December 8, 2014

Mr. David Pudwill
Biomedical Engineer
U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: K141752 NxStage System One – S002 Response

Dear Mr. Pudwill,

This letter is in response to your email request dated December 1, 2014 relative to our 510(k) premarket notification (K141752) to market the device referenced above. All of your requests and questions are noted in bold below, followed by our corresponding response.

(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

Thank you. If you have any questions regarding this response, please contact me directly at (978) 687-4872 or via e-mail at mstroumbos@nxstage.com.

Sincerely,

Mary Lou Stroumbos

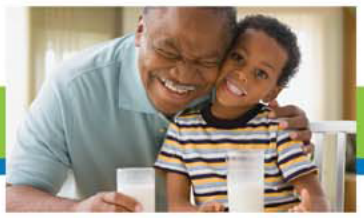
Mary Lou Stroumbos
Director, Regulatory Affairs

Appendix A – NxStage System One Supplement for Nocturnal Hemodialysis

NxSTAGE
Invent. Improve. Inspire.

NxStage System One

Supplement for Nocturnal Hemodialysis



Disclaimer

This document is a supplement to the *NxStage System One User Guide*. This document is one part of a user-training program. This document is not intended to replace the *NxStage System One User Guide* and does not include all of the information necessary to use the system safely and effectively. Providers should review and refer to the *NxStage System One User Guide* for complete information including all warnings and precautions.

1: Supplement to NxStage System One User Guide

This supplement is to be used only with the *NxStage System One User Guide* that you currently have. It is intended to supplement, not replace, the *NxStage System One User Guide*. Patients, partners, and providers must review and refer to the *NxStage System One User Guide* for all additional warnings and precautions.

This supplement describes the increased risks associated with nocturnal home hemodialysis therapy and the ancillary equipment that is recommended or required to use the System One for nocturnal home hemodialysis therapy. When using the system for nocturnal therapy, thoroughly read this supplement for additional details for operation.

Healthcare providers must refer to this supplement to select the proper ancillary equipment to provide to their patients. Patients using the system at home are expected to use the equipment provided by their clinic or hospital. If patients have questions about the ancillary devices they have been given, they should consult with their healthcare provider.

Please review these procedures and contact your healthcare provider or local distributor, as specified during your training, if you have any questions.

Indications for Use

The NxStage System One is indicated for the treatment of acute and chronic renal failure or fluid overload using hemofiltration, hemodialysis, and/or ultrafiltration, in an acute or chronic care facility.

The system is also indicated for home hemodialysis, including home nocturnal hemodialysis.

All treatments must be administered under physician's prescription, and must be performed by a trained and qualified person, considered to be competent in the use of this device by the prescribing physician.

Increased Risks Associated with Nocturnal Home Hemodialysis Therapy

The NxStage System One may be used at night while the patient and care partner are sleeping. Certain risks associated with hemodialysis treatment are increased when performing nocturnal therapy due to the length of treatment time and because therapy is performed while the patient and care partner are sleeping. These risks include, but are not limited to, blood access disconnects and blood loss during sleep, blood clotting due to slower blood flow or increased treatment time or both, and delayed response to alarms when waking from sleep.

Ancillary anticoagulant infusion pumps, single needle devices, and fluid leak detection devices may be used to decrease certain risks for home hemodialysis treatments performed at any time, but NxStage requires the use of fluid leak detectors to identify leaks from the vascular access, Cycler and Cartridge when performing nocturnal therapy with the NxStage System One.

Patients should consult with their physician to understand the risks and responsibilities associated with nocturnal home hemodialysis using the NxStage System One, including those described in this supplement.

PRECAUTION

Treatment with nocturnal therapy may require adjustments to medications, including but not limited to iron, Erythropoiesis-Stimulating Agents (ESA), insulin/oral hypoglycemics, anticoagulants, and phosphate binders. Please be aware of this when initiating patients on nocturnal hemodialysis.

Symbols

Table 1-1: Symbol definitions

	This symbol indicates a warning or precaution; consultation of the User Guide prior to equipment operation is critical to the safe operation of the device. A warning is a statement that alerts you to the possibility of serious injury, other adverse reactions, or death associated with the use or misuse of the NxStage System One. A precaution or caution is a statement that alerts you to the possibility of a problem with the device associated with its use or misuse. Such problems include device malfunction, device failure, damage to the device, or damage to other property.
	This symbol indicates to consult the instructions for use (operating instructions) prior to use.
Rx Only	This symbol indicates that Federal law (USA) restricts this device to sale by or on the order of a physician (or properly licensed practitioner).
CE 0413	This symbol indicates compliance with the requirements for the European Union.
	This symbol indicates the manufacturer.
EC REP	This symbol indicates the authorized representative in the European Community.
	This symbol indicates that separate waste collection is required for electrical and electronic equipment.

This page intentionally left blank.

2: Nocturnal Use of the System One

Anticoagulation

WARNINGS

- Follow manufacturer's Instructions for Use of the Anticoagulant Pump to deliver proper Anticoagulation Therapy.
- Prime the anticoagulant pump and administration line with outlet pressure applied. Failure to do so could delay anticoagulant being administered.
- When using low anticoagulant delivery rates, an initial bolus of anticoagulant is recommended, since the anticoagulant will take longer to enter the blood lines at the beginning of treatment. This delay may increase the risk of blood clotting.
- Turn on the anticoagulant pump when treatment is started to avoid clotting.
- Turn off the anticoagulant pump when treatment is stopped for any time exceeding 2 minutes to avoid excessive anticoagulant administered to the patient.
- Anticoagulant pumps are not connected to the NxStage System One Cycler. In the event of an alarm from the anticoagulant pump, the user must press the STOP key on the Cycler to stop all pumps and clamp off the venous and waste lines if necessary. Failure to do so may increase the risk of blood clotting.

Longer treatments typically require continuous anticoagulant infusion. It is possible to give boluses of anticoagulant at regular periods during longer treatments. However, nocturnal therapy usually requires a continuous infusion of anticoagulant. An infusion pump should be used if continuous anticoagulant infusion is desired.

The physician prescription usually includes:

- initial loading or bolus dose;
- a patient-specific rate for continuous infusion;
- the maximum amount of anticoagulant to be infused; and
- when to begin and end the infusion during treatment.

When choosing an anticoagulant infusion pump, make sure it:

- can deliver the required infusion rate of anticoagulant;
- can operate with the specified infusion line tubing Inner Diameter (ID) containing a check valve;
- has locking connectors compliant with ISO 594 parts 1 & 2;
- has a maximum pressure limit that is greater than 600 mmHg; and
- can accept a syringe large enough to supply the required amount of anticoagulant for the duration of the treatment.

The following pumps have been validated for use with the NxStage System One for infusing anticoagulants:

- Medex® 2000 SERIES Medfusion Syringe Infusion Pump 2010H-VX.
- Caesarea T34L PCA Syringe Pump.

Other devices that meet the requirements above may be available.

A one-way check valve may be used between the anticoagulant infusion line and the blood lines. The use of a one-way check valve may reduce the chance of blood entering the anticoagulant line at high blood flow rates and low anticoagulant flow rates.

Vascular Access Leaks and Disconnections

WARNINGS

- Follow manufacturer's Instructions for Use to ensure correct operation of the leak detection device.
- A leak detection device has been validated for use with the NxStage System One to detect access leaks in patients with arteriovenous fistulas or grafts; however, NxStage has not tested or validated an access leak detection device for use with hemodialysis catheters.
- Before each patient treatment, the Fluid Detection Sensor alarm must be tested. Failure to do so could result in a vascular access leak or disconnection or a fluid leak that goes undetected and may lead to significant blood loss, patient injury or death.
- Leak detection devices are separate from the NxStage System One Cycler and do not control the Cycler. When the leak detection device sounds an alarm, the user must press the STOP key on the Cycler to stop all pumps and close the clamps on the venous and waste lines. Failure to do so may result in significant blood loss, patient injury or death.

The vascular access and the blood lines should be correctly positioned and secure to avoid accidental dislodgement.

The use of an access leak detection device helps to detect blood leaks during treatment. The sensors of the access leak detection device should be positioned correctly so that the leak detection device alarms immediately if blood leaks from the vascular access. A stand-alone access leak detection device is required during nocturnal therapy. Test the access leak detection device following the manufacturer's Instructions for Use before each use.

When choosing an access leak detection device, make sure it can:

- detect blood when in contact with the sensor and trigger an audible alarm of 75 decibels or greater (loud enough to interrupt sleep);
- be positioned in a way that allows leaked blood to contact the sensor;
- be tested for functionality before use; and
- continue working properly when the patient moves.

The following access leak detection device has been validated for use with the NxStage System One to detect access leaks:

- Redsense Medical Blood Loss Detection Device (Alarm Unit and Sensor).

Other devices that meet the requirements above may be available.

While the risk of vascular access disconnects with hemodialysis catheter access was not evaluated in the NxStage Nocturnal Study, there may be situations where a patient and their physician believe that the benefit/risk profile favors the use of nocturnal hemodialysis in this situation. As there are currently no blood leak detection devices designed specifically to detect blood leaks from hemodialysis catheters, additional measures could be used in an attempt to protect the patient from this risk. As an example, at the discretion of the treating physician, patients with catheter access may use a bloodline connector clip that is designed to minimize tubing disconnects by securing the connections of the catheter to the bloodlines.

Single Needle Cannulation of the Vascular Access

WARNING

- Follow manufacturer's Instructions for Use to ensure correct operation of the single needle device.

A single needle device indicated for dialysis procedures may be used to access an arteriovenous fistula or graft to perform nocturnal hemodialysis. The vascular access and the blood lines should be correctly positioned and secure to avoid accidental dislodgement.

The use of a single needle device helps to avoid the risks associated with vascular access disconnection during treatment. In the event of a needle dislodgement using a single needle device, the patient's arterial and venous lines are removed simultaneously drawing air into the arterial line, causing a machine alarm and stopping all cycler pumps.

When choosing a single needle device, make sure it can be used with a single blood pump device such as the NxStage System One Cycler.

The following single needle device has been validated for use with the NxStage System One:

- Medisystems OneSite Dual Lumen Needle

Other devices that meet the requirement of compatibility with a single blood pump device may be available.

Cycler/Cartridge Fluid Leak Detection

WARNINGS

- Follow manufacturer's Instructions for Use to ensure correct operation of the leak detection device.
- Before each patient treatment, the Fluid Detection Sensor alarm must be tested. Failure to do so could result in a vascular access leak or disconnection or a fluid leak that goes undetected and may lead to significant blood loss, patient injury or death.
- Leak detection devices are separate from the NxStage System One Cycler and do not control the Cycler. When the leak detection device sounds an alarm, the user must press the STOP key on the Cycler to stop all pumps and close the clamps on the venous and waste lines. Failure to do so may result in significant blood loss, patient injury or death.

The use of a fluid leak detection device helps detect fluid and blood leaks from the Cycler or Cartridge during treatment.

A leak detection device is required during nocturnal therapy. Position the device under the Cycler so that any fluids dripping from the Cycler or Cartridge fall directly onto the device.

When choosing a leak detection device, make sure it can:

- detect blood or conductive fluid when in contact with the sensor and trigger an audible alarm loud enough to interrupt sleep;
- be positioned in a way that allows leaking blood or fluid to fall directly onto the sensor; and
- be tested for functionality before use.

The following fluid leak detection device has been validated for use with the NxStage System One to detect fluid and blood leaks from the Cycler or Cartridge:

- NxStage Fluid Detection System

Other devices that meet the requirements above may be available.

This page intentionally left blank.

NxStage Customer Service Center (United States only)

Tel: 1-866-NXSTAGE (1-866-697-8243)

Fax: 1-978-687-4809

Email: customerservice@nxstage.com

Outside the United States, contact your local distributor.

CE 0413

EC REP

MEDISYSTEMS EUROPE, S.p.A.
Via G. Galilei, 20
Sorbara Di Bomporto (MO)
Italy 41030

NxSTAGE Invent. Improve. Inspire.

NxStage Medical, Inc.
350 Merrimack Street
Lawrence, MA 01843 USA

Contains Nonbinding Recommendations

Print Form

Acceptance Checklist for Traditional 510(k)s

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.

510(k) #: K141752 Date Received by DCC: Jun 30, 2014

Lead Reviewer: David Pudwill

Branch: RNDB Division: DRGUD Center/Office: CDRH/ODE

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete. It means the reviewer did not assess the element during RTA and the element will be assessed during the substantive review.

Preliminary Questions **Answers in the shaded blocks indicate consultations with Center advisor is needed**	Yes	No
1) Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)? If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Office Jurisdiction Liaison to determine the appropriate action, and inform division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If the product does not appear to be a device or such a combination product, mark "No."	×	
Comments?		
2. Is the application with the appropriate Center? If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the application is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or CBER Office Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If application should not be reviewed by your Center mark "No."	×	
Comments?		
3) If a Request for Designation was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following: a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission? b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission ? If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Jurisdictional Officer or appropriate CBER Jurisdiction Liaison to determine the appropriate action and inform your division management. Provide summary of Jurisdictional Officer's/Liaison's determination. If the answer to either question is no, mark "No." If there was no RFD, skip this question.		
Comments?		
4) Is this device type eligible for a 510(k) submission? If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), you should consult with the CDRH 510(k) Program Director or appropriate CBER staff during the acceptance review. If 510(k) is not the appropriate regulatory submission, mark "No."	×	
Comments?		

5) Is there a pending PMA for the same device with the same indications for use? If yes, consult division management and the CDRH 510(k) Program Director or appropriate CBER staff to determine the appropriate action.		X
Comments?		
6) If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)? If yes, consult with the CDRH Office of Compliance/Division of Bioresearch Monitoring (OC/DBM - BIMO) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action. Check on web at http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm		X
Comments?		

If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and issue the "Original Jurisdictional Product" letter.
If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Jurisdictional Officer or CBER Office of Jurisdiction Liaison.
If the answer to 4 is "No," the lead reviewer should consult division management and other Center resources to determine the appropriate action.
If the answer to 5 is "Yes," then stop review of the 510(k), contact the CDRH 510(k) Staff and PMA Staff, or appropriate CBER staff.
If the answer to 6 is "Yes," then contact CDRH/OC/DBM-BIMO or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with the BIMO Staff, and indicate BIMO's recommendation/action.

Organizational Elements

Failure to include these items alone generally should not result in an RTA designation.

	Yes	No
1) Submission contains a Table of Contents	X	
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	X	
3) All pages of the submission are numbered.	X	
4) Type of 510(k) is identified (i.e., traditional, abbreviated, or special)	X	
Comments?		

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
A. Administrative				
1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	X			
2) Submission identifies the following (such as in CDRH Premarket Review Submission Cover Sheet (Form 3514) or 510(k) cover letter):	X			
a) Device trade name or proprietary name	X			
b) Device common name	X			
c) Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	X			
3) Submission contains Indications for Use Statement with Rx and/or OTC designation (see also 21 CFR 801.109).	X			
4) Submission contains 510(k) Summary or 510(k) Statement	X			X
a) Summary contains all elements per 21 CFR 807.92 *(See also 510(k) Summary Checklist)*		X		
b) Statement contains all elements per 21 CFR 807.93			X	

(b)(4) Confidential and Proprietary Information

[redacted]

5) Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k) *See recommended* format.	X			
6) Submission contains Class III Summary and Certification. *See recommended* content			X	
7) Submission contains clinical data	X			
a) Submission includes completed Financial Certification (Form 3454) or Disclosure (Form 3455) information for each covered clinical study included in the submission.	X			
b) Submission includes completed Certification of Compliance with the requirements of ClinicalTrials.gov Data Bank (Form 3674) (42 U.S.C. 282(j)(5)(B)) for each applicable device clinical trial included in the submission.	X			

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
8) If submission references use of a national or international standard as part of demonstration of substantial equivalence, submission contains Standards Data Report for 510(k)s (Form 3654) or includes detailed information about how and the extent to which the standard has been followed.	X			
9) The submission identifies prior submissions for the same device for which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., submission numbers for Pre-Submission, IDE, prior not substantially equivalent (NSE) determination, prior 510(k) that was deleted or withdrawn) or states that there were no prior submissions for the subject device.	X			X
a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence outlined in prior communications are addressed. For additional information regarding the Pre-Submission process, please refer to the Draft Guidance "Medical Devices: The Pre-Submission Program and Meetings with FDA Staff." Once finalized, this guidance will represent the Agency's current thinking on this topic.		X		

(b)(4) Confidential and Proprietary Information

[redacted]

B. Device Description

10)				
a) If there are requirements regarding the device description, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes device description information to establish that the submitter has followed the device-specific requirement.	X			
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes device description information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	
11) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including:				X
a) A description of the principle of operation and mechanism of action for achieving the intended effect.	X			
b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	X			
c) A list and description of each device for which clearance is requested.		X		

(b)(4) Confidential and Proprietary Information

[redacted]

12) Submission contains representative engineering drawing(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled, and include dimensions.	X			

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
13) If device is intended to be marketed with multiple components, accessories, and/or as part of a system				X
a) Submission includes a list of all components and accessories to be marketed with the subject device.		X		
b) Submission includes a description (as detailed in item 11(a) and (b) and 12 above) of each component or accessory.		X		
c) A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance.	X			

(b)(4) Confidential and Proprietary Information

C. Substantial Equivalence Discussion

14) Submitter has identified a predicate device.	X			
a) Predicate's 510(k) number, trade name, and model number (if applicable) provided. For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding* documenting preamendment status *is available online.*	X			
b) The identified predicate(s) is consistent throughout the submission (i.e., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing.	X			
15) Submission includes a comparison of the following for the predicate(s) and subject device				
a) Indications for Use	X			
b) Technology, including features, materials, and principles of operation	X			
16) Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., does not constitute a new intended use; and any differences in technological characteristics are accompanied by information that demonstrates the device is as safe and effective as the predicate and do not raise different questions of safety and effectiveness than the predicate), affect safety or effectiveness, or raise different questions of safety and effectiveness (see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f))	X			

D. Proposed Labeling (see also 21 CFR part 801)

If *in vitro* diagnostic (IVD) device, criteria 17 & 19 may be omitted.

17) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual) that include a description of the device, its intended use, and the directions for use.	X			
a) Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided).	X			
b) Submission includes directions for use that - include statements of all conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) AND - includes directions for layperson (see 21 CFR 801.5) OR submission states that device qualifies for exemption per 21 CFR 801 Subpart D	X			

Elements of a Complete Submission (RTA Items)
(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
18) If indicated for prescription use, labeling includes the prescription use statement (see 21 CFR 801.109(b)(1)) or "Rx only" symbol [See also Alternative to Certain Prescription Device Labeling Requirements]	X			
19) General labeling provisions				
a) Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1).	X			
b) Labeling includes device common or usual name. (21 CFR 801.61)	X			
20)				
a) If there are requirements regarding labeling, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes labeling to establish that the submitter has followed the device-specific requirement.	X			
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes labeling to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	
c) If there is a special controls document applicable to the device, the submission includes labeling to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.	X			
21) If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10.			X	
E. Sterilization				
If IVD device and sterilization is not applicable, select "N/A" and criteria below will be omitted from checklist.			X	X
(b)(4) Confidential and Proprietary Information [redacted]				
F. Shelf Life				
26) Proposed shelf life/expiration date stated			X	
27) For sterile device, submission includes summary of methods used to establish that device will remain sterile through the proposed shelf life or a rationale for why testing to establish shelf life is not applicable.			X	
28) Submission includes summary of methods used to establish that device performance is not adversely affected by aging or includes a rationale for why the storage conditions are not expected to affect device safety or effectiveness.	X			
G. Biocompatibility				
If IVD device, select "N/A" and the below criteria will be omitted from checklist.			X	X

Elements of a Complete Submission (RTA Items)
(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment

(b)(4) Confidential and Proprietary Information

H. Software

Submission states that the device: (one of the below must be checked)

X	does contain software/firmware.
	does not contain software/firmware.
	Information regarding whether the device contains software is not provided.

