow rate.

i. Continue with step 8.

7. Press TREATMENT. , the Yellow Caution Window will display "12. " wait 5 seconds and press TREATMENT. again to clear the caution #12 and return to ordered blood flow rate.

8. Flush Pre-filter "T" with 3mL of saline to clear the blood, then clamp the "T" securely. Continue to observe the postfilter cap for air.

If another RED ALARM "11" occurs, check the vascular access and/or reduce the blood flow rate.
Appendix B
NxView 1.3 Troubleshooting Instructions

11 – Check for Arterial Air (Red Alarm)

Perform arterial air recovery.

1. Press MUTE.
2. Check the arterial/access pressure reading to determine if this is a catheter issue or actual air.
   a. Catheter issue = a large negative number indicating a vacuum, for example (AP -500 mm/Hg).
   b. Actual Air = a pressure of 0 or within normal limits (-50 to -200).
3. Press STOP.
4. If it is a catheter issue follow your facilities policies for catheter issues and continue with step 7.
5. If it is air, identify and correct the source of air in the arterial/access patient line (red clamp)
6. To remove the air through the Pre-filter “T” follow these steps.
   a. Attach a 20mL syringe to the Pre-filter “T” and unclamp.
   b. Press TREATMENT, the Yellow Caution Window will display “12.”
   c. The Blood Pump is running at 100 (or slower) so that you can remove the air moving toward the filter (air may not be clearly visible).
   d. Slowly pull back on the syringe when air is visible.
   e. When air is removed, inject blood but not air back through the Pre-filter “T” and re-clamp securely.
   f. Verify that the source of air is corrected by observing the arterial/access patient line (red clamp) for air (5 to 10 seconds).
   g. If air is seen, open the red clamp and repeat steps d through f.
   h. Press TREATMENT to return to ordered flowrate.
   i. Continue with step 8.
7. Press TREATMENT, the Yellow Caution Window will display “12.”, wait 5 seconds and press TREATMENT again to clear the caution #12 and return to ordered blood flow rate.
8. Flush Pre-filter “T” with 3mL of saline to clear the blood, then clamp the “T” securely. Continue to observe the post-filter cap for air.

If another RED ALARM “11” occurs, check the vascular access and/or reduce the blood flow rate.