



URGENT PRODUCT SAFETY NOTICE

For the NxStage System One S Cyclers Catalog no. NX1000-5 / NX1000-5-A

October 29, 2015

Dear NxStage Clinician,

NxStage has identified a software error present in the NxStage System One S Cyclers Catalog no. NX1000-5 or NX1000-5-A with software versions 4.9 and 4.10. The software error only occurs under isolated conditions and only impacts the NxStage System One S cyclers. There have been no serious injuries reported to NxStage related to this software error.

The software error may occur only in the following isolated scenarios:


1. If the user follows the default setting of ultrafiltration rate mode (UF volume is set at “---”) and turns off power or the power is lost at any time during “Patient Connect” or “Treatment” mode the UF volume will switch to a ‘target’ mode. The UF volume will then decrease from the maximum numeric setting of 9.99 liters during the treatment at the commanded pump rate. The ultrafiltration pump will stop once the target reaches zero (0).
2. If the user sets a specific UF volume to remove (e.g. ‘target mode’) and turns off power or the power is lost at any time during “Patient Connect” or “Treatment” mode AND the UF volume target is changed the UF volume will switch to a ‘rate’ mode. The ultrafiltration target volume will not decrease during the treatment and the pump will remain on and continue to remove fluid even after the target volume has been reached.
3. If a user enables the low fluid temperature monitoring Cyclers setting (System setting 79 = 1) and a Low Fluid Temperature yellow caution 53 occurs, the Cyclers will not account for UF removed until the user clears the caution by pressing the Mute and Treatment keys. Additionally, the NxView history screen Ultrafiltration volume totals will not include the UF removed until the caution is cleared.

What is the risk to the patient?

If the UF software error occurs and remains undetected by the user for a prolonged time, then the patient is at risk for inaccurate fluid removal. Additionally if a low fluid temperature software error occurs and remains undetected by the user for a prolonged time, then the patient is also at risk for excess fluid removal. Fluid overload may result in symptoms of hypertension and excess fluid removal may result in symptoms of hypotension. In the critical care setting where patient’s vital signs are continuously monitored by trained health care professionals, the symptoms of hypertension and hypotension are immediately recognized and appropriately responded to prior to any further clinical consequence.

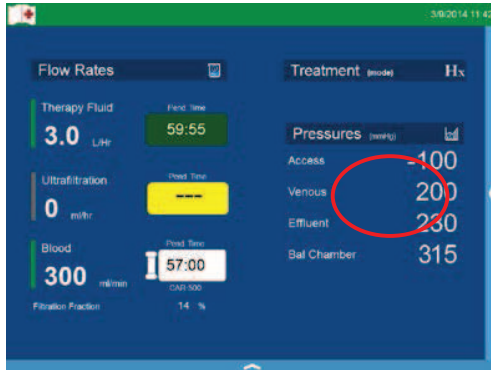
How will I know if the software error has occurred?

If the number 53 is displayed in the Cyclers yellow caution window or 53 - Low Fluid Temperature (Yellow Caution) is displayed on the NxView home screen, the software error will occur if the caution is not cleared promptly.

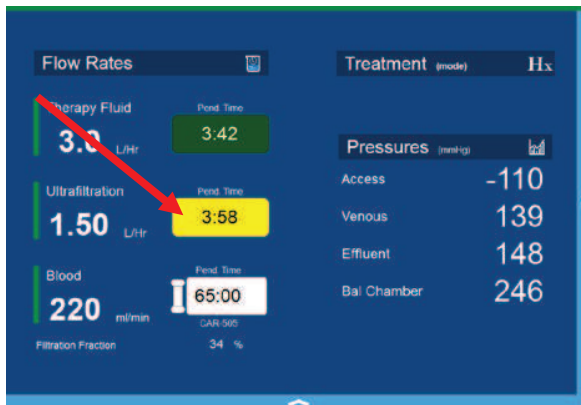
If the UF volume was initially at  and the UF volume has counted down to zero, the UF pump will turn off. NxView will display the UF pump rate as 0. See example below.

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If the UF volume was initially set at a specific target value, the software error has occurred if the UF Pend. Time on the NxView home screen remains the same and does not change at the set pump rate as expected.



What should I do?

Until the software update is implemented, NxStage recommends the following:

A. Disable low fluid temperature monitoring by changing system setting 79 to 0. If a yellow caution 53- Low Fluid Temperature occurs, return the patient's blood and prime a new cartridge to start a new treatment.	
B. When the UF volume setting is set to	Do the following if the software error has occurred
	<ul style="list-style-type: none"> Manually adjust the UF volume following the attached instructions.
a specific target volume in L.	<ul style="list-style-type: none"> Return the patient's blood. Prime a new cartridge to start a new treatment.

What is NxStage doing?