This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.

32) Submission includes a statement of software level of concern and rationale for the software level of concern.	X			
33) All applicable software documentation provided based on level of concern identified by the submitter, as described in Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, or the submitter has provided an alternative approach with a rationale.	X			

I. EMC and Electrical Safety

Submission states that the device: (one of the below must be checked)

X	does require EMC and Electrical Safety evaluation.
	does not require EMC and Electrical Safety evaluation.
	Information regarding whether the device requires EMC and Electrical Safety evaluation is not provided.

This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.

34) Submission includes evaluation of electrical safety (e.g., per IEC 60601-1, or equivalent FDA-recognized standard, and if applicable, the device-specific standard), OR submission includes electrical safety evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).	X			X

(b)(4) Confidential and Proprietary Information

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
35) Submission includes evaluation of electromagnetic compatibility (e.g., per IEC 60601-1-2 or equivalent FDA-recognized standard and if applicable, the device-specific standard) OR submission includes electromagnetic compatibility evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).	X			X

(b)(4) Confidential and Proprietary Information

[redacted]

J. Performance Data - General If IVD device, select "N/A" and the below criteria will be omitted from checklist. Performance data criteria relating to IVD devices will be addressed in Section K.				
36) Full test report is provided for each completed test. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre-defined pass/fail criteria, results summary, conclusions, and an explanation of how the data generated from the test supports a finding of substantial equivalence.	X			
37)				
a) If there are requirements regarding performance data, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes performance data to establish that the submitter has followed the device-specific requirement.	X			
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes performance data to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	
c) If there is a special controls document applicable to the device, the submission includes performance data to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.	X			
38) If literature is referenced in the submission, submission includes:			X	
39) For each completed nonclinical (i.e., animal) study conducted			X	

K. Performance Characteristics - In Vitro Diagnostic Devices Only **(Also see 21 CFR 809.10(b)(12))**	
Submission states that the device: (one of the below must be checked)	
	is an in vitro diagnostic device.
X	is not an in vitro diagnostic device.

Decision: ○ Accept ◉ Refuse to Accept

If Accept, notify applicant.

If Refuse to Accept, notify applicant in writing and include a copy of this checklist.

Digital Signature Concurrence Table

Reviewer Sign-Off	David A. Pudwill -S 2014.07.11 15:33:48 -04'00'
Branch Chief Sign-Off (digital signature optional)*	Frank Hurst -S Acting for CYN 2014.07.11 17:05:16 -04'00'
Division Sign-Off (digital signature optional)*	Glenn B. Bell -S 2014.07.11 17:30:12 -04'00'

* Branch and Division review of checklist and concurrence with decision required. Branch and Division digital signature optional.

NxStage Medical, Inc.
NxStage System One
510(k) Premarket Notification

This 510(k) Summary is being submitted in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990. The content contained in this 510(k) summary has been provided in conformance with 21 CFR §807.92

A. Date Prepared: June 27, 2014

B. Submitter's Information:

Name:	NxStage Medical, Inc.
Address:	350 Merrimack Street Lawrence, MA 01843
FDA Establishment Owner/Operator Number:	9045797
Contact Person:	Mary Lou Stroumbos Director, Regulatory Affairs
Phone:	(978) 687-4872
Fax:	(978) 687-4750
Manufacturer:	NxStage Medical, Inc. 350 Merrimack Street Lawrence, MA 01843
FDA Establishment Registration Number:	3003464075
Sterilization Site:	Steris Isomedix (NxStage Cartridge Express) 1000 S. Sarah Place Ontario, CA 91761

C. Device Name:

Trade/Proprietary Name:	NxStage System One
Common/Usual Name:	Hemodialysis System
Classification Name:	High Permeability Hemodialysis System
Regulation Number:	876.5860
Product Code:	ODN
Device Classification:	Class II
Device Panel:	Gastroenterology/Urology

D. Substantial Equivalence:

The NxStage System One has the same intended use and utilizes the same fundamental technology as the predicate NxStage System One. The NxStage System One has been compared to the legally marketed predicate device as cleared through K140526 (May 19, 2014) and was found to be substantially equivalent.

E. Device Description/Indications for Use:

The NxStage System One is comprised of the NxStage Cycler, an electromechanical control unit; the NxStage Cartridge, a sterile, single-use extracorporeal blood and fluid management circuit (with or without a pre-attached high permeability filter) that mounts integrally within the NxStage Cycler. The combined system is designed to deliver hemofiltration, hemodialysis and/or ultrafiltration in an acute or chronic care facility. The NxStage System One is also indicated for home hemodialysis, including home nocturnal hemodialysis.

Indications for use:

The NxStage System One is indicated for the treatment of acute and chronic renal failure or fluid overload using hemofiltration, hemodialysis, and/or ultrafiltration, in an acute or chronic care facility.

The System is also indicated for home hemodialysis, including home nocturnal hemodialysis.

All treatments must be administered under physician's prescription, and must be performed by a trained and qualified person, considered to be competent in the use of this device by the prescribing physician.

F. Technological Characteristics:

The proposed device has the same technological characteristics and is similar in design and configuration as compared to the predicate device. The proposed device is designed with similar software, components and features also used in the predicate device.

Table 1
Device Technological Characteristics Comparison Table

Parameter	Proposed Device NxStage System One	Predicate Device NxStage System One (K140526)
Intended Use		
Hemodialysis	Yes	Yes
Hemofiltration	Yes	Yes
Ultrafiltration	Yes	Yes
Technology / Components:		
Pumps	Same	4 peristaltic pumps
Valves (clamps)	Same	2 solenoid actuated pinch clamps
	Same	8 cam driven pinch clamps
Air / fluid detectors	Same	3 ultrasonic air/ fluid detectors
Blood leak detector	Same	1 optical blood leak detector
Pressure transducers	Same	5 electronic pressure transducers
Temperature sensors	Same	1 electronic temperature sensor

NxStage Medical, Inc.
NxStage System One
510(k) Premarket Notification

Table 1
Device Technological Characteristics Comparison Table

Parameter	**Proposed Device NxStage System One**	**Predicate Device NxStage System One (K140526)**
Flow Rates:		
Blood	Same	10-600 ml/min
Prescription Fluid /Dialysate Flow	Same	0-18000 ml/hr
Ultrafiltration	Same	0-2400 ml/hr
Transmembrane Pressure Monitoring Specification	Same	Yes
Venous Pressure Monitor	Same	0 to 400 mmHg
Effluent fluid Pressure Monitor	Same	0 to 500 mmHg
Air Detector	Same	Reduction of detector signal lasting 6 ms minimum (Approximates a 60 micro liter bubble at 400 mmHg venous pressure and 600 ml/min blood flow)
Blood Leak Detector	Same	15% reduction in detector signal lasting 20 seconds minimum. Signal reduction % based on a 0.35 ml/min leak rate of 32 Hct blood.
Effluent Volume Accuracy	Same	Greater of 300 ml/ 12 hr or 3% of exchange volume (For software versions 4.7 and below) For software versions 4.8 and higher: Therapy Fluid Flow Rate L/hr) / Specification greater of > 3 / + 5% UF* or / ±100 ml/hr* ≤ 3 / + 5% UF* or / ± 25 ml/hr* *Representing 95/90 tolerance interval established under controlled laboratory testing conditions.
IV Prescription Fluid	Same	Off-line, sterile- physician prescribed, indicated for infusion
Dialysate	Same	Dialysate available as pre-packaged pre-mixed sterile fluids or via the PureFlow SL (K043436 K060296, K090919, K111174 & K140571)
Compatible Blood Tubing Set	Same	NxStage Standard Cartridge
Software	Software version 4.10	Software version 4.9

G. Summary of Non-Clinical Test/Performance Testing – Bench and Clinical Testing

NxStage believes that the information and data provided in this submission clearly describes the proposed device and demonstrates that the device is adequately designed for the labeled indications for use. Performance, verification and validation; and clinical testing was conducted to characterize performance of the proposed device and the predetermined acceptance criteria were met.

The following non-clinical testing was conducted:

- System Verification and Software Validation
  - Software verification & validation
  - Regression testing
  - Safety systems verification
  - Labeling verification testing
  - Simulated dialysis treatments

The following clinical testing was conducted:

Clinical testing included 2 crossover studies with a total of 58 patients. There were 38 in the first study and 20 in the second study. Results were provided separately and pooled together to show substantial equivalence of nocturnal hemodialysis to daily hemodialysis in the home setting.

Pivotal Studies:

NxStage conducted a US prospective, multi-center, two-treatment, two-phase, open-label, cross-over Investigational Device Exemption clinical study titled "Comparison of Nocturnal Hemodialysis (NHD) and Short Daily Hemodialysis (DHD) with the NxStage System One." The objective of the study was to determine whether or not NHD (6-10 hours) was substantially equivalent to DHD (2-4 hours) on a per treatment basis, using the NxStage System One (NSO) in the home setting. The first phase (DHD) consisted of 2 to 4 hour treatments, and the second phase (NHD) consisted of 6 to 10 hour treatments. Both phases consisted of either 5 or 6 treatments per week over an 8 week period (40 or 48 treatments in total) using the NSO in the home environment. A 4 week training/transition period took place between the two phases. A total of 58 End Stage Renal Disease (ESRD)

patients >18 years of age who were currently stable on home DHD were enrolled, of which 39 completed the study period and 19 discontinued.

Primary effectiveness endpoint:
The primary efficacy endpoint for the study was the ability to deliver the clinically prescribed amount of therapy, defined by attainment of a delivered volume that was at least 90% of the prescribed volume (10% difference in success rate is the upper boundary of the 95% confidence interval).

Primary safety endpoint:
The primary safety endpoint was the composite intradialytic and interdialytic adverse event (AE) profile.

Effectiveness:
The primary endpoint for the study focused on the ability to deliver the clinically prescribed amount of therapy (success or failure). For the ITT population, the probability of a successful treatment was 90.9% in the DHD phase versus 91.7% in the NHD phase. The upper limit of the confidence interval (2.9%) was less than the protocol-specified limit (10%). Hence, the treatment success rates were similar and the protocol specified non-inferiority criterion was attained.

Safety:
For the ITT population, the composite AE rate per 100 treatments was 8.3 in the DHD phase versus 6.9 in the NHD phase. The event profiles were similar for both phases. Results were similar for the PP population.

The study reported one death not related to study participation or the study device and no unanticipated adverse device effects. In the DHD phase there were 21 severe AEs reported, and in the NHD phase there were 6 severe AEs reported. Device relatedness was recorded as cannot be ruled out for one of the severe AEs: patient was unable to self-cannulate due to a non-dialysis related surgery. The remaining 26 severe AEs were considered not related to the device. The rate of severe AEs per 100 treatments was 0.9 for DHD vs. 0.3 for NHD.

The most commonly occurring AEs were OTH-other, hypotension, and muscle cramping. OTH-other included non-dialysis related injuries and surgeries (e.g. broken ankle, knee surgery, toe infection, etc.), out of range blood laboratory values, access related events, episodes of depression, infection, kidney stone, and other isolated events. OTH-other occurred at a rate of 1.3 vs. 1.6 per 100 treatments in DHD vs. NHD, respectively. Hypotension occurred at a rate of 1.9 vs. 0.2 per 100 treatments. The rate of muscle cramping was 1.1 per 100 treatments for both study phases.

The rates of adverse events were similar in the DHD and NHD phases, and the events experienced were typical of those commonly reported for dialysis patients, including episodes of hypotension and muscle cramping.

Summary

Based on the clinical performance as documented in the pivotal clinical studies, the NxStage System One in the home setting delivers NHD therapy that is substantially equivalent to DHD therapy on a per treatment basis.

Conclusion: Results of the non-clinical testing and clinical data have documented that the proposed NxStage System One is substantially equivalent to the predicate device and is suitable for the labeled indications for use.

NxStage Medical, Inc.
NxStage System One
510(k) Premarket Notification

This 510(k) Summary is being submitted in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990. The content contained in this 510(k) summary has been provided in conformance with 21 CFR §807.92

A. Date Prepared: June 27, 2014

B. Submitter's Information:

Name:	NxStage Medical, Inc.
Address:	350 Merrimack Street Lawrence, MA 01843
FDA Establishment Owner/Operator Number:	9045797
Contact Person:	Mary Lou Stroumbos Director, Regulatory Affairs
Phone:	(978) 687-4872
Fax:	(978) 687-4750
Manufacturer:	NxStage Medical, Inc. 350 Merrimack Street Lawrence, MA 01843
FDA Establishment Registration Number:	3003464075
Sterilization Site:	Steris Isomedix (NxStage Cartridge Express) 1000 S. Sarah Place Ontario, CA 91761

C. Device Name:

Trade/Proprietary Name:	NxStage System One
Common/Usual Name:	Hemodialysis System
Classification Name:	High Permeability Hemodialysis System
Regulation Number:	876.5860
Product Code:	ODN
Device Classification:	Class II
Device Panel:	Gastroenterology/Urology

D. Substantial Equivalence:

The NxStage System One has the same intended use and utilizes the same fundamental technology as the predicate NxStage System One. The NxStage System One has been compared to the legally marketed predicate device as cleared through K140526 (May 19, 2014) and was found to be substantially equivalent.

E. Device Description/Indications for Use:

The NxStage System One is comprised of the NxStage Cycler, an electromechanical control unit; the NxStage Cartridge, a sterile, single-use extracorporeal blood and fluid management circuit (with or without a pre-attached high permeability filter) that mounts integrally within the NxStage Cycler. The combined system is designed to deliver hemofiltration, hemodialysis and/or ultrafiltration in an acute or chronic care facility. The NxStage System One is also indicated for home hemodialysis, including home nocturnal hemodialysis.

Indications for use:

The NxStage System One is indicated for the treatment of acute and chronic renal failure or fluid overload using hemofiltration, hemodialysis, and/or ultrafiltration, in an acute or chronic care facility.

The System is also indicated for home hemodialysis, including home nocturnal hemodialysis.

All treatments must be administered under physician's prescription, and must be performed by a trained and qualified person, considered to be competent in the use of this device by the prescribing physician.

F. Technological Characteristics:

The proposed device has the same technological characteristics and is similar in design and configuration as compared to the predicate device. The proposed device is designed with similar software, components and features also used in the predicate device.

Table 1
Device Technological Characteristics Comparison Table

Parameter	Proposed Device NxStage System One	Predicate Device NxStage System One (K140526)
Intended Use		
Hemodialysis	Yes	Yes
Hemofiltration	Yes	Yes
Ultrafiltration	Yes	Yes
Technology / Components:		
Pumps	Same	4 peristaltic pumps
Valves (clamps)	Same	2 solenoid actuated pinch clamps
	Same	8 cam driven pinch clamps
Air / fluid detectors	Same	3 ultrasonic air/ fluid detectors
Blood leak detector	Same	1 optical blood leak detector
Pressure transducers	Same	5 electronic pressure transducers
Temperature sensors	Same	1 electronic temperature sensor

NxStage Medical, Inc.
NxStage System One
510(k) Premarket Notification

Table 1
Device Technological Characteristics Comparison Table

Parameter	**Proposed Device NxStage System One**	**Predicate Device NxStage System One (K140526)**
Flow Rates:		
Blood	Same	10-600 ml/min
Prescription Fluid /Dialysate Flow	Same	0-18000 ml/hr
Ultrafiltration	Same	0-2400 ml/hr
Transmembrane Pressure Monitoring Specification	Same	Yes
Venous Pressure Monitor	Same	0 to 400 mmHg
Effluent fluid Pressure Monitor	Same	0 to 500 mmHg
Air Detector	Same	Reduction of detector signal lasting 6 ms minimum (Approximates a 60 micro liter bubble at 400 mmHg venous pressure and 600 ml/min blood flow)
Blood Leak Detector	Same	15% reduction in detector signal lasting 20 seconds minimum. Signal reduction % based on a 0.35 ml/min leak rate of 32 Hct blood.
Effluent Volume Accuracy	Same	Greater of 300 ml/ 12 hr or 3% of exchange volume (For software versions 4.7 and below) For software versions 4.8 and higher: Therapy Fluid Flow Rate L/hr) / Specification greater of > 3 / + 5% UF* or / ±100 ml/hr* ≤ 3 / + 5% UF* or / ± 25 ml/hr* *Representing 95/90 tolerance interval established under controlled laboratory testing conditions.
IV Prescription Fluid	Same	Off-line, sterile- physician prescribed, indicated for infusion
Dialysate	Same	Dialysate available as pre-packaged pre-mixed sterile fluids or via the PureFlow SL (K043436 K060296, K090919, K111174 & K140571)
Compatible Blood Tubing Set	Same	NxStage Standard Cartridge
Software	Software version 4.10	Software version 4.9

G. Summary of Non-Clinical Test/Performance Testing – Bench and Clinical Testing

NxStage believes that the information and data provided in this submission clearly describes the proposed device and demonstrates that the device is adequately designed for the labeled indications for use. Performance, verification and validation; and clinical testing was conducted to characterize performance of the proposed device and the predetermined acceptance criteria were met.

The following non-clinical testing was conducted:

- System Verification and Software Validation
  - Software verification & validation
  - Regression testing
  - Safety systems verification
  - Labeling verification testing
  - Simulated dialysis treatments

The following clinical testing was conducted:

Clinical testing included 2 crossover studies with a total of 58 patients. There were 38 in the first study and 20 in the second study. Results were provided separately and pooled together to show substantial equivalence of nocturnal hemodialysis to daily hemodialysis in the home setting.

Pivotal Studies:

NxStage conducted a US prospective, multi-center, two-treatment, two-phase, open-label, cross-over Investigational Device Exemption clinical study titled "Comparison of Nocturnal Hemodialysis (NHD) and Short Daily Hemodialysis (DHD) with the NxStage System One." The objective of the study was to determine whether or not NHD (6-10 hours) was substantially equivalent to DHD (2-4 hours) on a per treatment basis, using the NxStage System One (NSO) in the home setting. The first phase (DHD) consisted of 2 to 4 hour treatments, and the second phase (NHD) consisted of 6 to 10 hour treatments. Both phases consisted of either 5 or 6 treatments per week over an 8 week period (40 or 48 treatments in total) using the NSO in the home environment. A 4 week training/transition period took place between the two phases. A total of 58 End Stage Renal Disease (ESRD)

patients >18 years of age who were currently stable on home DHD were enrolled, of which 39 completed the study period and 19 discontinued.

Primary effectiveness endpoint:
The primary efficacy endpoint for the study was the ability to deliver the clinically prescribed amount of therapy, defined by attainment of a delivered volume that was at least 90% of the prescribed volume (10% difference in success rate is the upper boundary of the 95% confidence interval).

