



URGENT PRODUCT SAFETY NOTICE

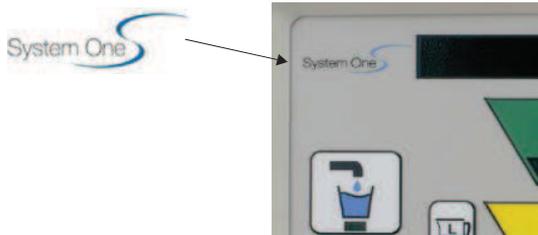
For the NxStage System One S Cyclers Catalog no. NX1000-3 / NX1000-3-A

October 29, 2015

Dear NxStage Clinician,

NxStage has identified a software error in the NxStage System One S Cycler Model no. NX1000-3 or NX1000-3-A with software versions 4.9 and 4.10. The software error only occurs under limited and specific conditions. There have been no serious injuries reported to NxStage related to this software error. If specific conditions are met and a software error does occur, the ultrafiltration (UF) volume target will not decrease during the treatment even if the UF pump is running. If the software error is not detected and resolved, the UF pump may continue to run and remove fluid even after the target UF volume has been removed.

This software error only affects the System One S Cycler. Earlier Cycler models are not affected. To determine if you have a System One S, look for the System One S logo in the upper left corner of the display as shown in the picture below.



What should I do?

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

1. For patients performing nocturnal treatments:
 - Call NxStage Technical Support to arrange for a replacement of their Cyclers to a NX1000-1 Cycler.
 - Do not redeploy any NX1000-3 System One S Cyclers to any new patients performing nocturnal therapy
2. All other patients should be instructed as follows:
 - Do not turn off the Cycler after priming the cartridge. Only prime the cartridge when ready to start treatment.
 - If patients experience loss of power or a red alarm greater than "99" during a treatment, advise them to end treatment and perform rinseback.
 - If patients experience a yellow caution 53 Low Fluid Temperature during treatment, advise them to either resolve the caution promptly or end treatment and perform rinseback.
 - Patients should be instructed to contact their center nurse for instructions on restarting the treatment or changing their treatment schedule.

How do I check to see if the software error has occurred?

- While the number 53 is displayed in the yellow caution window, the software error is occurring.
- If the UF volume target does not change from the original volume target set by the user as treatment progresses, then the Cyclor is not performing correctly.

What is the risk to the patient?

If the software error occurs and remains undetected by the user for a prolonged time, then the patient is at risk for excess fluid removal. If too much fluid is removed, then the patient may develop low blood pressure (hypotension) and experience symptoms such as cramping, nausea, dizziness, blurry vision, or lightheadedness.

Patients are trained to recognize the signs and symptoms of hypotension and excess fluid removal and instructions are provided in the User Guide. However, patients who perform nocturnal treatments are at a slightly higher risk than patients performing short daily treatments because they are asleep during their treatments. To address even this remote risk, we will be replacing all cyclers for nocturnal patients.

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 upgrade the Cyclor software. 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.

Please follow the instructions on the attached reply form.

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 feel free to contact [DISTRIBUTOR NAME] Customer Service at [CONTACT NUMBER].

Regards,

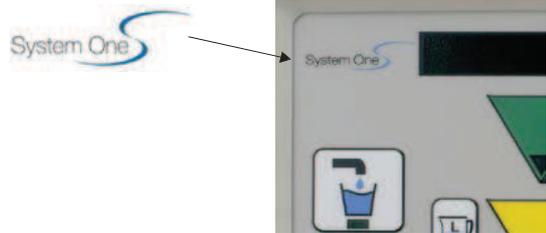
[CONTACT NAME]
[TITLE]



FIELD SAFETY NOTICE REPLY FORM for Hospital / Centres
NxStage System One S Cyclor Model NX1000-3 / NX1000-3-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 _____



URGENT PRODUCT SAFETY NOTICE

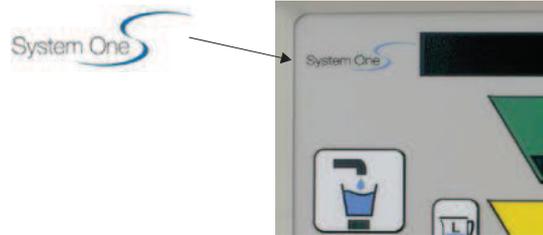
For the NxStage System One S Cyclers Model no. NX1000-3 / NX1000-3-A

October 29, 2015

Dear NxStage Patient,

NxStage has identified a software error in the NxStage System One S Cycler Model no. NX1000-3 or NX1000-3-A with software versions 4.9 and 4.10. The software error only occurs under limited and specific conditions. There have been no serious injuries reported to NxStage related to this software error. If specific conditions are met and a software error does occur, the ultrafiltration (UF) volume target will not decrease during the treatment even if the UF pump is running. If the software error is not detected and resolved, the UF pump may continue to run and remove fluid even after the target UF volume has been removed.