NxStage is developing a software update to correct the error. Once the new software is released, [DISTRIBUTOR NAME] will contact you to arrange to upgrade the software on your cyclers. The NxStage Engineering team is working diligently to resolve this issue and we will keep you updated when the new software is ready to be released.

[DISTRIBUTOR NAME] will be sending a representative to your facility to attach detailed instructions on each cyclor as a user reference. Please also return the attached reply form to acknowledge your receipt of this letter.




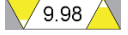




Please know that we are committed to continuous improvement in order to provide you and your patients with the best products available and apologize for any inconvenience that this issue may have caused. If you have any questions or comments, please contact [DISTRIBUTOR NAME] at [CONTACT NUMBER].

Regards,




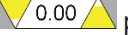




[CONTACT NAME]
[TITLE]

Instructions for Manually Adjusting Ultrafiltration Volume

If you receive a #40 Perform Power Recovery Caution or turn off the power during “Patient Connect” or “Treatment” mode:

1. Press the Volume Toggle key  on the Cyclor user interface after the first history interval.
2. Make sure the interface has switched to the volume screen. You should see “VOL” in the red window .
3. The yellow volume window should display three dashes .
4. If the UF volume is counting down, for example,  press the yellow up arrow  until you see three dashes again .
5. Press the Volume Toggle key  again to switch back to the rate screen.
6. After the next history interval repeat steps 1-3 to make sure the UF volume is at the maximum allowable setting .
7. At any time you can return the patient’s blood and prime a new cartridge.

If your UF rate is at zero  and you are unable to change it:

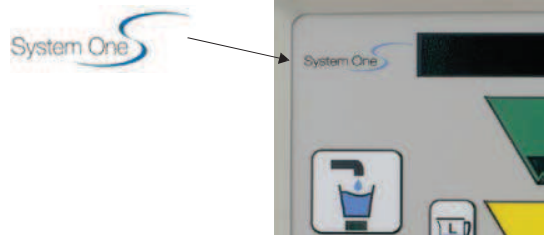
1. Press the Volume Toggle key  on the Cyclor user interface.
2. Make sure the interface has switched to the volume screen. You should see “VOL” in the red window .
3. The yellow volume window should display three dashes .
4. If the UF volume is at zero, for example,  press the yellow up arrow  until you see three dashes again .
5. Press the Volume Toggle key  again to switch back to the rate screen.
6. After the next history interval repeat steps 1-3 to make sure the UF volume is at the maximum allowable setting .
7. At any time you can return the patient’s blood and prime a new cartridge.



FIELD SAFETY NOTICE REPLY FORM for Hospital / Centres
NxStage System One S Cyclor Model NX1000-5 / NX1000-5-A

Please complete this form even if you do not have any System One S Cyclers at your centre.

Please return the completed form to [DISTRIBUTOR NAME] in the prepaid enclosed envelope. You may also return the completed form via FAX to [FAX NUMBER] or email to [DISTRIBUTOR EMAIL ADDRESS].



Check your Cyclor for the System One S logo.

PLEASE CHECK ALL BOXES THAT APPLY:

- We acknowledge receipt of the Field Safety Notice dated October 29, 2015.
- We have the following System One S Cyclor Serial Numbers in our centre

_____	_____	_____	_____
_____	_____	_____	_____

- We do not have any System One S Cyclors at our centre

Hospital / Centre Name _____

Hospital / Centre City _____

Country _____

Person Completing Form:

Signature: _____ Date: _____

Print Name: _____ Email: _____

May we contact you if we have any questions? Yes No

Contact Phone _____ Email _____

NX1000-5 and NX1000-5-A Shipped to EU

Ship Date	Part No	Serial No	Date of Mfg
3/21/2014	NX1000-5	16460	3/30/2013
3/21/2014	NX1000-5	16464	3/30/2013
3/21/2014	NX1000-5	16467	4/11/2013
4/1/2014	NX1000-5	16463	3/30/2013
4/1/2014	NX1000-5	16472	4/11/2013
7/11/2014	NX1000-5	16459	3/30/2013
7/11/2014	NX1000-5	16466	4/11/2013
7/11/2014	NX1000-5	16469	4/11/2013
7/11/2014	NX1000-5	16470	4/11/2013
7/11/2014	NX1000-5	16471	4/11/2013
7/11/2014	NX1000-5	16473	4/11/2013
7/11/2014	NX1000-5	16475	4/11/2013
7/11/2014	NX1000-5	16477	4/11/2013
7/11/2014	NX1000-5	16478	4/11/2013
4/29/2015	NX1000-5-A	32098	3/10/2015
4/29/2015	NX1000-5-A	32099	3/13/2015
7/31/2015	NX1000-5-A	32100	3/13/2015
7/31/2015	NX1000-5-A	32101	3/10/2015
8/28/2015	NX1000-5-A	32102	3/13/2015
8/28/2015	NX1000-5-A	32103	3/13/2015