Primary safety endpoint:
The primary safety endpoint was the composite intradialytic and interdialytic adverse event (AE) profile.

Effectiveness:
The primary endpoint for the study focused on the ability to deliver the clinically prescribed amount of therapy (success or failure). For the ITT population, the probability of a successful treatment was 90.9% in the DHD phase versus 91.7% in the NHD phase. The upper limit of the confidence interval (2.9%) was less than the protocol-specified limit (10%). Hence, the treatment success rates were similar and the protocol specified non-inferiority criterion was attained.

Safety:
For the ITT population, the composite AE rate per 100 treatments was 8.3 in the DHD phase versus 6.9 in the NHD phase. The event profiles were similar for both phases. Results were similar for the PP population.

The study reported one death not related to study participation or the study device and no unanticipated adverse device effects. In the DHD phase there were 21 severe AEs reported, and in the NHD phase there were 6 severe AEs reported. Device relatedness was recorded as cannot be ruled out for one of the severe AEs: patient was unable to self-cannulate due to a non-dialysis related surgery. The remaining 26 severe AEs were considered not related to the device. The rate of severe AEs per 100 treatments was 0.9 for DHD vs. 0.3 for NHD.

The most commonly occurring AEs were OTH-other, hypotension, and muscle cramping. OTH-other included non-dialysis related injuries and surgeries (e.g. broken ankle, knee surgery, toe infection, etc.), out of range blood laboratory values, access related events, episodes of depression, infection, kidney stone, and other isolated events. OTH-other occurred at a rate of 1.3 vs. 1.6 per 100 treatments in DHD vs. NHD, respectively. Hypotension occurred at a rate of 1.9 vs. 0.2 per 100 treatments. The rate of muscle cramping was 1.1 per 100 treatments for both study phases.

The rates of adverse events were similar in the DHD and NHD phases, and the events experienced were typical of those commonly reported for dialysis patients, including episodes of hypotension and muscle cramping.

Summary

Based on the clinical performance as documented in the pivotal clinical studies, the NxStage System One in the home setting delivers NHD therapy that is substantially equivalent to DHD therapy on a per treatment basis.

Conclusion: Results of the non-clinical testing and clinical data have documented that the proposed NxStage System One is substantially equivalent to the predicate device and is suitable for the labeled indications for use.

INDICATIONS FOR USE

510(k) Number (if known): K141752

Device Name: NxStage® System One™

Indications for Use: The NxStage System One is indicated for the treatment of acute and chronic renal failure, or fluid overload using hemofiltration, hemodialysis, and/or ultrafiltration, in an acute or chronic care facility.

The System is also indicated for home hemodialysis, including home nocturnal hemodialysis.

All treatments must be administered under physician's prescription, and must be performed by a trained and qualified person, considered to be competent in the use of this device by the prescribing physician.

Prescription Use ___X____ **AND/OR** **Over-The-Counter Use_____**
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

INDICATIONS FOR USE

510(k) Number (if known): K141752

Device Name: NxStage® System One™

Indications for Use: The NxStage System One is indicated for the treatment of acute and chronic renal failure, or fluid overload using hemofiltration, hemodialysis, and/or ultrafiltration, in an acute or chronic care facility.

The System is also indicated for home hemodialysis, including home nocturnal hemodialysis.

All treatments must be administered under physician's prescription, and must be performed by a trained and qualified person, considered to be competent in the use of this device by the prescribing physician.

Prescription Use ___X____ **AND/OR** **Over-The-Counter Use_____**
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 19, 2014

NxStage Medical, Inc.
Mary Lou Strombos
Director, Regulatory Affairs
350 Merrimack Street
Lawrence, MA 01843

Re: K141752
Trade/Device Name: NxStage System One
Regulation Number: 21 CFR 876.5860
Regulation Name: High Permeability Hemodialysis System
Regulatory Class: Class II
Product Code: ODN
Dated: November 20, 2014
Received: November 21, 2014

Dear Mary Lou Strombos,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Contains Nonbinding Recommendations

Print Form

Acceptance Checklist for Traditional 510(k)s

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.

510(k) #: K141752 Date Received by DCC: Jul 25, 2014

Lead Reviewer: David Pudwill

Branch: RNDB Division: DRGUD Center/Office: CDRH/ODE

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete. It means the reviewer did not assess the element during RTA and the element will be assessed during the substantive review.

Preliminary Questions **Answers in the shaded blocks indicate consultations with Center advisor is needed**	Yes	No
1) Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)? If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Office Jurisdiction Liaison to determine the appropriate action, and inform division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If the product does not appear to be a device or such a combination product, mark "No."	X	
Comments?		
2. Is the application with the appropriate Center? If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the application is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or CBER Office Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If application should not be reviewed by your Center mark "No."	X	
Comments?		
3) If a Request for Designation was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following: a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission? b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission ? If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Jurisdictional Officer or appropriate CBER Jurisdiction Liaison to determine the appropriate action and inform your division management. Provide summary of Jurisdictional Officer's/Liaison's determination. If the answer to either question is no, mark "No." If there was no RFD, skip this question.		
Comments?		
4) Is this device type eligible for a 510(k) submission? If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), you should consult with the CDRH 510(k) Program Director or appropriate CBER staff during the acceptance review. If 510(k) is not the appropriate regulatory submission, mark "No."	X	
Comments?		

5) Is there a pending PMA for the same device with the same indications for use? If yes, consult division management and the CDRH 510(k) Program Director or appropriate CBER staff to determine the appropriate action.		X
Comments?		
6) If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)? If yes, consult with the CDRH Office of Compliance/Division of Bioresearch Monitoring (OC/DBM - BIMO) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action. Check on web at http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm		X
Comments?		

If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and issue the "Original Jurisdictional Product" letter.
If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Jurisdictional Officer or CBER Office of Jurisdiction Liaison.
If the answer to 4 is "No," the lead reviewer should consult division management and other Center resources to determine the appropriate action.
If the answer to 5 is "Yes," then stop review of the 510(k), contact the CDRH 510(k) Staff and PMA Staff, or appropriate CBER staff.
If the answer to 6 is "Yes," then contact CDRH/OC/DBM-BIMO or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with the BIMO Staff, and indicate BIMO's recommendation/action.

Organizational Elements

Failure to include these items alone generally should not result in an RTA designation.

	Yes	No
1) Submission contains a Table of Contents	X	
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	X	
3) All pages of the submission are numbered.	X	
4) Type of 510(k) is identified (i.e., traditional, abbreviated, or special)	X	
Comments?		

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
A. Administrative				
1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	X			
2) Submission identifies the following (such as in CDRH Premarket Review Submission Cover Sheet (Form 3514) or 510(k) cover letter):	X			
a) Device trade name or proprietary name	X			
b) Device common name	X			
c) Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	X			
3) Submission contains Indications for Use Statement with Rx and/or OTC designation (see also 21 CFR 801.109).	X			
4) Submission contains 510(k) Summary or 510(k) Statement	X			
a) Summary contains all elements per 21 CFR 807.92 *(See also 510(k) Summary Checklist)*	X			
b) Statement contains all elements per 21 CFR 807.93			X	
5) Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k) *See recommended format.*	X			
6) Submission contains Class III Summary and Certification. *See recommended content*			X	
7) Submission contains clinical data	X			
a) Submission includes completed Financial Certification (Form 3454) or Disclosure (Form 3455) information for each covered clinical study included in the submission.	X			
b) Submission includes completed Certification of Compliance with the requirements of ClinicalTrials.gov Data Bank (Form 3674) (42 U.S.C. 282(j)(5)(B)) for each applicable device clinical trial included in the submission.	X			
8) If submission references use of a national or international standard as part of demonstration of substantial equivalence, submission contains Standards Data Report for 510(k)s (Form 3654) or includes detailed information about how and the extent to which the standard has been followed.	X			
9) The submission identifies prior submissions for the same device for which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., submission numbers for Pre-Submission, IDE, prior not substantially equivalent (NSE) determination, prior 510(k) that was deleted or withdrawn) or states that there were no prior submissions for the subject device.	X			
a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence outlined in prior communications are addressed. For additional information regarding the Pre-Submission process, please refer to the Draft Guidance "Medical Devices: The Pre-Submission Program and Meetings with FDA Staff." Once finalized, this guidance will represent the Agency's current thinking on this topic.	X			

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
B. Device Description				
10)				
a) If there are requirements regarding the device description, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes device description information to establish that the submitter has followed the device-specific requirement.	X			
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes device description information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	
11) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including:				
a) A description of the principle of operation and mechanism of action for achieving the intended effect.	X			
b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	X			
c) A list and description of each device for which clearance is requested.	X			
12) Submission contains representative engineering drawing(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled, and include dimensions.	X			
13) If device is intended to be marketed with multiple components, accessories, and/or as part of a system				
a) Submission includes a list of all components and accessories to be marketed with the subject device.	X			
b) Submission includes a description (as detailed in item 11(a) and (b) and 12 above) of each component or accessory.	X			
c) A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance.	X			
C. Substantial Equivalence Discussion				
14) Submitter has identified a predicate device.	X			
a) Predicate's 510(k) number, trade name, and model number (if applicable) provided. For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding* documenting preamendment status *is available online.*	X			
b) The identified predicate(s) is consistent throughout the submission (i.e., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing.	X			
15) Submission includes a comparison of the following for the predicate(s) and subject device				
a) Indications for Use	X			

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
b) Technology, including features, materials, and principles of operation	X			
16) Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., does not constitute a new intended use; and any differences in technological characteristics are accompanied by information that demonstrates the device is as safe and effective as the predicate and do not raise different questions of safety and effectiveness than the predicate), affect safety or effectiveness, or raise different questions of safety and effectiveness (see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f))	X			
D. Proposed Labeling (see also 21 CFR part 801)				
If *in vitro* diagnostic (IVD) device, criteria 17 & 19 may be omitted.				
17) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual) that include a description of the device, its intended use, and the directions for use.	X			
a) Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided).	X			
b) Submission includes directions for use that - include statements of all conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) AND - includes directions for layperson (see 21 CFR 801.5) OR submission states that device qualifies for exemption per 21 CFR 801 Subpart D	X			
18) If indicated for prescription use, labeling includes the prescription use statement (see 21 CFR 801.109(b)(1)) or "Rx only" symbol [See also Alternative to Certain Prescription Device Labeling Requirements]	X			
19) General labeling provisions				
a) Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1).	X			
b) Labeling includes device common or usual name. (21 CFR 801.61)	X			
20)				
a) If there are requirements regarding labeling, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes labeling to establish that the submitter has followed the device-specific requirement.	X			
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes labeling to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	
c) If there is a special controls document applicable to the device, the submission includes labeling to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.	X			

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
21) If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10.			X	
E. Sterilization				
If IVD device and sterilization is not applicable, select "N/A" and criteria below will be omitted from checklist.			X	X
(b)(4) Confidential and Proprietary Information				
F. Shelf Life				
26) Proposed shelf life/expiration date stated			X	
27) For sterile device, submission includes summary of methods used to establish that device will remain sterile through the proposed shelf life or a rationale for why testing to establish shelf life is not applicable.			X	
28) Submission includes summary of methods used to establish that device performance is not adversely affected by aging or includes a rationale for why the storage conditions are not expected to affect device safety or effectiveness.	X			
G. Biocompatibility				
If IVD device, select "N/A" and the below criteria will be omitted from checklist.			X	X
(b)(4) Confidential and Proprietary Information				
H. Software				
Submission states that the device: (one of the below must be checked)				
X does contain software/firmware.				
does not contain software/firmware.				
Information regarding whether the device contains software is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
32) Submission includes a statement of software level of concern and rationale for the software level of concern.	X			
33) All applicable software documentation provided based on level of concern identified by the submitter, as described in Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, or the submitter has provided an alternative approach with a rationale.	X			
I. EMC and Electrical Safety				
Submission states that the device: (one of the below must be checked)				
X does require EMC and Electrical Safety evaluation.				

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
does not require EMC and Electrical Safety evaluation.				
Information regarding whether the device requires EMC and Electrical Safety evaluation is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
34) Submission includes evaluation of electrical safety (e.g., per IEC 60601-1, or equivalent FDA-recognized standard, and if applicable, the device-specific standard), OR submission includes electrical safety evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).	X			X
(b)(4) Confidential and Proprietary Information [redacted]				
35) Submission includes evaluation of electromagnetic compatibility (e.g., per IEC 60601-1-2 or equivalent FDA-recognized standard and if applicable, the device-specific standard) OR submission includes electromagnetic compatibility evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e. the submitter has identified alternate methods or standards with a rationale).	X			X
(b)(4) Confidential and Proprietary Information [redacted]				
J. Performance Data - General If IVD device, select "N/A" and the below criteria will be omitted from checklist. Performance data criteria relating to IVD devices will be addressed in Section K.				
36) Full test report is provided for each completed test. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre-defined pass/fail criteria, results summary, conclusions, and an explanation of how the data generated from the test supports a finding of substantial equivalence.	X			
37)				
a) If there are requirements regarding performance data, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes performance data to establish that the submitter has followed the device-specific requirement.	X			
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes performance data to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	

Elements of a Complete Submission (RTA Items)
(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
c) If there is a special controls document applicable to the device, the submission includes performance data to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.	X			
38) If literature is referenced in the submission, submission includes:			X	
39) For each completed nonclinical (i.e., animal) study conducted			X	

K. Performance Characteristics - In Vitro Diagnostic Devices Only

(Also see 21 CFR 809.10(b)(12))

Submission states that the device: (one of the below must be checked)

	is an in vitro diagnostic device.
X	is not an in vitro diagnostic device.

Decision: (●) Accept ( ) Refuse to Accept

If Accept, notify applicant.

If Refuse to Accept, notify applicant in writing and include a copy of this checklist.

Digital Signature Concurrence Table

Reviewer Sign-Off	David A. Pudwill -S 2014.08.01 12:38:48 -04'00'
Branch Chief Sign-Off (digital signature optional)*	Carolyn Y. Neuland -S 2014.08.01 22:08:28 -04'00'
Division Sign-Off (digital signature optional)*	Carolyn Y. Neuland -S 2014.08.01 22:08:48 -04'00'

* Branch and Division review of checklist and concurrence with decision required. Branch and Division digital signature optional.

DEPARTMENT OF HEALTH AND HUMAN SERVICES **M E M O R A N D U M**

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Traditional

K141752/S001

Date: September 22, 2014
To: The Record
From: David Pudwill, Biomedical Engineer

Office: ODE
Division: DRGUD
Branch: RNDB

510(k) Holder: NxStage Medical, Inc.
Device Name: NxStage System One for Nocturnal Home Hemodialysis
Contact: Mary Lou Stroumbos
Address: 439 South Union Street 5th Floor
Lawrence, MA 01843
Phone: (978) 687-4872
Fax: (978) 687-4750
Email: mstroumbos@nxstage.com

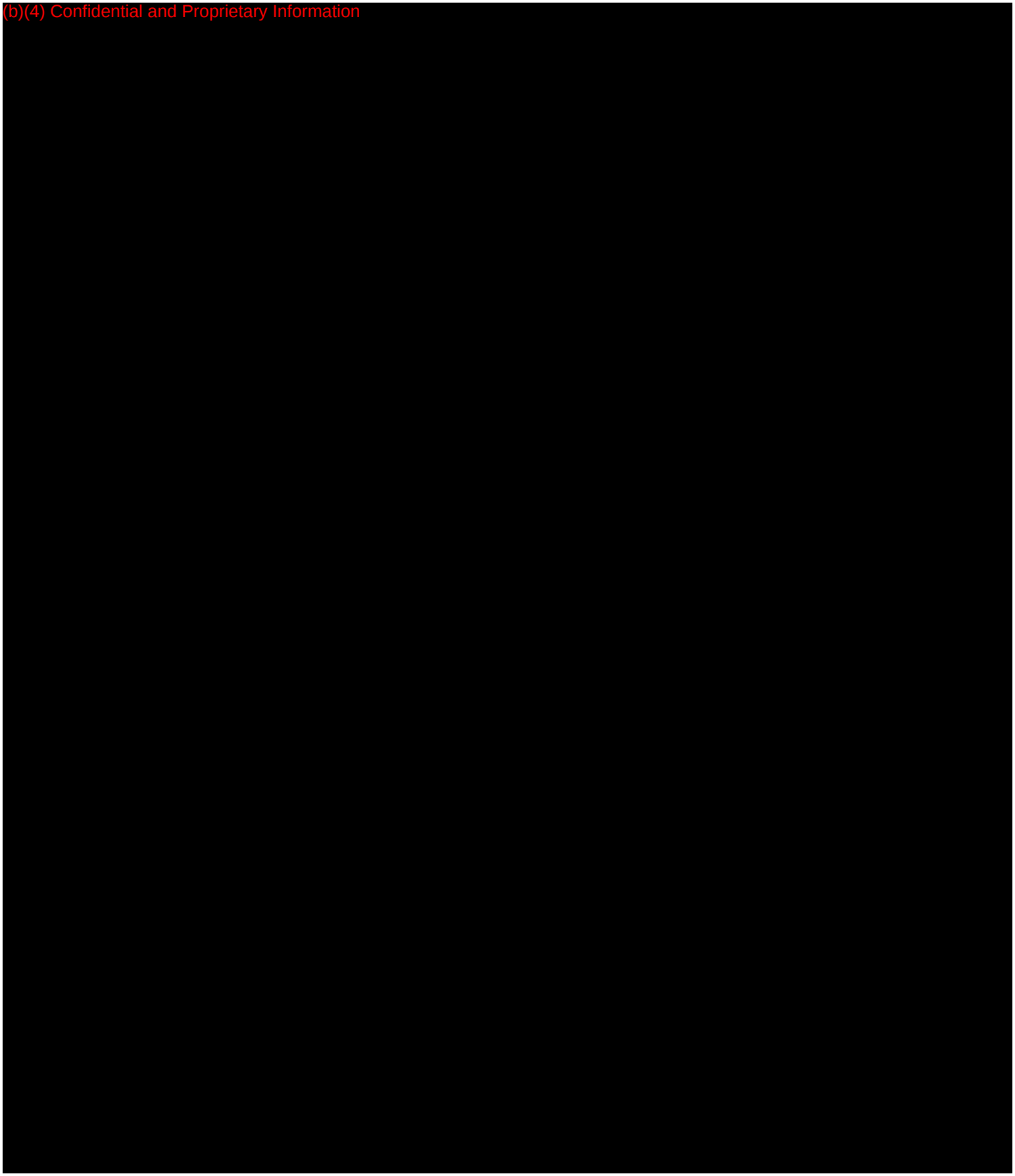
(b)(4) Confidential and Proprietary Information

[redacted]

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	✓		
Truthful and Accuracy Statement	✓		
510(k) Summary or 510(k) Statement	✓		
Standards Form #3654 http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf			✓
Clinical Trials Form http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3674.pdf	✓		