This software error only affects the System One S Cycler. Earlier Cycler models are not affected. To determine if you have a System One S, look for the System One S logo in the upper left corner of the display as shown in the picture.



What should I do to avoid the software error?

- For patients performing nocturnal treatments: Call your Center to arrange for a replacement of your Cycler to a NX1000-1 Cycler.
- Do not turn off the Cycler after priming the cartridge. Only prime the cartridge when you are ready to start your treatment.
- If you experience loss of power or a red alarm greater than "99" during a treatment, end your treatment and perform rinseback.
- If you experience a yellow caution 53 Low Fluid Temperature during your treatment, either resolve the caution promptly or end your treatment and perform rinseback.
- If you ended your treatment early, contact your center nurse for instructions on restarting the treatment or changing your treatment schedule.

If you experience any symptoms of excess fluid removal, contact your center nurse. If instructed to administer a saline bolus, follow your center protocol and the User Guide instructions.

How do I check to see if the software error has occurred?

- While the number 53 is displayed in the yellow caution window, the software error is occurring.
- If the UF volume target does not change from the original volume target set by the user as treatment progresses, then the Cycler is not performing correctly.

What is the risk to you?

If the software error occurs and remains undetected for a prolonged time, you may be at risk for excess fluid removal. If too much fluid is removed, then you may develop low blood pressure (hypotension) and experience symptoms such as cramping, nausea, dizziness, blurred vision, or lightheadedness. Signs and symptoms of hypotension and excess fluid removal and instructions are provided in the NxStage System One User Guide. The risk is slightly higher for nocturnal treatments because you are asleep during treatment and may not recognize excess fluid removal symptoms. To address even this remote risk, we will be replacing all cyclers for nocturnal patients.

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 a software upgrade for the Cyclor. 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.

Please complete and return the attached reply form.

Please know that we are committed to continuous improvement in order to provide you 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] Customer Service at [CONTACT NUMBER].

Regards,

[CONTACT NAME]
[TITLE]

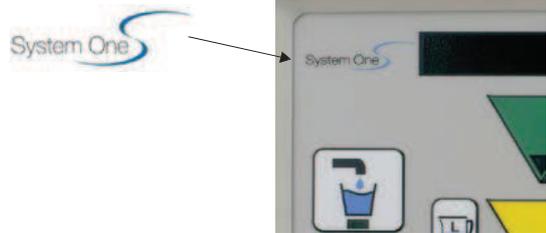


FIELD SAFETY NOTICE REPLY FORM for Patients

NxStage System One S Cyclor Model NX1000-3 / NX1000-3-A

Please complete this form even if you do not have a System One S Cyclor.

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:

- I acknowledge receipt of the Field Safety Notice dated October 29, 2015.
- I have the following System One S Cyclor Serial Number _____
- I do not have a System One S Cyclor
- I perform treatments nocturnally and understand that I should contact my centre nurse to arrange to swap my cyclor

Patient Name _____
Print Name

Hospital / Centre Name _____

Hospital Centre City _____

Country _____

Person Completing Form:

Signature: _____ Date: _____

Print Name: _____

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

Contact Phone _____ Email _____

NX1000-3 and NX1000-3-A Cyclers Shipped to EU

Part No	Ship Date	Serial No	Date of Mfg
NX1000-3	6/5/2014	18017	4/25/2014
NX1000-3	6/5/2014	18022	4/25/2014
NX1000-3	6/5/2014	18217	4/8/2014
NX1000-3	6/5/2014	18218	4/10/2014
NX1000-3	6/5/2014	18223	4/10/2014
NX1000-3	6/5/2014	18233	4/13/2014
NX1000-3	6/5/2014	18228	4/9/2014
NX1000-3	6/5/2014	18235	4/13/2014
NX1000-3	9/25/2014	19094	8/22/2014
NX1000-3	11/25/2014	19620	10/10/2014
NX1000-3	11/25/2014	19621	10/10/2014
NX1000-3	11/25/2014	19622	10/10/2014
NX1000-3	11/25/2014	19623	10/13/2014
NX1000-3	11/25/2014	19624	10/13/2014
NX1000-3-A	12/22/2014	32003	10/1/2014
NX1000-3-A	12/22/2014	32005	10/1/2014
NX1000-3-A	12/22/2014	32007	10/1/2014
NX1000-3-A	12/22/2014	32015	10/23/2014
NX1000-3-A	12/22/2014	32016	10/23/2014
NX1000-3-A	12/22/2014	32017	10/23/2014
NX1000-3-A	12/22/2014	32018	10/23/2014
NX1000-3-A	12/22/2014	32019	10/23/2014
NX1000-3-A	12/22/2014	32022	10/23/2014
NX1000-3-A	12/22/2014	32023	10/23/2014
NX1000-3-A	12/22/2014	32024	10/23/2014
NX1000-3-A	12/22/2014	32027	10/23/2014
NX1000-3	1/9/2015	19973	12/4/2014
NX1000-3	1/9/2015	19974	12/2/2014
NX1000-3	1/9/2015	19975	11/28/2014
NX1000-3	1/9/2015	19977	12/8/2014
NX1000-3	1/9/2015	19882	11/18/2014
NX1000-3	1/9/2015	19883	11/25/2014
NX1000-3	1/9/2015	19884	11/12/2014
NX1000-3	1/9/2015	19885	11/19/2014
NX1000-3	1/9/2015	19886	11/28/2014
NX1000-3-A	2/3/2015	32011	10/1/2014
NX1000-3-A	2/3/2015	32031	10/23/2014
NX1000-3-A	2/3/2015	32032	10/23/2014
NX1000-3-A	2/3/2015	32033	10/23/2014
NX1000-3-A	2/3/2015	32034	10/23/2014
NX1000-3-A	2/3/2015	32035	10/23/2014
NX1000-3-A	2/3/2015	32036	10/23/2014
NX1000-3-A	2/27/2015	32039	12/23/2014
NX1000-3-A	2/27/2015	32043	12/23/2014
NX1000-3-A	2/27/2015	32045	12/23/2014
NX1000-3-A	2/27/2015	32055	12/23/2014

NX1000-3 and NX1000-3-A Cyclers Shipped to EU

Part No	Ship Date	Serial No	Date of Mfg
NX1000-3-A	2/27/2015	32057	12/23/2014
NX1000-3-A	2/27/2015	32063	12/23/2014
NX1000-3-A	2/27/2015	32065	12/23/2014
NX1000-3-A	2/27/2015	32067	12/23/2014
NX1000-3-A	2/27/2015	32069	12/23/2014
NX1000-3-A	3/11/2015	32004	10/1/2014
NX1000-3-A	3/11/2015	32037	12/22/2014
NX1000-3-A	3/11/2015	32038	12/29/2014
NX1000-3-A	3/11/2015	32040	12/22/2014
NX1000-3-A	3/11/2015	32041	12/22/2014
NX1000-3-A	3/25/2015	32044	12/23/2014
NX1000-3-A	3/25/2015	32046	12/22/2014
NX1000-3-A	3/25/2015	32048	12/29/2014
NX1000-3-A	3/25/2015	32049	12/22/2014
NX1000-3-A	3/25/2015	32050	12/22/2014
NX1000-3-A	3/25/2015	32051	12/22/2014
NX1000-3-A	3/25/2015	32052	12/22/2014
NX1000-3-A	3/25/2015	32053	12/22/2014
NX1000-3-A	4/6/2015	32060	12/29/2014
NX1000-3-A	4/6/2015	32061	12/22/2014
NX1000-3-A	4/6/2015	32062	12/22/2014
NX1000-3-A	4/6/2015	32064	12/22/2014
NX1000-3-A	4/6/2015	32068	12/23/2014
NX1000-3-A	4/6/2015	32070	12/22/2014
NX1000-3-A	4/6/2015	32071	12/22/2014
NX1000-3-A	4/6/2015	32072	12/29/2014
NX1000-3-A	4/6/2015	32073	12/30/2014
NX1000-3-A	4/6/2015	32074	12/22/2014
NX1000-3-A	4/8/2015	32058	12/22/2014
NX1000-3-A	4/8/2015	32059	12/22/2014
NX1000-3-A	4/8/2015	32054	12/22/2014
NX1000-3-A	4/8/2015	32056	12/22/2014
NX1000-3-A	5/15/2015	32010	10/31/2014
NX1000-3-A	5/15/2015	32013	10/31/2014
NX1000-3	5/19/2015	20358	3/16/2015
NX1000-3	5/19/2015	20360	3/13/2015
NX1000-3	5/19/2015	20361	3/16/2015
NX1000-3	5/19/2015	20443	3/27/2015
NX1000-3	5/19/2015	20444	3/27/2015
NX1000-3	5/21/2015	19123	9/22/2014
NX1000-3-A	5/27/2015	32086	5/6/2015
NX1000-3-A	5/27/2015	32087	5/5/2015
NX1000-3-A	5/27/2015	32088	5/7/2015
NX1000-3-A	5/27/2015	32084	4/30/2015
NX1000-3-A	5/27/2015	32085	4/30/2015
NX1000-3-A	5/28/2015	32089	4/30/2015