(b)(4) Confidential and Proprietary Information



(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

K141752
NxStage Medical Inc.
NxStage System One

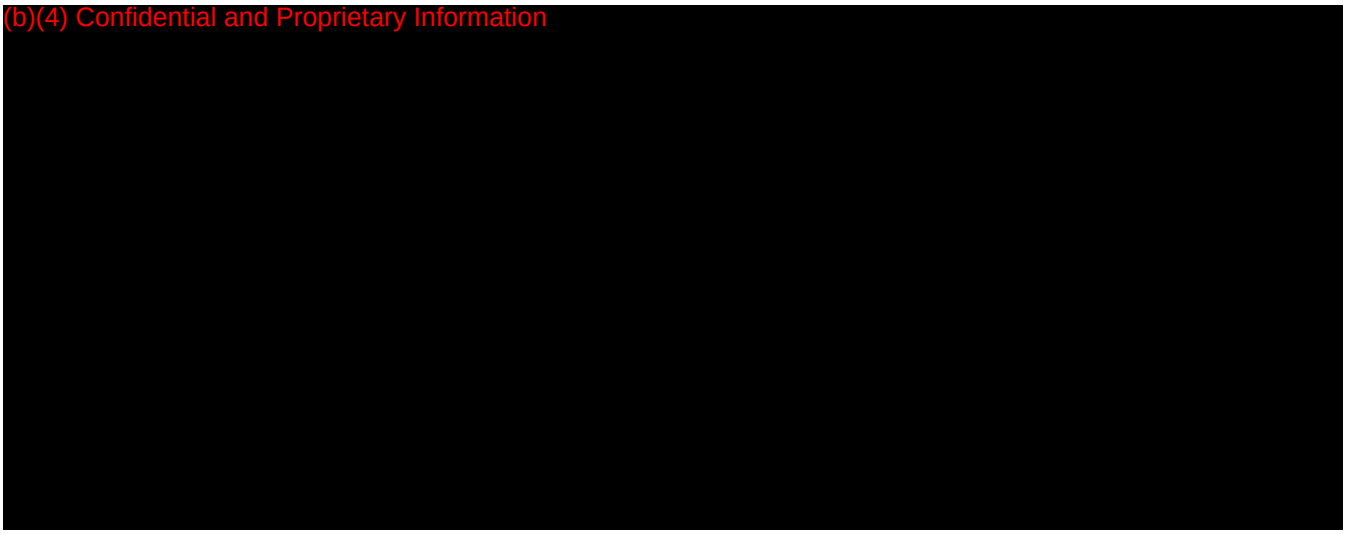
(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information



DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

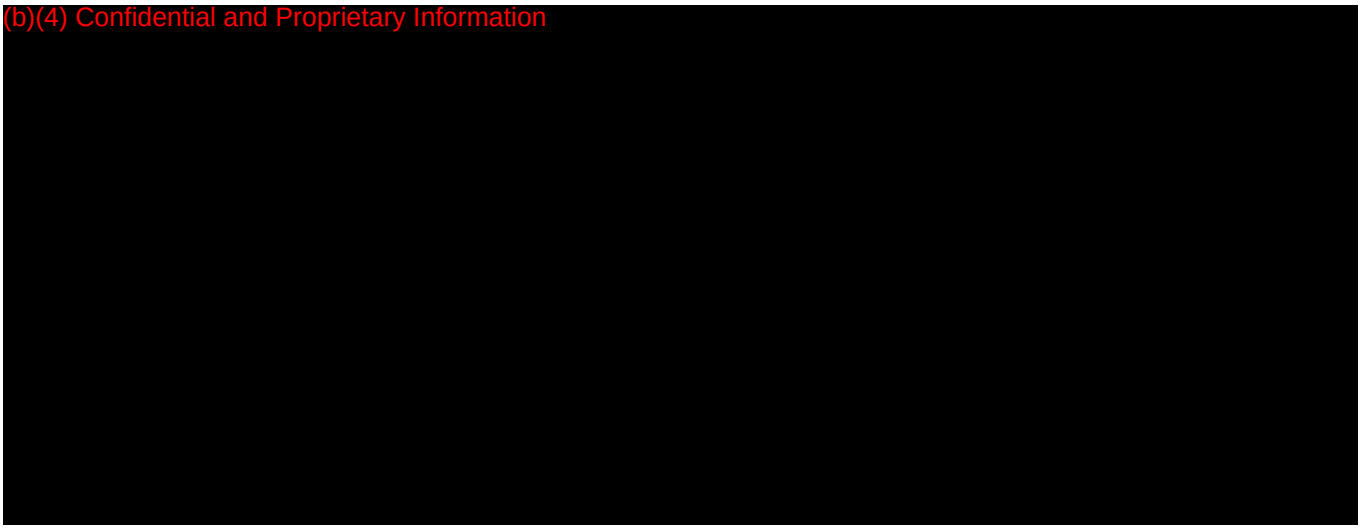
Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

K141752
NxStage Medical Inc.
NxStage System One

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

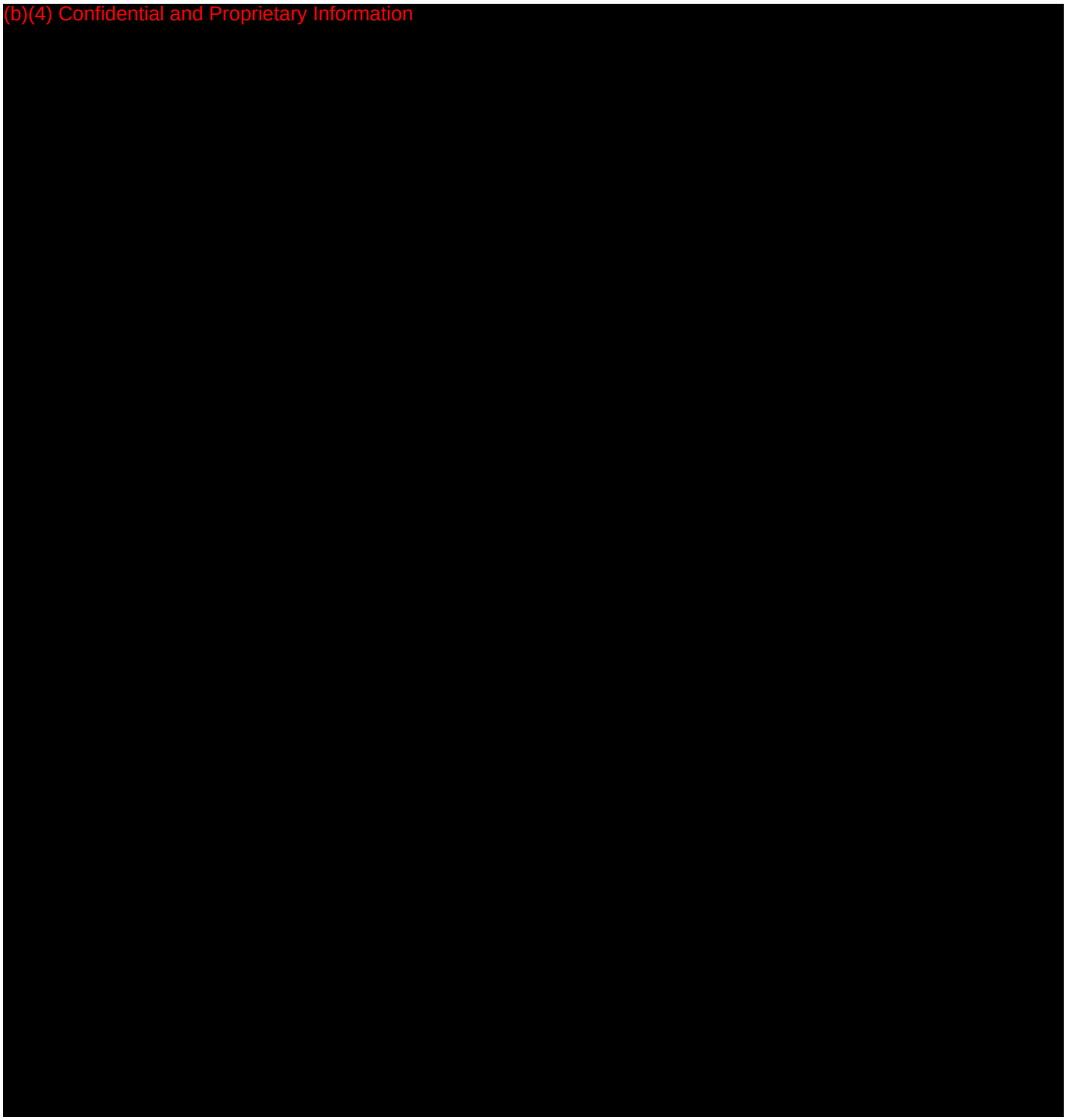


DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

K141752
NxStage Medical Inc.
NxStage System One

(b)(4) Confidential and Proprietary Information



(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

[redacted]

DEPARTMENT OF HEALTH AND HUMAN SERVICES **M E M O R A N D U M**

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Ave
Silver Spring, MD 20993

Premarket Notification [510(k)] Review
Traditional

K141752/S002

Date: December 15, 2014
To: The Record
From: David Pudwill, Biomedical Engineer

Office: ODE
Division: DRGUD
Branch: RNDB

510(k) Holder: NxStage Medical, Inc.
Device Name: NxStage System One for Nocturnal Home Hemodialysis
Contact: Mary Lou Stroumbos
Address: 439 South Union Street 5th Floor
Lawrence, MA 01843
Phone: (978) 687-4872
Fax: (978) 687-4750
Email: mstroumbos@nxstage.com

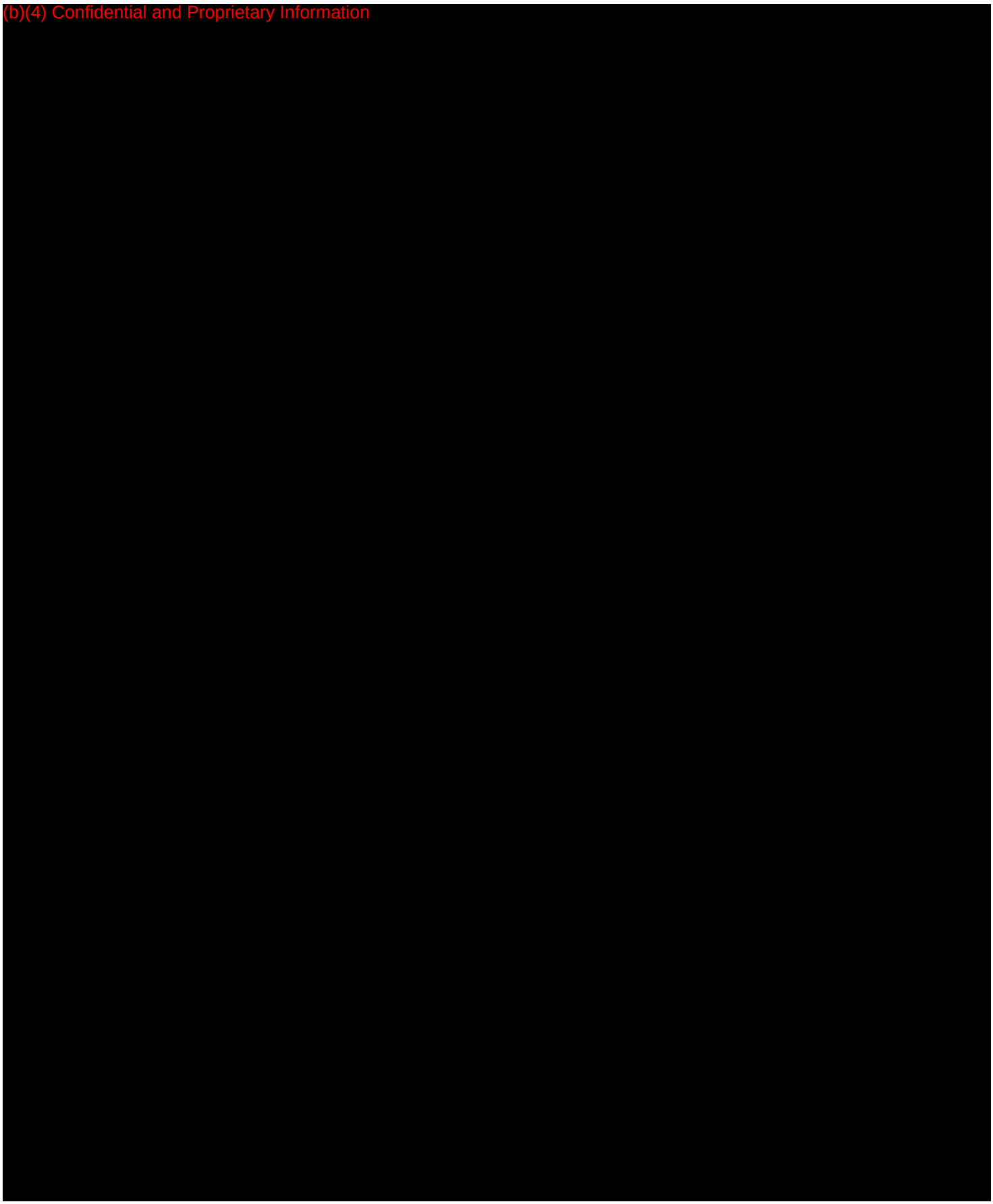
(b)(4) Confidential and Proprietary Information

[redacted]

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	✓		
Truthful and Accuracy Statement	✓		
510(k) Summary or 510(k) Statement	✓		
Standards Form #3654 http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf			✓
Clinical Trials Form http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3674.pdf	✓		

(b)(4) Confidential and Proprietary Information



(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

[redacted]

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
OFFICE OF DEVICE EVALUATION

Memorandum

DATE: December 9, 2014

FROM: Frank P. Hurst, MD, Medical Officer
Renal Devices Branch/DRGUD

TO: David Pudwill, Lead Reviewer
Renal Devices Branch/DRGUD

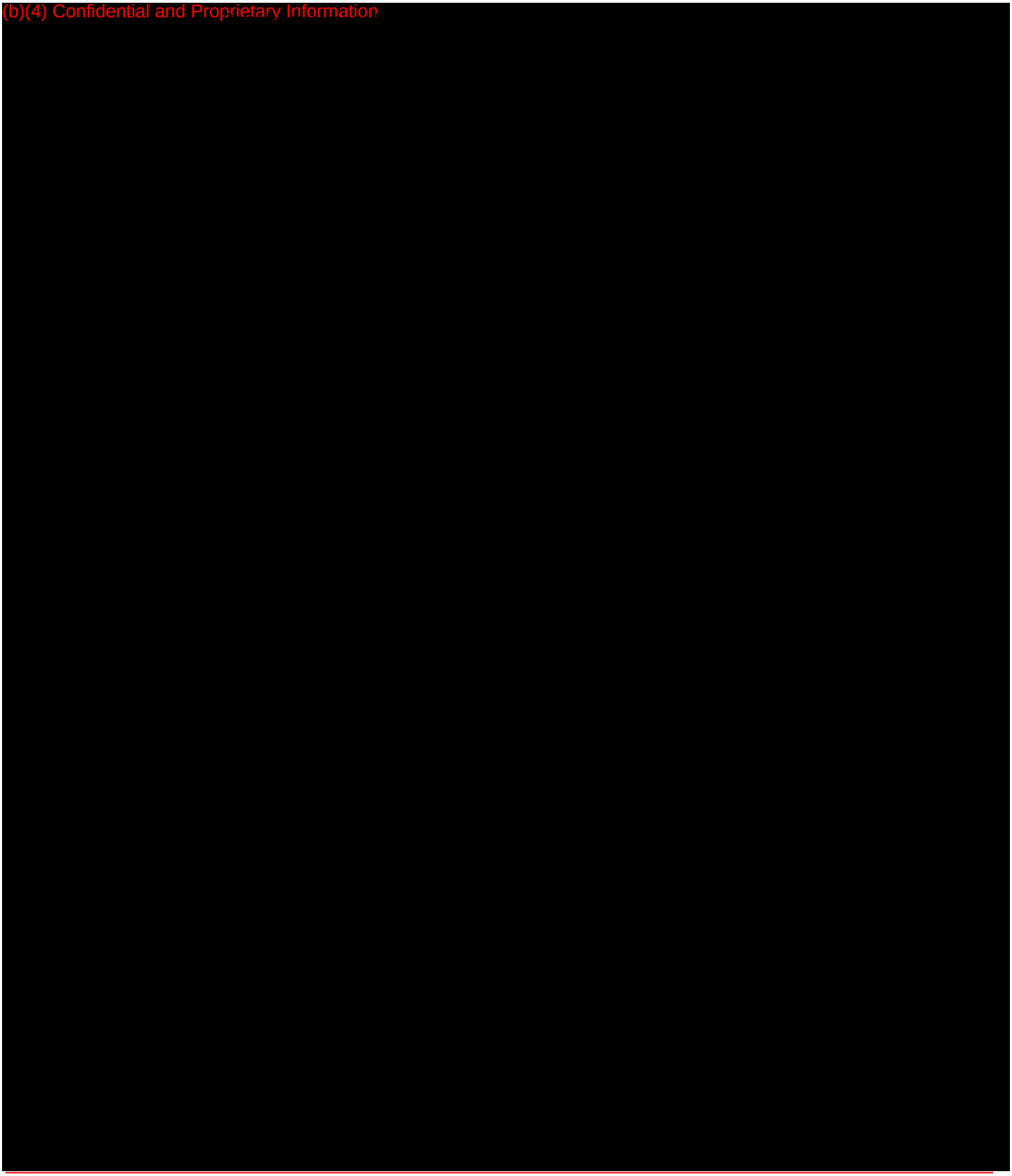
THROUGH: Carolyn Neuland, Ph.D., Branch Chief
Renal Devices Branch/DRGUD

SUBJECT: K141752/S002 - Clinical Consult
Expanded indications of NxStage System One to include Nocturnal Hemodialysis, NxStage Medical

(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information



(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

[redacted]

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center WO66 G609
Silver Spring, MD 20993 0002

December 19, 2014

NxStage Medical, Inc.
Mary Lou Strombos
Director, Regulatory Affairs
350 Merrimack Street
Lawrence, MA 01843

Re: K141752
Trade/Device Name: NxStage System One
Regulation Number: 21 CFR 876.5860
Regulation Name: High Permeability Hemodialysis System
Regulatory Class: Class II
Product Code: ODN
Dated: November 20, 2014
Received: November 21, 2014

Dear Mary Lou Strombos,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K141752

Device Name: NxStage® System One™

Indications for Use: The NxStage System One is indicated for the treatment of acute and chronic renal failure, or fluid overload using hemofiltration, hemodialysis, and/or ultrafiltration, in an acute or chronic care facility.

The System is also indicated for home hemodialysis, including home nocturnal hemodialysis.

All treatments must be administered under physician's prescription, and must be performed by a trained and qualified person, considered to be competent in the use of this device by the prescribing physician.

Prescription Use ___X___ **AND/OR** **Over-The-Counter Use_____**
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

NxStage Medical, Inc.
NxStage System One
510(k) Premarket Notification

This 510(k) Summary is being submitted in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990. The content contained in this 510(k) summary has been provided in conformance with 21 CFR §807.92

A. Date Prepared: June 27, 2014

B. Submitter's Information:

Name:	NxStage Medical, Inc.
Address:	350 Merrimack Street Lawrence, MA 01843
FDA Establishment Owner/Operator Number:	9045797
Contact Person:	Mary Lou Stroumbos Director, Regulatory Affairs
Phone:	(978) 687-4872
Fax:	(978) 687-4750
Manufacturer:	NxStage Medical, Inc. 350 Merrimack Street Lawrence, MA 01843
FDA Establishment Registration Number:	3003464075
Sterilization Site:	Steris Isomedix (NxStage Cartridge Express) 1000 S. Sarah Place Ontario, CA 91761

C. Device Name:

Trade/Proprietary Name:	NxStage System One
Common/Usual Name:	Hemodialysis System
Classification Name:	High Permeability Hemodialysis System
Regulation Number:	876.5860
Product Code:	ODN
Device Classification:	Class II
Device Panel:	Gastroenterology/Urology

D. Substantial Equivalence:

The NxStage System One has the same intended use and utilizes the same fundamental technology as the predicate NxStage System One. The NxStage System One has been compared to the legally marketed predicate device as cleared through K140526 (May 19, 2014) and was found to be substantially equivalent.

E. Device Description/Indications for Use:

The NxStage System One is comprised of the NxStage Cycler, an electromechanical control unit; the NxStage Cartridge, a sterile, single-use extracorporeal blood and fluid management circuit (with or without a pre-attached high permeability filter) that mounts integrally within the NxStage Cycler. The combined system is designed to deliver hemofiltration, hemodialysis and/or ultrafiltration in an acute or chronic care facility. The NxStage System One is also indicated for home hemodialysis, including home nocturnal hemodialysis.

Indications for use:

The NxStage System One is indicated for the treatment of acute and chronic renal failure or fluid overload using hemofiltration, hemodialysis, and/or ultrafiltration, in an acute or chronic care facility.

The System is also indicated for home hemodialysis, including home nocturnal hemodialysis.

All treatments must be administered under physician's prescription, and must be performed by a trained and qualified person, considered to be competent in the use of this device by the prescribing physician.

F. Technological Characteristics:

The proposed device has the same technological characteristics and is similar in design and configuration as compared to the predicate device. The proposed device is designed with similar software, components and features also used in the predicate device.

Table 1
Device Technological Characteristics Comparison Table

Parameter	Proposed Device NxStage System One	Predicate Device NxStage System One (K140526)
Intended Use		
Hemodialysis	Yes	Yes
Hemofiltration	Yes	Yes
Ultrafiltration	Yes	Yes
Technology / Components:		
Pumps	Same	4 peristaltic pumps
Valves (clamps)	Same	2 solenoid actuated pinch clamps
	Same	8 cam driven pinch clamps
Air / fluid detectors	Same	3 ultrasonic air/ fluid detectors
Blood leak detector	Same	1 optical blood leak detector
Pressure transducers	Same	5 electronic pressure transducers
Temperature sensors	Same	1 electronic temperature sensor

NxStage Medical, Inc.
NxStage System One
510(k) Premarket Notification

Table 1
Device Technological Characteristics Comparison Table

Parameter	**Proposed Device NxStage System One**	**Predicate Device NxStage System One (K140526)**
Flow Rates:		
Blood	Same	10-600 ml/min
Prescription Fluid /Dialysate Flow	Same	0-18000 ml/hr
Ultrafiltration	Same	0-2400 ml/hr
Transmembrane Pressure Monitoring Specification	Same	Yes
Venous Pressure Monitor	Same	0 to 400 mmHg
Effluent fluid Pressure Monitor	Same	0 to 500 mmHg
Air Detector	Same	Reduction of detector signal lasting 6 ms minimum (Approximates a 60 micro liter bubble at 400 mmHg venous pressure and 600 ml/min blood flow)
Blood Leak Detector	Same	15% reduction in detector signal lasting 20 seconds minimum. Signal reduction % based on a 0.35 ml/min leak rate of 32 Hct blood.
Effluent Volume Accuracy	Same	Greater of 300 ml/ 12 hr or 3% of exchange volume (For software versions 4.7 and below) For software versions 4.8 and higher: Therapy Fluid Flow Rate L/hr) / Specification greater of > 3 / + 5% UF* or / ±100 ml/hr* ≤ 3 / + 5% UF* or / ± 25 ml/hr* *Representing 95/90 tolerance interval established under controlled laboratory testing conditions.
IV Prescription Fluid	Same	Off-line, sterile- physician prescribed, indicated for infusion
Dialysate	Same	Dialysate available as pre-packaged pre-mixed sterile fluids or via the PureFlow SL (K043436 K060296, K090919, K111174 & K140571)
Compatible Blood Tubing Set	Same	NxStage Standard Cartridge
Software	Software version 4.10	Software version 4.9

G. Summary of Non-Clinical Test/Performance Testing – Bench and Clinical Testing

NxStage believes that the information and data provided in this submission clearly describes the proposed device and demonstrates that the device is adequately designed for the labeled indications for use. Performance, verification and validation; and clinical testing was conducted to characterize performance of the proposed device and the predetermined acceptance criteria were met.

The following non-clinical testing was conducted:

- System Verification and Software Validation
  - Software verification & validation
  - Regression testing
  - Safety systems verification
  - Labeling verification testing
  - Simulated dialysis treatments

The following clinical testing was conducted:

Clinical testing included 2 crossover studies with a total of 58 patients. There were 38 in the first study and 20 in the second study. Results were provided separately and pooled together to show substantial equivalence of nocturnal hemodialysis to daily hemodialysis in the home setting.

Pivotal Studies:

NxStage conducted a US prospective, multi-center, two-treatment, two-phase, open-label, cross-over Investigational Device Exemption clinical study titled "Comparison of Nocturnal Hemodialysis (NHD) and Short Daily Hemodialysis (DHD) with the NxStage System One." The objective of the study was to determine whether or not NHD (6-10 hours) was substantially equivalent to DHD (2-4 hours) on a per treatment basis, using the NxStage System One (NSO) in the home setting. The first phase (DHD) consisted of 2 to 4 hour treatments, and the second phase (NHD) consisted of 6 to 10 hour treatments. Both phases consisted of either 5 or 6 treatments per week over an 8 week period (40 or 48 treatments in total) using the NSO in the home environment. A 4 week training/transition period took place between the two phases. A total of 58 End Stage Renal Disease (ESRD)

patients >18 years of age who were currently stable on home DHD were enrolled, of which 39 completed the study period and 19 discontinued.

Primary effectiveness endpoint:
The primary efficacy endpoint for the study was the ability to deliver the clinically prescribed amount of therapy, defined by attainment of a delivered volume that was at least 90% of the prescribed volume (10% difference in success rate is the upper boundary of the 95% confidence interval).

Primary safety endpoint:
The primary safety endpoint was the composite intradialytic and interdialytic adverse event (AE) profile.

Effectiveness:
The primary endpoint for the study focused on the ability to deliver the clinically prescribed amount of therapy (success or failure). For the ITT population, the probability of a successful treatment was 90.9% in the DHD phase versus 91.7% in the NHD phase. The upper limit of the confidence interval (2.9%) was less than the protocol-specified limit (10%). Hence, the treatment success rates were similar and the protocol specified non-inferiority criterion was attained.

Safety:
For the ITT population, the composite AE rate per 100 treatments was 8.3 in the DHD phase versus 6.9 in the NHD phase. The event profiles were similar for both phases. Results were similar for the PP population.

The study reported one death not related to study participation or the study device and no unanticipated adverse device effects. In the DHD phase there were 21 severe AEs reported, and in the NHD phase there were 6 severe AEs reported. Device relatedness was recorded as cannot be ruled out for one of the severe AEs: patient was unable to self-cannulate due to a non-dialysis related surgery. The remaining 26 severe AEs were considered not related to the device. The rate of severe AEs per 100 treatments was 0.9 for DHD vs. 0.3 for NHD.

The most commonly occurring AEs were OTH-other, hypotension, and muscle cramping. OTH-other included non-dialysis related injuries and surgeries (e.g. broken ankle, knee surgery, toe infection, etc.), out of range blood laboratory values, access related events, episodes of depression, infection, kidney stone, and other isolated events. OTH-other occurred at a rate of 1.3 vs. 1.6 per 100 treatments in DHD vs. NHD, respectively. Hypotension occurred at a rate of 1.9 vs. 0.2 per 100 treatments. The rate of muscle cramping was 1.1 per 100 treatments for both study phases.

The rates of adverse events were similar in the DHD and NHD phases, and the events experienced were typical of those commonly reported for dialysis patients, including episodes of hypotension and muscle cramping.

Summary

Based on the clinical performance as documented in the pivotal clinical studies, the NxStage System One in the home setting delivers NHD therapy that is substantially equivalent to DHD therapy on a per treatment basis.

Conclusion: Results of the non-clinical testing and clinical data have documented that the proposed NxStage System One is substantially equivalent to the predicate device and is suitable for the labeled indications for use.

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
OFFICE OF DEVICE EVALUATION

Memorandum

DATE: September 4, 2014

FROM: Frank P. Hurst, MD, Medical Officer
Renal Devices Branch/DRGUD

TO: David Pudwill, Lead Reviewer
Renal Devices Branch/DRGUD

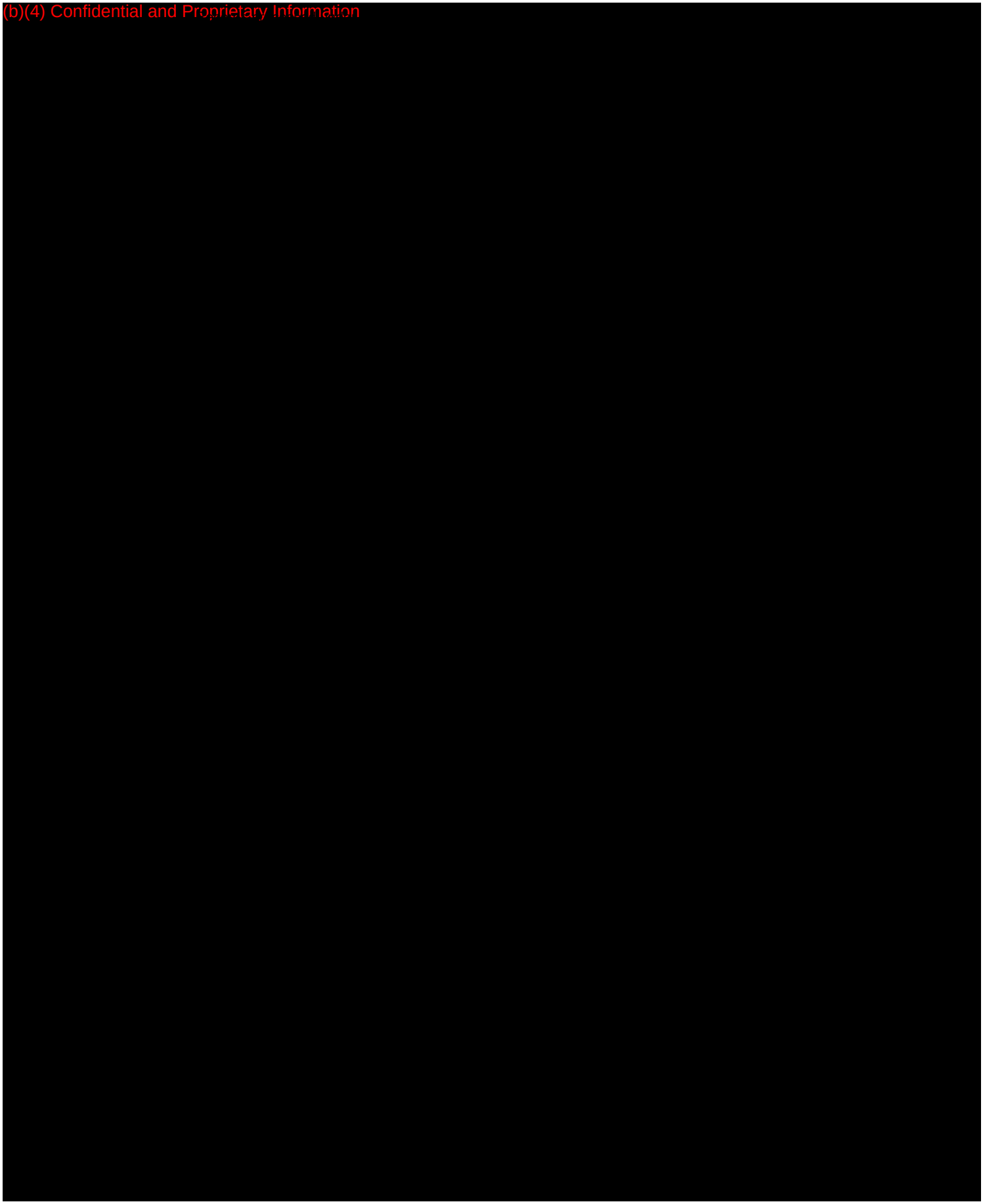
THROUGH: Carolyn Neuland, Ph.D., Branch Chief
Renal Devices Branch/DRGUD

SUBJECT: K141752 - Clinical Consult
Expanded indications of NxStage System One to include Nocturnal Hemodialysis, NxStage Medical

(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information



(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

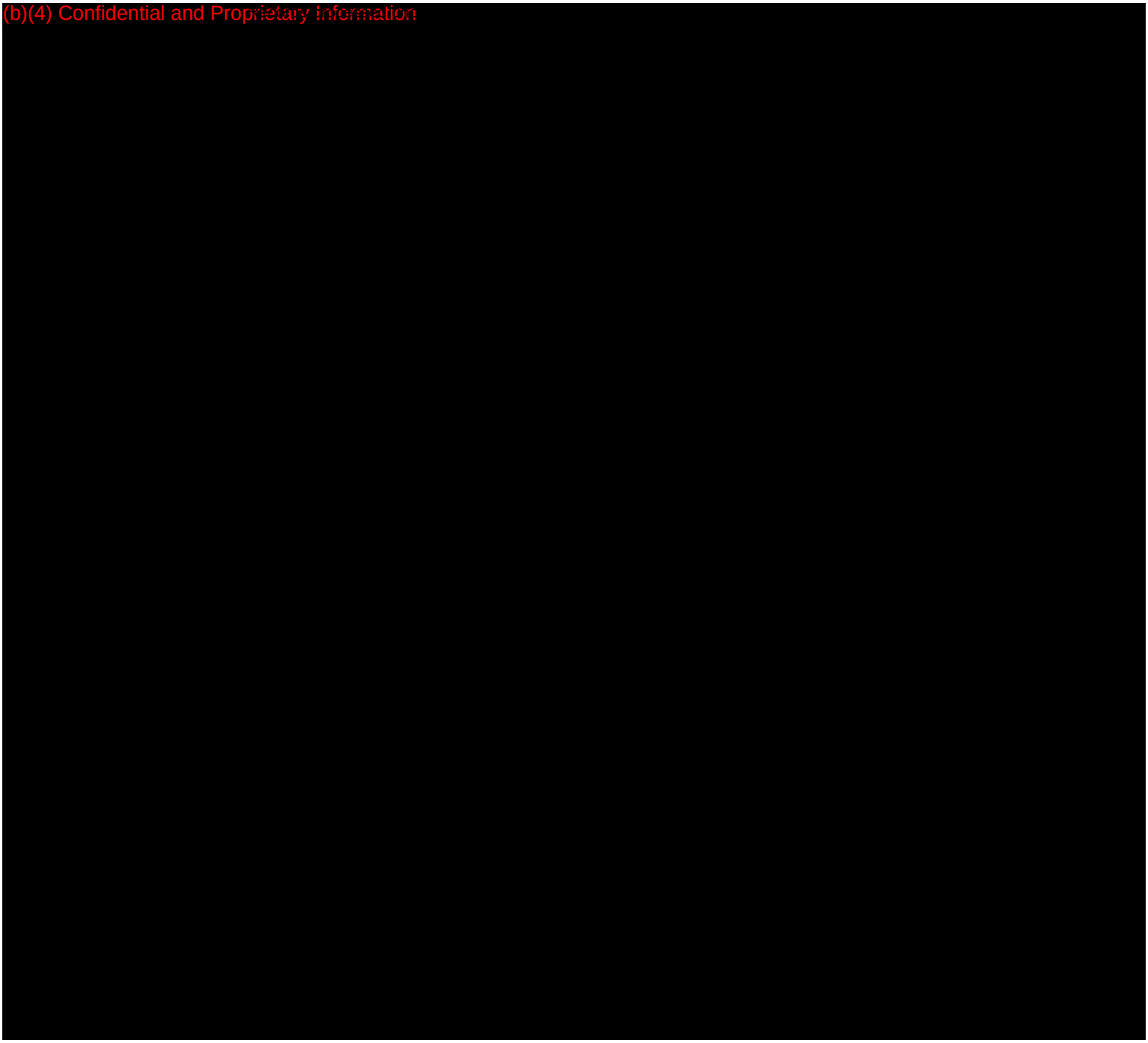
(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

MEMORANDUM

Date: September 2, 2014

To: David A. Pudwill, Lead reviewer
ODE/DRGUD/GRDB

From: Zhiwei Zhang, Mathematical Statistician
OSB/DBS/GSDB

Subject: Statistical Review of 510(k) Supplement K141752/S1, NxStage System One, NxStage

---

(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

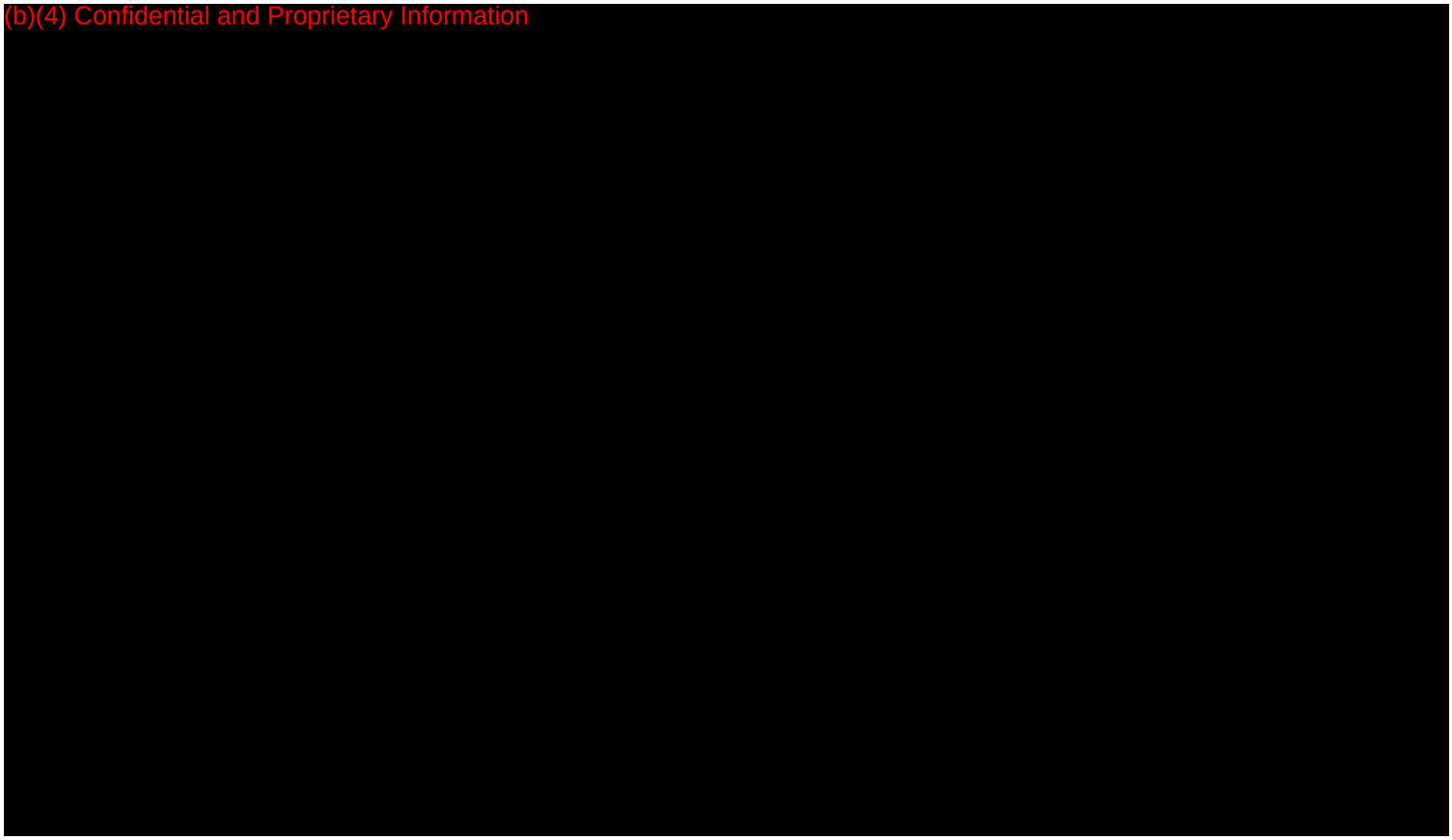
(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

MEMORANDUM

Date: December 11, 2014

To: David A. Pudwill, Lead Reviewer
ODE/DRGUD/GRDB

From: Zhiwei Zhang, Mathematical Statistician
OSB/DBS/GSDB

Subject: Statistical Review of 510(k) Supplement K141752/S2, NxStage System One, NxStage

---

(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

PROPOSED ADDITIONAL LANGUAGE TO BE INCLUDED AT THE END OF "VASCULAR ACCESS LEAKS AND DISCONNECTIONS" SECTION (page 7)

Patients with catheter access may use a bloodline connector clip that is designed to minimize tubing disconnects by securing the connections of the catheter to the bloodlines. Use of a bloodline connector clip eliminates the requirement for an access leak detection device for catheter patients.