NX1000-3 and NX1000-3-A Cyclers Shipped to EU

Part No	Ship Date	Serial No	Date of Mfg
NX1000-3-A	5/28/2015	32090	4/30/2015
NX1000-3-A	5/28/2015	32091	4/30/2015
NX1000-3-A	5/28/2015	32092	4/30/2015
NX1000-3-A	5/28/2015	32093	4/30/2015
NX1000-3-A	5/28/2015	32094	4/30/2015
NX1000-3-A	5/28/2015	32080	4/30/2015
NX1000-3-A	5/28/2015	32081	4/30/2015
NX1000-3-A	5/28/2015	32082	4/30/2015
NX1000-3-A	6/1/2015	32014	10/31/2014
NX1000-3-A	6/1/2015	32083	4/30/2015
NX1000-3-A	6/11/2015	32116	5/13/2015
NX1000-3-A	6/11/2015	32118	5/13/2015
NX1000-3-A	6/11/2015	32120	5/13/2015
NX1000-3-A	6/16/2015	32117	5/13/2015
NX1000-3-A	6/16/2015	32119	5/13/2015
NX1000-3-A	6/16/2015	32113	5/12/2015
NX1000-3-A	6/18/2015	32075	5/6/2015
NX1000-3-A	6/18/2015	32076	4/30/2015
NX1000-3-A	6/18/2015	32077	4/30/2015
NX1000-3-A	6/18/2015	32078	4/30/2015
NX1000-3-A	6/18/2015	32079	4/30/2015
NX1000-3-A	6/19/2015	32095	4/30/2015
NX1000-3-A	6/19/2015	32096	5/5/2015
NX1000-3-A	6/19/2015	32097	5/12/2015
NX1000-3-A	6/19/2015	32115	5/13/2015
NX1000-3-A	6/24/2015	32114	5/13/2015
NX1000-3-A	6/24/2015	32121	5/13/2015
NX1000-3-A	8/6/2015	32125	5/12/2015
NX1000-3-A	8/6/2015	32126	5/13/2015
NX1000-3-A	8/6/2015	32127	5/27/2015
NX1000-3-A	8/6/2015	32128	5/26/2015
NX1000-3-A	8/6/2015	32129	5/26/2015
NX1000-3-A	8/6/2015	32130	5/26/2015
NX1000-3-A	8/6/2015	32131	5/28/2015
NX1000-3-A	8/6/2015	32132	5/28/2015
NX1000-3-A	8/6/2015	32133	5/28/2015
NX1000-3-A	8/6/2015	32134	5/27/2015
NX1000-3-A	8/10/2015	32135	5/27/2015
NX1000-3-A	8/10/2015	32136	5/26/2015
NX1000-3-A	8/10/2015	32137	5/29/2015
NX1000-3-A	8/17/2015	32138	5/28/2015
NX1000-3-A	8/17/2015	32139	5/26/2015
NX1000-3-A	8/17/2015	32140	5/27/2015
NX1000-3-A	8/20/2015	32122	5/12/2015
NX1000-3-A	8/20/2015	32123	5/13/2015
NX1000-3-A	8/20/2015	32124	5/13/2015

NX1000-3 and NX1000-3-A Cyclers Shipped to EU

Part No	Ship Date	Serial No	Date of Mfg
NX1000-3-A	10/7/2015	32141	5/28/2015
NX1000-3-A	10/7/2015	32142	5/28/2015
NX1000-3-A	10/7/2015	32143	5/27/2015
NX1000-3-A	10/7/2015	32144	5/27/2015
NX1000-3-A	10/22/2015	32146	5/28/2015
NX1000-3-A	10/22/2015	32151	5/27/2015
NX1000-3-A	10/22/2015	32155	5/28/2015
NX1000-3-A	10/22/2015	32156	6/27/2015
NX1000-3-A	10/22/2015	32157	6/18/2015
NX1000-3-A	10/22/2015	32158	6/24/2015
NX1000-3-A	10/22/2015	32165	6/20/2015
NX1000-3-A	10/22/2015	32166	6/18/2015
NX1000-3-A	10/22/2015	32167	6/20/2015
NX1000-3-A	10/22/2015	32168	6/20/2015
NX1000-3-A	10/26/2015	32145	5/29/2015
NX1000-3-A	10/26/2015	32147	5/28/2015
NX1000-3-A	10/26/2015	32148	5/27/2015
NX1000-3-A	10/26/2015	32149	5/29/2015
NX1000-3-A	10/26/2015	32150	5/28/2015
NX1000-3-A	10/26/2015	32154	5/27/2015
NX1000-3-A	10/26/2015	32159	6/18/2015
NX1000-3-A	10/26/2015	32160	6/18/2015
NX1000-3-A	10/26/2015	32161	6/18/2015
NX1000-3-A	10/26/2015	32164	6/18/2015