NEW SECTION TO FOLLOW "VASCULAR ACCESS LEAKS AND DISCONNECTIONS" PAGE

Single Needle Cannulation of the Vascular Access

WARNINGS

Follow manufacturer's Instructions for Use to ensure correct operation of the single needle device.

A single needle device indicated for dialysis procedures may be used to access an arteriovenous fistula or graft to perform nocturnal hemodialysis. The vascular access and the blood lines should be correctly positioned and secure to avoid accidental dislodgement.

The use of a single needle device helps to avoid the risks associated with vascular access disconnection during treatment. In the event of a needle dislodgement using a single needle device, the patient's arterial and venous lines are removed simultaneously drawing air into the arterial line, causing a machine alarm and stopping all cycler pumps.

The use of a single needle device eliminates the requirement for use of a vascular access leak detection device.

When choosing a single needle device, make sure it can be used with a single blood pump device such as the NxStage System One Cycler.

The following single needle device has been validated for use with the NxStage System One:

- Medisystems OneSite Dual Lumen Needle

Other devices that meet the requirement above may be available.

PROPSED ADDITIONAL LANGUAGE TO BE INCLUDED AT THE END OF "VASCULAR ACCESS LEAKS AND DISCONNECTIONS" SECTION (page 7)

Patients with catheter access may use a bloodline connector clip that is designed to minimize tubing disconnects by securing the connections of the catheter to the bloodlines.

NEW SECTION TO FOLLOW "VASCULAR ACCESS LEAKS AND DISCONNECTIONS" PAGE

Single Needle Cannulation of the Vascular Access

WARNINGS

Follow manufacturer's Instructions for Use to ensure correct operation of the single needle device.

A single needle device indicated for dialysis procedures may be used to access an arteriovenous fistula or graft to perform nocturnal hemodialysis. The vascular access and the blood lines should be correctly positioned and secure to avoid accidental dislodgement.

The use of a single needle device helps to avoid the risks associated with vascular access disconnection during treatment. In the event of a needle dislodgement using a single needle device, the patient's arterial and venous lines are removed simultaneously drawing air into the arterial line, causing a machine alarm and stopping all cycler pumps.

When choosing a single needle device, make sure it can be used with a single blood pump device such as the NxStage System One Cycler.

The following single needle device has been validated for use with the NxStage System One:

- Medisystems OneSite Dual Lumen Needle

Other devices that meet the requirement of compatibility with a single blood pump device may be available.

K141752

NxSTAGE®

June 27, 2014

US Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center – WO66-G609
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Re: eCopy for NxStage System One Traditional 510(k) Premarket Notification

Dear Document Control Center:

The enclosed eCopy is an exact duplicate of the paper copy except that it also includes the Raw Data Listings presented in Appendix 4 in a folder entitled Statistical Data. This PDF file contains NxStage Medical's Traditional 510(k) Premarket Notification for the NxStage System One.

Thank you. If you have any questions regarding this information, please contact me directly at (978) 687-4872 or via e-mail at mstroumbos@nxstage.com.

Sincerely,

Mary Lou Stroumbos

Mary Lou Stroumbos
Director, Regulatory Affairs

Traditional 510(k) Premarket Notification

NxStage® Medical, Inc.
NxStage® System One™

NxStage Medical, Inc
350 Merrimack Street
Lawrence, MA 01843

Confidential

Table of Contents

Appendices:

APPENDIX 1 Predicate Device Labeling

NxStage System One User Guide

APPENDIX 2 Software Documentation

A System One Assessment of Software Level of Concern, DD0071

B System One System Architecture Overview, DD0073

C System One Software Architecture Document, DD0021

D System One Trace Matrix, DD0059

E Software Development Procedures, SOP-04C-008 and SOP- 04C-018

F System Specification, SS0001

G Subsystem Specification, SSS0004

H Control Subsystem Specifications, SSS0008

I Safety Subsystem Specifications, SSS0009

J Software Verification & Validation Protocols VP0826 & VP0827

K Software Verification & Validation Reports VR1249, TR2722 & TR2927

L Cycler Software 4.10 Project Plan, PLN2052

APPENDIX 3 Risk Management

M System One Fault Tree Analysis, HA0001

N NxStage System One Cycler Usability Engineering File UE0001

APPENDIX 4 Clinical Study Report

O A. The Clinical Investigation Protocol

P B. Sample Case Report Forms (Unique Pages)

Q C. List of Investigators Including Institutions/Affiliations and IRBs

R D. Investigator Financial Disclosures

S E. Investigator Signed Signature Pages

T F. List of Key Study Personnel and Other Parties Involved

U G. IRB Approvals and Informed Consent Documents

V H. NxStage Home Hemodialysis Training Program

W I. Statistical Analysis Plan

X J. Data Dictionary

Y K. Data Listings

Z L. Data Analysis Table

Section 1 – Medical Device User Fee Cover Sheet

Form Approved: OMB No 0910-0511 Expiration Date: April 30, 2016 See Instructions for OMB Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION **MEDICAL DEVICE USER FEE COVER SHEET**	PAYMENT IDENTIFICATION NUMBER: (b) (4) Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)	2. CONTACT NAME
NXSTAGE MEDICAL INC 350 Merrimack Street Lawrence MA 01843 US	MaryLou Stroumbos
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****4702	2.1 E-MAIL ADDRESS mstroumbos@nxstage.com
	2.2 TELEPHONE NUMBER (include Area code) 978-6874872
	2.3 FACSIMILE (FAX) NUMBER (Include Area code) 978-6874800

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm

Select an application type:	3.1 Select a center
[X] Premarket notification(510(k)); except for third party	[X] CDRH
[ ] 513(g) Request for Information	[ ] CBER
[ ] Biologics License Application (BLA)	3.2 Select one of the types below
[ ] Premarket Approval Application (PMA)	[X] Original Application
[ ] Modular PMA	Supplement Types:
[ ] Product Development Protocol (PDP)	[ ] Efficacy (BLA)
[ ] Premarket Report (PMR)	[ ] Panel Track (PMA, PMR, PDP)
[ ] 30-Day Notice	[ ] Real-Time (PMA, PMR, PDP)
	[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)

[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA	[X] NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?

[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)

[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

[ ] This application is the first PMA submitted by a qualified small business, including any affiliates

[ ] The sole purpose of the application is to support conditions of use for a pediatric population

[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only

[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).

[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT

Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850

[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b) (4) [redacted]

28-Oct-2013

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

Section 2 – ClinicalTrials.gov Data Bank Sheet

Form Approved: OMB No. 0910-0616. Expiration Date: 2/28/2015. See PRA Statement on page 2.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance

Under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. Name of Sponsor/Applicant/Submitter
NxStage Medical, Inc.

2. Date of the Application/Submission Which This Certification Accompanies
06/27/2014

3. Address

Address 1 *(Street address, P.O. box, company name c/o)*
350 Merrimack Street

Address 2 *(Apartment, suite, unit, building, floor, etc.)*

City
Lawrence

State/Province/Region
MA

Country
USA

ZIP or Postal Code
01843

4. Telephone and Fax Numbers *(Include country code if applicable and area code)*

(Tel): 978-687-4700

(Fax): 978-687-4800

PRODUCT INFORMATION

5. **For Drugs/Biologics:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s).
For Devices: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)

NxStage System One

Continuation Page for #5

APPLICATION / SUBMISSION INFORMATION

6. Type of Application/Submission Which This Certification Accompanies

☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☒ 510(k) ☐ PDP ☐ Other

7. Include IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/ Other Number *(If number previously assigned)*

If BLA was selected in item 6, provide Supplement Number

8. Serial Number Assigned to Application/Submission Which This Certification Accompanies

CERTIFICATION STATEMENT / INFORMATION

9. Check only one of the following boxes *(See instructions for additional information and explanation)*

☐ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

☐ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

☒ C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

Certification Statement / Information section continued on page 2

CERTIFICATION STATEMENT / INFORMATION *(Continued)*

10. If you checked box C, in number 9, provide the National Clinical Trial (NCT) Number(s) for any "applicable clinical trial(s)," under 42 U.S.C. § 282(J)(1)(a)(i), section 402(j)(1)(a)(i) of the Public Health Service Act, referenced in the application/ submission which this Certification accompanies. *(Add continuation page as necessary.)*

NCT Number(s): NCT00667511

Continuation Page for #10

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.

Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. Name and Title of the Person who Signs Number 15

Name	Title
Mary Lou Stroumbos	Director, Regulatory Affairs

12. Address

Address 1 *(Street address, P.O. box, company name c/o)*	
350 Merrimack Street	
Address 2 *(Apartment, suite, unit, building, floor, etc.)*	
City: Lawrence	State/Province/Region: MA
Country: USA	ZIP or Postal Code: 01843

13. Telephone and Fax Numbers *(Include country code if applicable and area code)*

(Tel): 978-687-4700

(Fax): 978-687-4800

14. Date of Certification

06/27/2014

15. Signature of Sponsor/Applicant/Submitter or an Authorized Representative *(Sign)*

Sign

Mary Lou Stroumbos

This section applies only to requirements of the Paperwork Reduction Act of 1995.

*****DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*****

The burden time for this collection of information is estimated to average 15 minutes and 45 minutes (depending on the type of application/ submission) per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 3 – CDRH Premarket Review Submission Cover Sheet

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
06/27/2014	MD6071765-956733	

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Request for Feedback
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-Submission
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Informational Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Submision Issue Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Day 100 Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Agreement Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Determination Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Study Risk Determination
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify)*:
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission)*:
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☒ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
NxStage Medical, Inc.	9045797		
Division Name *(if applicable)*	**Phone Number *(including area code)***		
	978-687-4872		
Street Address	**FAX Number *(including area code)***		
350 Merrimack Street	978-687-4750		
City	**State / Province**	**ZIP/Postal Code**	**Country**
Lawrence	MA	01843	USA
Contact Name			
Mary Lou Stroumbos			
Contact Title	**Contact E-mail Address**		
Director, Regulatory Affairs	mstroumbos@nxstage.com		

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name *(if applicable)*	**Phone Number *(including area code)***		
Street Address	**FAX Number *(including area code)***		
City	**State / Province**	**ZIP Code**	**Country**
Contact Name			
Contact Title	**Contact E-mail Address**		

PSC Publishing Services (301) 443-6740 EF

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Process change:
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ Other *(specify below)*

- ☐ Response to FDA correspondence:

- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Other Reason *(specify)*:

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Response to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

- ☐ Other Reason *(specify)*:

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☐ New Device
- ☒ Additional or Expanded Indications
- ☐ Change in Technology

- ☐ Other Reason *(specify)*:

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	78 KDI	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- [x] 510 (k) summary attached
- [ ] 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number	Trade or Proprietary or Model Name	Manufacturer
1	K140526	NxStage System One	NxStage Medical, Inc
2			
3			
4			
5			
6			

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

High Permeability Hemodialysis System

	Trade or Proprietary or Model Name for This Device	Model Number
1	NxStage System One	NX1000-4, NX1000-3, NX1000-1
2		
3		
4		
5		

FDA document numbers of all prior related submissions *(regardless of outcome)*

1 K140526	2 K122051	3 K100535	4 K050525	5	6
7	8	9	10	11	12

Data Included in Submission

- [ ] Laboratory Testing
- [ ] Animal Trials
- [x] Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code: 78 KDI

C.F.R. Section *(if applicable)*: 21 CFR 876.5860

Device Class

- [ ] Class I
- [x] Class II
- [ ] Class III
- [ ] Unclassified

Classification Panel

Gastroenterology/Urology

Indications *(from labeling)*

NxStage System One is indicated for the treatment of acute and chronic failure, fluid overload or toxemic conditions using hemofiltration, hemodialysis, and/or ultrafiltration, in an acute or chronic care facility. The System is also indicated for home hemodialysis, including home nocturnal hemodialysis. All treatments must be administered under physician's prescription, and must be performed by by a trained and qualified person, considered to be competent in the use of this device by the prescribing physician.

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.	FDA Document Number *(if known)*

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☒ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name: NxStage Medical, Inc.		Establishment Registration Number: 303464075
Division Name *(if applicable)*		Phone Number *(including area code)*
Street Address: 350 Merrimack Street		FAX Number *(including area code)*
City: Lawrence	State / Province: MA	ZIP Code: 01843 / Country: USA
Contact Name: Karen St. Onge	Contact Title: Director, Corporate Quality	Contact E-mail Address: kstonge@nxstage.com

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer ☒ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name: Steris Isomedix (NxStage Cartridge Express)		Establishment Registration Number
Division Name *(if applicable)*		Phone Number *(including area code)*: 909-390-9942
Street Address: 100 S. Sarah Place		FAX Number *(including area code)*: 909-390-7854
City: Ontario	State / Province: CA	ZIP Code: 91761 / Country: USA
Contact Name: Mike Au	Contact Title: Plant Manager	Contact E-mail Address: Mike_Au@steris.com

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number
Division Name *(if applicable)*		Phone Number *(including area code)*
Street Address		FAX Number *(including area code)*
City	State / Province	ZIP Code / Country
Contact Name	Contact Title	Contact E-mail Address

SECTION I — UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	031	AAMI/ANSI	AAMI/ANSI ES60601:2005/(R)2010 & A1:2012, C1:2009(R)2012 & A2:2010 (Consolidated Text) Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)	2005/(R)2010 & A1:2012, C1:2009 (R)2012 & A2:2010	06/27/2014
2	Standards No.	Standards Organization	Standards Title	Version	Date
		IEC	IEC 60601-1 issued: 2005/01/01 Ed:3 Medical Electrical Equipment, Part 1: General requirements for basic safety & essential performance	Issued: 2005/01/01 Ed: 3	06/27/2014
3	Standards No.	Standards Organization	Standards Title	Version	Date
	031	IEC	IEC 60601-1-2, Edition 3:2007-03, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	Edition 3:2007-03	06/27/2014
4	Standards No.	Standards Organization	Standards Title	Version	Date
		IEC	IEC 60601-1-6 issued: 2010/01/27 Ed:3 Medical electrical equipment Part 1-6: General requirements for safety - Collateral standard: Usability	Issued 2010/01/27 Ed:3	06/27/2014
5	Standards No.	Standards Organization	Standards Title	Version	Date
	027	AAMI/ANSI/IEC	AAMI/ANSI/IEC 62366:2007, Medical devices - Applications of usability engineering to medical devices	2007	06/27/2014
6	Standards No.	Standards Organization	Standards Title	Version	Date
	031	IEC	IEC 60601-1-8 Edition 2.1 2012-11, Medical electrical equipment - Part 1-8, General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	Edition 2.1 2012-11	06/27/2014
7	Standards No.	Standards Organization	Standards Title	Version	Date
	031	IEC	IEC 60601-1-16 Edition 4.0 2012-03, Medical electrical equipment - Part 2-16: Particular requirements for the basic safety and essential performance of hemodialysis, hemodiafiltration and hemofiltration equipment	Edition 4.0 2012-03	06/27/2014

Please include any additional standards to be cited on a separate page.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS BELOW.

The burden time for this collection of information is estimated to average 0.5 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Section 4 – 510(k) Cover Letter

Traditional 510(k): Premarket Notification

June 27, 2014

Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center- WO66 Room G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Payment ID Number: MD6071765-956733

Dear Sir/Madam:

As required by section 510(k) of the Federal Food, Drug and Cosmetic Act, and in conformance with 21 CFR §807, NxStage Medical, Inc. is submitting this Traditional 510(k) premarket notification to expand the indications for use of the NxStage System One (NSO) to include home Nocturnal Hemodialysis (NHD). NxStage believes that the information and data enclosed demonstrates that the proposed NxStage System One is adequately designed for the expansion in the indications for use, and therefore, should be classified and regulated in the same manner as the predicate device.

Included in this submission is the final clinical study report CR0010-1 for IDE study G070128 and G070128-S, Comparison of Nocturnal Hemodialysis (NHD) and Short Daily Hemodialysis (DHD) with the NxStage System One. The results of the study show that NHD therapy, using the NxStage System One in the home setting, is equivalent to DHD therapy on a per treatment basis.

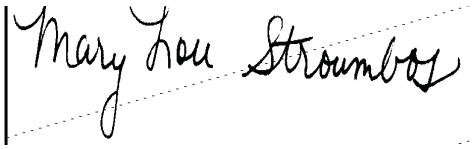
The premarket notification information required by 21 C.F. R. §807.87 is contained in the accompanying documents. One paper copy and one eCopy of the Notification with cover letter are supplied; the eCopy is an exact duplicate of the paper copy. NxStage believes that the materials marked “CONFIDENTIAL”

NxStage Medical, Inc. ▪ 350 Merrimack Street ▪ Lawrence, MA 01843 USA
tel: (978) 687-4700 ▪ fax: (978) 687-4800 ▪ **www.nxstage.com**

are either trade secret or confidential commercial information, as described in 21 C.F.R. §20.61, and therefore, exempt from public disclosure under exemption 4 of the Freedom of Information Act and under all of the legislative safeguards pertaining to non-disclosure of such materials to the public.

Thank you in advance for your consideration of our application. If you have any questions regarding this submission, please contact me directly at (978) 687-4872 or via e-mail at mstroumbos@nxstage.com.

Sincerely,



Mary Lou Stroumbos
Director, Regulatory Affairs

NxStage Medical, Inc. ▪ 350 Merrimack Street ▪ Lawrence, MA 01843 USA
tel: (978) 687-4700 ▪ fax: (978) 687-4800 ▪ **www.nxstage.com**

Section 5 – 510(k) Screening Check List

Screening Checklist for 510(k) Premarket Notification Submissions

Title/Related information	Present	Inadequate	N/A
MDUFMA Cover Sheet	Yes		
ClinicalTrials.gov Data Bank Sheet	Yes		
CDRH Premarket Review Submission Cover Sheet	Yes		
510(k) Cover Letter	Yes		
510(k) Screening Check List	Yes		
Indications for Use Statement	Yes		
510(k) Summary	Yes		
Standards Data Report for 510(k)s	Yes		
Truthful and Accuracy Statement	Yes		
Executive Summary	Yes		
Device Description	Yes		
Substantial Equivalence Discussion	Yes		
Declaration of Conformity	Yes		
Proposed Labeling	Yes		
Sterilization/Shelf Life	Yes		
Biocompatibility	Yes		
Software	Yes		
Electromagnetic Compatibility and Electrical Safety	Yes		
Performance Testing – Bench	Yes		
Performance Testing – Animal			N/A
Performance Testing – Clinical	Yes		

Title/Related information	Present	Inadequate	N/A
Class III Summary and Certification			N/A
Financial Certification and Disclosure Statements	Yes		

Section 6 – Indications for Use Statement

INDICATIONS FOR USE

510(k) Number (if known):

Device Name: NxStage® System One™

Indications for Use: The NxStage System One is indicated for the treatment of acute and chronic renal failure, or fluid overload using hemofiltration, hemodialysis, and/or ultrafiltration, in an acute or chronic care facility.

The System is also indicated for home hemodialysis, including home nocturnal hemodialysis.

All treatments must be administered under physician's prescription, and must be performed by a trained and qualified person, considered to be competent in the use of this device by the prescribing physician.

Prescription Use ____X_____ **AND/OR** **Over-The-Counter Use_____**
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Section 7 – 510(k) Summary

This 510(k) Summary is being submitted in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990. The content contained in this 510(k) summary has been provided in conformance with 21 CFR §807.92

A. Date Prepared: June 27, 2014

B. Submitter's Information:

Name:	NxStage Medical, Inc.
Address:	350 Merrimack Street Lawrence, MA 01843
FDA Establishment Owner/Operator Number:	9045797
Contact Person:	Mary Lou Stroumbos Director, Regulatory Affairs
Phone:	(978) 687-4872
Fax:	(978) 687-4750
Manufacturer:	NxStage Medical, Inc. 350 Merrimack Street Lawrence, MA 01843
FDA Establishment Registration Number:	3003464075
Sterilization Site:	Steris Isomedix (NxStage Cartridge Express) 1000 S. Sarah Place Ontario, CA 91761

C. Device Name:

Trade/Proprietary Name:	NxStage System One
Common/Usual Name:	Hemodialysis System
Classification Name:	High Permeability Hemodialysis System
Regulation Number:	876.5860
Product Code:	78 KDI
Device Classification:	Class II
Device Panel:	Gastroenterology/Urology

D. Substantial Equivalence:

The NxStage System One has the same intended use and utilizes the same fundamental technology as the predicate NxStage System One. The NxStage System One has been compared to the legally marketed predicate device as cleared through K140526 (May 19, 2014) and was found to be substantially equivalent.

E. Device Description/Indications for Use:

The NxStage System One is comprised of the NxStage Cycler, an electromechanical control unit; the NxStage Cartridge, a sterile, single-use extracorporeal blood and fluid management circuit (with or without a pre-attached high permeability filter) that mounts integrally within the NxStage Cycler. The combined system is designed to deliver hemofiltration, hemodialysis and/or ultrafiltration in an acute or chronic care facility. The NxStage System One is also indicated for home hemodialysis, including home nocturnal hemodialysis.

Indications for use:

The NxStage System One is indicated for the treatment of acute and chronic renal failure or fluid overload using hemofiltration, hemodialysis, and/or ultrafiltration, in an acute or chronic care facility.

The NxStage System One is also indicated for home hemodialysis, including home nocturnal hemodialysis.

All treatments must be administered under physician's prescription, and must be performed by a trained and qualified person, considered to be competent in the use of this device by the prescribing physician.

F. Technological Characteristics:

The proposed device has the same technological characteristics and is similar in design and configuration as compared to the predicate device. The proposed device is designed with similar software, components and features also used in the predicate device.

Table 1
Device Technological Characteristics Comparison Table

Parameter	Proposed Device NxStage System One	Predicate Device NxStage System One (K140526)
Intended Use		
Hemodialysis	Yes	Yes
Hemofiltration	Yes	Yes
Ultrafiltration	Yes	Yes
Technology / Components:		
Pumps	Same	4 peristaltic pumps
Valves (clamps)	Same	2 solenoid actuated pinch clamps
	Same	8 cam driven pinch clamps
Air / fluid detectors	Same	3 ultrasonic air/ fluid detectors
Blood leak detector	Same	1 optical blood leak detector
Pressure transducers	Same	5 electronic pressure transducers
Temperature sensors	Same	1 electronic temperature sensor

Table 1
Device Technological Characteristics Comparison Table

Parameter	**Proposed Device NxStage System One**	**Predicate Device NxStage System One (K140526)**
Flow Rates:		
Blood	Same	10-600 ml/min
Prescription Fluid /Dialysate Flow	Same	0-18000 ml/hr
Ultrafiltration	Same	0-2400 ml/hr
Transmembrane Pressure Monitoring Specification	Same	Yes
Venous Pressure Monitor	Same	0 to 400 mmHg
Effluent fluid Pressure Monitor	Same	0 to 500 mmHg
Air Detector	Same	Reduction of detector signal lasting 6 ms minimum (Approximates a 60 micro liter bubble at 400 mmHg venous pressure and 600 ml/min blood flow)
Blood Leak Detector	Same	15% reduction in detector signal lasting 20 seconds minimum. Signal reduction % based on a 0.35 ml/min leak rate of 32 Hct blood.
Effluent Volume Accuracy	Same	Greater of 300 ml/ 12 hr or 3% of exchange volume (For software versions 4.7 and below) For software versions 4.8 and higher: Therapy Fluid Flow Rate L/hr) / Specification greater of > 3 / + 5% UF* or / ±100 ml/hr* ≤ 3 / + 5% UF* or / ± 25 ml/hr* *Representing 95/90 tolerance interval established under controlled laboratory testing conditions.
IV Prescription Fluid	Same	Off-line, sterile- physician prescribed, indicated for infusion
Dialysate	Same	Dialysate available as pre-packaged pre-mixed sterile fluids or via the PureFlow SL (K043436 K060296, K090919, K111174 & K140571)
Compatible Blood Tubing Set	Same	NxStage Standard Cartridge
Software	Software version 4.10	Software version 4.9

G. Summary of Non-Clinical Test/Performance Testing - Bench

NxStage believes that the information and data provided in this submission clearly describes the proposed device and demonstrates that the device is adequately designed for the labeled indications for use. Performance, verification and validation; and clinical testing was conducted to characterize performance of the proposed device and the predetermined acceptance criteria were met. Results of this testing have documented that the proposed NxStage System One is substantially equivalent to the predicate device and is suitable for the labeled indications for use.

Section 8 – Standards Data Report for 510(k)s

8.0 Standards Data Report for 510(k)s

The NxStage System One retains the same fundamental scientific technology as has been previously cleared for the predicate device through K140526. There are no changes to any components as a result of this 510(k) submission. The proposed modification to the indication for use described in this 510(k) does not impact our prior declaration of conformity to recognized standards. The NxStage System One continues to comply with the following recognized standards:

ANSI/AAMI ES60601-1
IEC 60601-1 Ed: 3
IEC 60601-1-2 Ed: 3
IEC 60601-1-6 Ed: 3
IEC 60601-1-11 Ed:3
IEC 62366 Ed: 1
IEC 60601-1-8 Ed: 2
IEC 60601-2-16 Ed 4.0 b: 2012
IEC 62304
ISO 14971

.

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

AAMI/ANSI ES60601-1:2005/(R)2010 & A1:2012,C1:2009(R)2012 & A2:2010/(R)2012 (Conso. Txt) Med Electrical Equip-Part 1

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#031	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☐
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
AAMI/ANSI ES60601-1:2005/(R)2010 & A1:2012,C1:2009(R)2012 & A2:2010/(R)2012 (Conso. Txt) Med Electrical Equip-Part 1

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All	All	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◆ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601-1issued:2005/01/01 Ed:3 Medical Electrical Equip. Part 1: General requirements for basic safety & essential performanc

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☐
FDA Recognition number [3] # _____		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
IEC 60601-1issued:2005/01/01 Ed:3 Medical Electrical Equip. Part 1: General requirements for basic safety & essential performanc

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All	All	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◆ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601-1-2, 3rd Edition, Medical Electrical Equipment - Part 1-2: General requirements for basic safety & essential performance

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#025	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☐
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: Guidance for the Content of Premarket Notifications for Hemodialysis Delivery System

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
IEC 60601-1-2, 3rd Edition, Medical Electrical Equipment - Part 1-2: General requirements for basic safety & essential performance

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
IEC61000-4-2 Ed 2.0	Electrostatic Discharge (ESD)	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
CISPR 11 Class B	Radiated Emission per IEC 60601-1-2	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
IEC 61000-4-3 Ed. 3	Radiated Immunity	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◆ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601-1-6 issued:2010/01/27 Ed:3 Med. Electric. Equip. Part 1-6:General requirements for safety-collateral standard: Usability

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3] # _____		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
IEC 60601-1-6 issued:2010/01/27 Ed:3 Med. Electric. Equip. Part 1-6:General requirements for safety-collateral standard: Usability

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All	All	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◆ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC60601-1-11 Ed:1.0:2010, Med. elec.equip-Part1-11:General req.for basic safety & ess. perf-req. for med. elec. systems in home

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#028	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: Guidance on Medical Device Patient Labeling: Final guidance for industry & FDA reviewers

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
IEC60601-1-11 Ed:1.0:2010, Med. elec.equip-Part1-11:General req.for basic safety & ess. perf-req. for med. elec. systems in home

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All	All	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◆ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

AAMI/ANSI/IEC 62366:2007, Medical Devices- Application of usability engineering to medical devices

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#027	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: Medical Device Use-Safety: Incorporating Human Factors into Risk Management

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
AAMI/ANSI/IEC 62366:2007, Medical Devices- Application of usability engineering to medical devices

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All	All	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◆ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601-1-8 Ed 2.12012-11,Med. Elect. Equip.-Part 1-8: General Req. for basic safety & essential performance: Alarm Systems

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#031	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
IEC 60601-1-8 Ed 2.12012-11,Med. Elect. Equip.-Part 1-8: General Req. for basic safety & essential performance: Alarm Systems

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All	All	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◆ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601-2-16 Ed 4.0 2012-03, Med Elec Equip-Part 2-16:Particular Req for basic safety & ess. perf. of hrmodialysis, hemodiafilt

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#031	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: Guidance for the content of Premarket Notifications for Hemodialysis Delivery Systems

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

PSC Graphics (301) 443-6740 EF

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
IEC 60601-2-16 Ed 4.0 2012-03, Med Elec Equip-Part 2-16:Particular Req for basic safety & ess. perf. of hrmodialysis, hemodiafilt

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All	All	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◆ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 62304 1st Edition 2006-05, Medical Device Software - Software life cycle processes (Software/Informatics)

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#029	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
IEC 62304 1st Edition 2006-05, Medical Device Software - Software Life Cycle processes (Software/Informatics)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All	All	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◆ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

AAMI/ANSI/ISO 14971:2007/(R)2010 (Corrected 4 October 2007), Med Dev Application of risk management to med dev (General

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#028	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
AAMI/ANSI/ISO 14971:2007/(R)2010 (Corrected 4 October 2007), Med Dev Application of risk management to med dev (General

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All	All	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◆ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Section 9 – Truthful and Accurate Statement

9.0 Truthful and Accurate Statement

I certify that, in my capacity as Director, Regulatory Affairs of NxStage Medical, Inc., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Mary Lou Stroumbos — 6-27-14

Mary Lou Stroumbos
Director, Regulatory Affairs

Date

Section 10 – Executive Summary

(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information

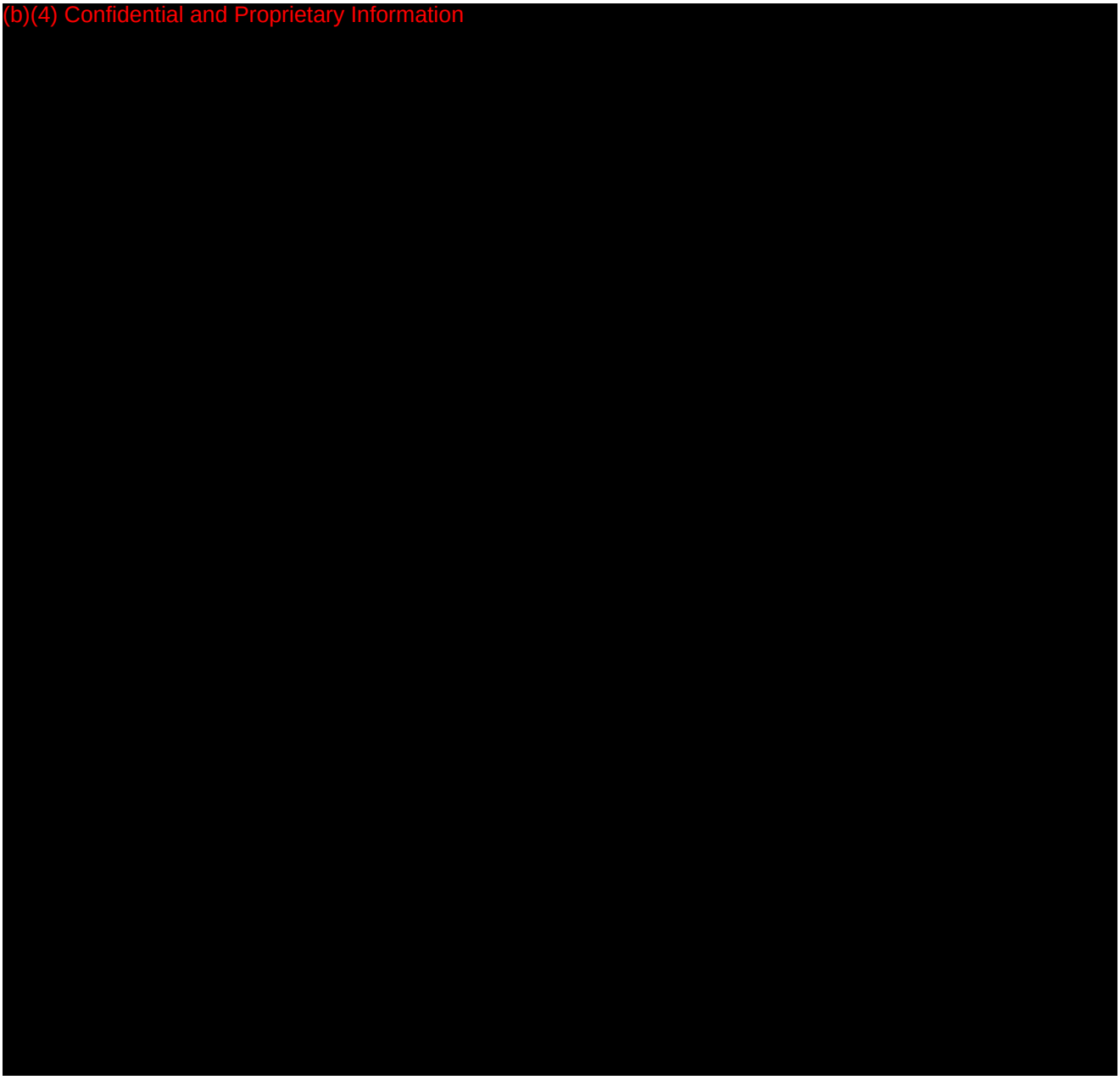
[redacted]

(b)(4) Confidential and Proprietary Information

[redacted]

Section 11 – Device Description

(b)(4) Confidential and Proprietary Information



(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information

[redacted]

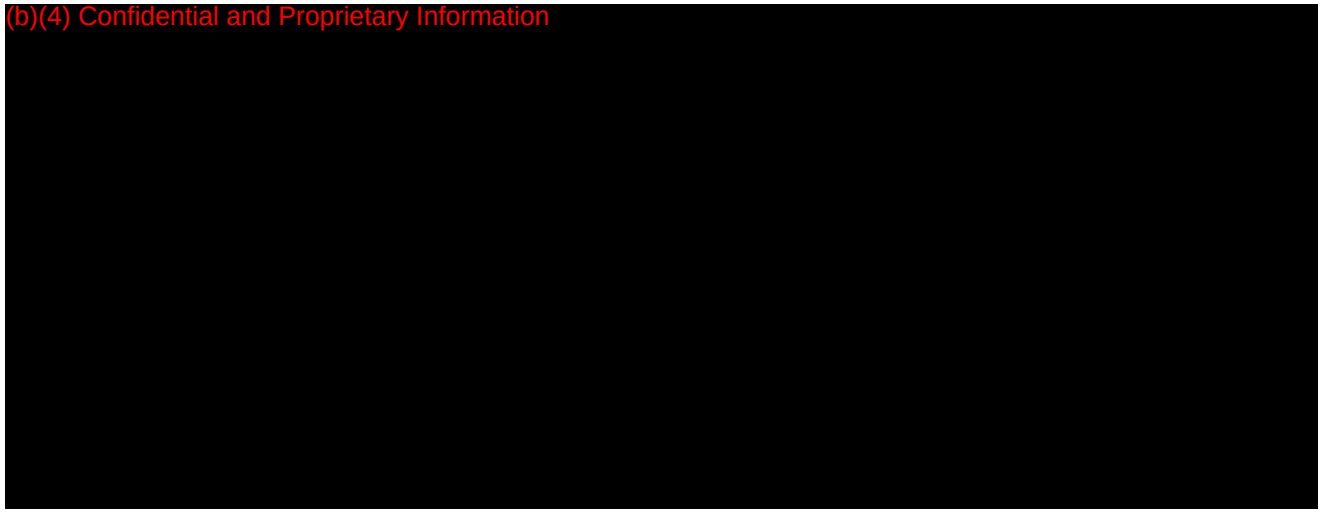
(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information



Section 12 – Substantial Equivalence

(b)(4) Confidential and Proprietary Information

[redacted]

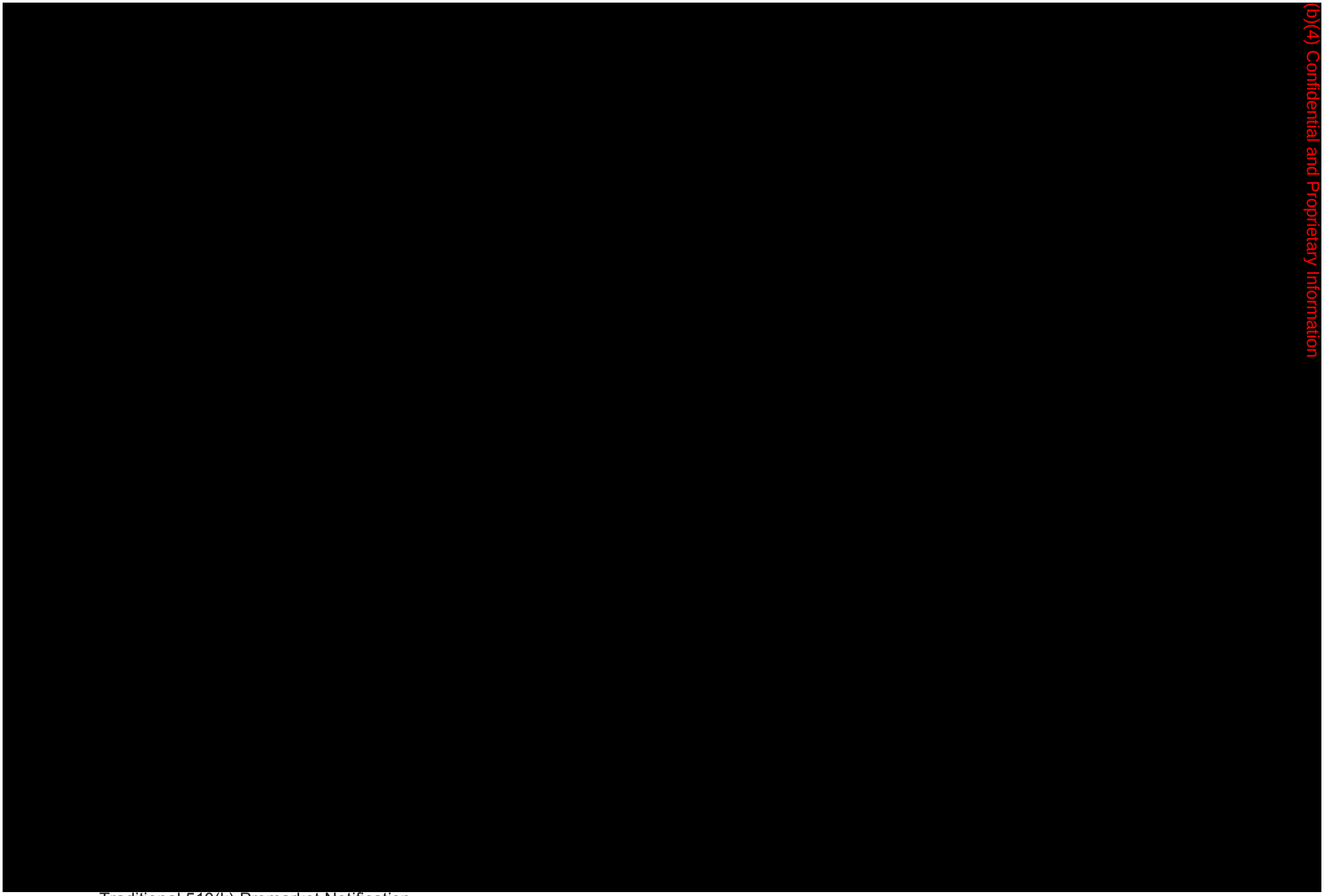
(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information

[redacted]

[redacted]



(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary information

[redacted]

[redacted]

Section 13 – Declaration of Conformity

13.0 Declaration of Conformity with Design Controls

NxStage design control procedures are compliant with the Design Control Requirements defined in the FDA Quality System Regulation, 21 CFR §820.30. A Declaration of Conformity with design controls is provided in this section.

Verification Activities

To the best of my knowledge, the verification activities, as required by the risk analysis, for the modification were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met.

Bill Weigel
VP, Product Development and Engineering
NxStage Medical, Inc.

6/25/14
Date

Manufacturing Facility

The manufacturing facility, NxStage Medical, Inc., is in conformance with the design control requirements as specified in 21 CFR §820. 30 and the records are available for review.

Thomas Shea
Sr. VP, Operations
NxStage Medical, Inc.

6/25/14
Date

Section 14 – Proposed Device Labeling

14.0 Labeling

The following proposed draft labeling is provided in this section. A supplement for Nocturnal Hemodialysis was created to accompany the NxStage System One User Guide.

- NxStage System One Supplement for Nocturnal Hemodialysis, NC6982, Rev 1.
- NxStage System One User Guide, NC4820, Rev 8

The NxStage System One Supplement for Nocturnal Hemodialysis and System One User Guide were written following FDA's Guidance Document *"Write it right" - Recommendations for Developing User Instruction Manuals for Medical Devices Used in Home Health Care* and the *FDA Guidance on Medical Device Patient Labeling; Final Guidance for Industry and FDA Reviewers*. NxStage chose to follow these guidance documents when developing these Instructions for Use so that the device installation and use would be understood by, and appropriate for, audiences such as lay users in the home environment.

14.1 Labeling Modifications

The proposed Nocturnal Hemodialysis supplement is a new document created based on the labeling used during the IDE study**.**

To facilitate review of this Traditional 510(k), the labeling modifications made to the NxStage System One User's Guide are presented in Table 5.

Table 5
NxStage System One User Guide Changes

Page No.	Description of Change
Cover	Added Software version 4.10 to the cover
ii	Added the following paragraph to page ii: Refer to the NxStage System One Supplement for Nocturnal Hemodialysis which describes the increased risks associated with nocturnal home hemodialysis therapy and the ancillary equipment that is recommended or required to use the System One for nocturnal home hemodialysis therapy. When using the system for nocturnal therapy, thoroughly read this supplement for additional instructions and information required to safely perform nocturnal therapy.
1-3	Modified the indications for use to state: The NxStage System One is indicated for the treatment of acute and chronic renal failure or fluid overload using hemofiltration, hemodialysis, and/or ultrafiltration, in an acute or chronic care facility. The system is also indicated for home hemodialysis, including home nocturnal hemodialysis. All treatments must be administered under a physician's prescription, and must be performed by a trained and qualified person, considered to be competent in the use of this device by the prescribing physician.
9-19	Added System Settings 80 and 81

80	Max UFR[2]	Maximum Ultrafiltration rate (UFR)	L/hr	0.01	0	2.40	2.40 L/hr
81	Max FPR[1]	Maximum Fluid Pump (FP) rate.	L/hr	0.1	0.1	12.0 18.0[3]	12.0 L/hr 18.0L/hr[2]

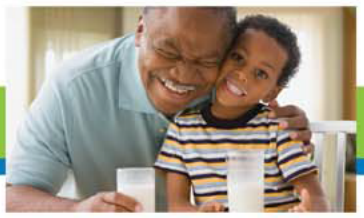
1 Only for software versions 4.9 and higher
2 Only applies to software versions 4.10 and higher
3 For NX1000-3 or NX1000-4

NxStage System One
Supplement for Nocturnal Hemodialysis

NxSTAGE
Invent. Improve. Inspire.

NxStage System One

Supplement for Nocturnal Hemodialysis



Disclaimer

This document is a supplement to the *NxStage System One User Guide*. This document is one part of a user-training program. This document is not intended to replace the *NxStage System One User Guide* and does not include all of the information necessary to use the system safely and effectively. Providers should review and refer to the *NxStage System One User Guide* for complete information including all warnings and precautions.

1: Supplement to NxStage System One User Guide

This supplement is to be used only with the *NxStage System One User Guide* that you currently have. It is intended to supplement, not replace, the *NxStage System One User Guide*. Patients, partners, and providers must review and refer to the *NxStage System One User Guide* for all additional warnings and precautions.

This supplement describes the increased risks associated with nocturnal home hemodialysis therapy and the ancillary equipment that is recommended or required to use the System One for nocturnal home hemodialysis therapy. When using the system for nocturnal therapy, thoroughly read this supplement for additional details for operation.

Healthcare providers must refer to this supplement to select the proper ancillary equipment to provide to their patients. Patients using the system at home are expected to use the equipment provided by their clinic or hospital. If patients have questions about the ancillary devices they have been given, they should consult with their healthcare provider.

Please review these procedures and contact your healthcare provider or local distributor, as specified during your training, if you have any questions.

Indications for Use

The NxStage System One is indicated for the treatment of acute and chronic renal failure or fluid overload using hemofiltration, hemodialysis, and/or ultrafiltration, in an acute or chronic care facility.

The system is also indicated for home hemodialysis, including home nocturnal hemodialysis.

All treatments must be administered under physician's prescription, and must be performed by a trained and qualified person, considered to be competent in the use of this device by the prescribing physician.

Increased Risks Associated with Nocturnal Home Hemodialysis Therapy

The NxStage System One may be used at night while the patient and care partner are sleeping. Certain risks associated with hemodialysis treatment are increased when performing nocturnal therapy due to the length of treatment time and because therapy is performed while the patient and care partner are sleeping. These risks include, but are not limited to, blood access disconnects and blood loss during sleep, blood clotting due to slower blood flow or increased treatment time or both, and delayed response to alarms when waking from sleep.

Ancillary anticoagulant infusion pumps and fluid leak detection devices may be used to decrease certain risks for home hemodialysis treatments performed at any time, but NxStage requires the use of fluid leak detectors to identify leaks from the vascular access, Cycler and Cartridge when performing nocturnal therapy with the NxStage System One.

Patients should consult with their physician to understand the risks and responsibilities associated with nocturnal home hemodialysis using the NxStage System One, including those described in this supplement.

Symbols

Table 1-1: Symbol definitions

	This symbol indicates a warning; consultation of the *User Guide* prior to equipment operation is critical to the safe operation of the device. A warning is a statement that alerts you to the possibility of serious injury, other adverse reactions, or death associated with the use or misuse of the NxStage System One.
	This symbol indicates to consult the instructions for use (operating instructions) prior to use.
Rx Only	This symbol indicates that Federal law (USA) restricts this device to sale by or on the order of a physician (or properly licensed practitioner).
CE 0413	This symbol indicates compliance with the requirements for the European Union.
	This symbol indicates the manufacturer.
EC REP	This symbol indicates the authorized representative in the European Community.
	This symbol indicates that separate waste collection is required for electrical and electronic equipment.

This page intentionally left blank.

2: Nocturnal Use of the System One

Anticoagulation

WARNINGS

- Follow manufacturer's Instructions for Use of the Anticoagulant Pump to deliver proper Anticoagulation Therapy.
- Prime the anticoagulant pump and administration line with outlet pressure applied. Failure to do so could delay anticoagulant being administered.
- When using low anticoagulant delivery rates, an initial bolus of anticoagulant is recommended, since the anticoagulant will take longer to enter the blood lines at the beginning of treatment. This delay may increase the risk of blood clotting.
- Turn on the anticoagulant pump when treatment is started to avoid clotting.
- Turn off the anticoagulant pump when treatment is stopped for any time exceeding 2 minutes to avoid excessive anticoagulant administered to the patient.
- Anticoagulant pumps are not connected to the NxStage System One Cycler. In the event of an alarm from the anticoagulant pump, the user must press the STOP key on the Cycler to stop all pumps and clamp off the venous and waste lines if necessary. Failure to do so may increase the risk of blood clotting.

Longer treatments typically require continuous anticoagulant infusion. It is possible to give boluses of anticoagulant at regular periods during longer treatments. However, nocturnal therapy usually requires a continuous infusion of anticoagulant. An infusion pump should be used if continuous anticoagulant infusion is desired.

The physician prescription usually includes:

- initial loading or bolus dose;
- a patient-specific rate for continuous infusion;
- the maximum amount of anticoagulant to be infused; and
- when to begin and end the infusion during treatment.

When choosing an anticoagulant infusion pump, make sure it:

- can deliver the required infusion rate of anticoagulant;
- can operate with the specified infusion line tubing Inner Diameter (ID) containing a check valve;
- has locking connectors compliant with ISO 594 parts 1 & 2;
- has a maximum pressure limit that is greater than 600 mmHg; and
- can accept a syringe large enough to supply the required amount of anticoagulant for the duration of the treatment.

The following pumps have been validated for use with the NxStage System One for infusing anticoagulants:

- Medex® 2000 SERIES Medfusion Syringe Infusion Pump 2010H-VX.
- Caesarea T34L PCA Syringe Pump.

Other devices that meet the requirements above may be available.

A one-way check valve may be used between the anticoagulant infusion line and the blood lines. The use of a one-way check valve may reduce the chance of blood entering the anticoagulant line at high blood flow rates and low anticoagulant flow rates.

Vascular Access Leaks and Disconnections

WARNINGS

- Follow manufacturer's Instructions for Use to ensure correct operation of the leak detection device.
- Before each patient treatment, the Fluid Detection Sensor alarm must be tested. Failure to do so could result in a vascular access leak or disconnection or a fluid leak that goes undetected and may lead to significant blood loss, patient injury or death.
- Leak detection devices are separate from the NxStage System One Cycler and do not control the Cycler. When the leak detection device sounds an alarm, the user must press the STOP key on the Cycler to stop all pumps and close the clamps on the venous and waste lines. Failure to do so may result in significant blood loss, patient injury or death.

The vascular access and the blood lines should be correctly positioned and secure to avoid accidental dislodgement.

The use of an access leak detection device helps to detect blood leaks during treatment. The sensors of the access leak detection device should be positioned correctly so that the leak detection device alarms immediately if blood leaks from the vascular access. A stand-alone access leak detection device is required during nocturnal therapy. Test the access leak detection device following the manufacturer's Instructions for Use before each use.

When choosing an access leak detection device, make sure it can:

- detect blood when in contact with the sensor and trigger an audible alarm loud enough to interrupt sleep;
- be positioned in a way that allows leaked blood to contact the sensor;
- be tested for functionality before use; and
- continue working properly when the patient moves.

The following access leak detection device has been validated for use with the NxStage System One to detect access leaks:

- Redsense Medical Blood Loss Detection Device (Alarm Unit and Sensor).

Other devices that meet the requirements above may be available.

Cycler/Cartridge Fluid Leak Detection

WARNINGS

- Follow manufacturer's Instructions for Use to ensure correct operation of the leak detection device.
- Before each patient treatment, the Fluid Detection Sensor alarm must be tested. Failure to do so could result in a vascular access leak or disconnection or a fluid leak that goes undetected and may lead to significant blood loss, patient injury or death.
- Leak detection devices are separate from the NxStage System One Cycler and do not control the Cycler. When the leak detection device sounds an alarm, the user must press the STOP key on the Cycler to stop all pumps and close the clamps on the venous and waste lines. Failure to do so may result in significant blood loss, patient injury or death.

The use of a fluid leak detection device helps detect fluid and blood leaks from the Cycler or Cartridge during treatment.

A leak detection device is required during nocturnal therapy. Position the device under the Cycler so that any fluids dripping from the Cycler or Cartridge fall directly onto the device.

When choosing a leak detection device, make sure it can:

- detect blood or conductive fluid when in contact with the sensor and trigger an audible alarm loud enough to interrupt sleep;
- be positioned in a way that allows leaking blood or fluid to fall directly onto the sensor; and
- be tested for functionality before use.

The following fluid leak detection device has been validated for use with the NxStage System One to detect fluid and blood leaks from the Cycler or Cartridge:

- NxStage Fluid Detection System

Other devices that meet the requirements above may be available.

This page intentionally left blank.

NxStage Customer Service Center (United States only)

Tel: 1-866-NXSTAGE (1-866-697-8243)

Fax: 1-978-687-4809

Email: customerservice@nxstage.com

Outside the United States, contact your local distributor.

CE 0413

EC REP

MEDISYSTEMS EUROPE, S.p.A.
Via G. Galilei, 20
Sorbara Di Bomporto (MO)
Italy 41030

NxStage Invent. Improve. Inspire.

NxStage Medical, Inc.
350 Merrimack Street
Lawrence, MA 01843 USA

NxStage System One User Guide

NxSTAGE®
Invent. Improve. Inspire.

NxStage® System One™
User Guide

Software Versions 4.5, 4.6, 4.7, 4.8, 4.9 and 4.10

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

NC4820 Rev. 8 2014-06-27

This user guide describes the use of the NxStage System One. This guide is one part of a user-training program. This guide is applicable to NxStage System One Cycler chronic models CYC-D2E (NX1000-1), CYC-D2E (NX1000-3) and NX1000-4 for chronic renal replacement therapies.

Refer to the NxStage System One Supplement for Nocturnal Hemodialysis which describes the increased risks associated with nocturnal home hemodialysis therapy and the ancillary equipment that is recommended or required to use the System One for nocturnal home hemodialysis therapy. When using the system for nocturnal therapy, thoroughly read this supplement for additional instructions and information required to safely perform nocturnal therapy.

Please note that the use of the NxStage System One, like all medical devices, involves some risks. Patients should consult with their physicians to understand the risks and responsibilities associated with home hemodialysis using the NxStage System One, including those described in this user guide.

WARNINGS

All NxStage equipment and disposables must be used as described in the applicable User Guides and Instructions for Use, and in accordance with a physician's prescription. Make sure that all User Guides are carefully read and understood, and are always available to the operator at the treatment location. Improper use may cause injury or death.

Treatment with the NxStage System One should only be done under the responsibility of a physician and performed by a trained and qualified person. A trained and qualified person must observe all treatments so that alarms and harmful conditions can be responded to promptly. Possible harmful conditions include, but are not limited to venous disconnects, inadvertent fluid administration, or excessive ultrafiltration. A patient should not dialyze alone, even if they are trained and qualified.

Customer Service and Technical Support

In the United States and Canada

Customer Service

For questions about ordering and supplies contact NxStage Customer Service:

Phone: 1-866-NXSTAGE (1-866-697-8243)

Fax: 1-978-687-4809

Email: customerservice@nxstage.com

Technical Support

For questions about equipment contact NxStage Technical Support:

Phone: 1-866-NXSTAGE (1-866-697-8243)

When calling Technical Support, have the following information available:

- Patient's name, name of person placing the call, and their relationship to the patient
- Dialysis center name, city, and state
- Serial number of cycler (4- or 5-digit number on back of cycler near the power cord)
- Cartridge lot number
- Whether cycler is in Prime or Treatment Mode
- If in Prime, which step number is shown in the green dialysate rate window?
- If calling about an alarm, which alarm number and color?

If using PureFlow SL also include:

- Serial number of PureFlow SL Control Unit (4- or 5-digit number on top of Control Panel door)
- Serial number of PureFlow SL Cabinet (6-digit number on front of PureFlow SL tub)
- Lot number of dialysate bags, or SAK and PAK

Outside the United States and Canada

Outside the United States and Canada, contact your local distributor for technical support and customer service.

This page intentionally left blank.

Contents

Chapter 1 Introduction

General information about using the NxStage System One includes:

Electromagnetic compatibility (EMC) notice

The equipment generates and uses radio frequency (RF) energy. It also radiates RF energy. For protection against electromagnetic interference (EMI), install and use the equipment according to instructions.

The equipment was tested and found to comply with the limits of acceptance specified in Standard IEC 60601-1-2 for Medical Products. These limits provide reasonable protection against EMI when using the equipment in the specified environments.

This equipment can be affected by portable and mobile RF communications equipment.

Do not stack this equipment with other equipment, except as indicated.

The equipment was tested using a NX1054 - Shielded LAN Cable, length 3.05 m (10 ft). Using other cables may result in increased emissions or decreased immunity.

See Chapter 7, Hardware specifications for additional information.

Indications for Use

The NxStage System One is indicated for the treatment of acute and chronic renal failure or fluid overload using hemofiltration, hemodialysis, and/or ultrafiltration, in an acute or chronic care facility.

The system is also indicated for home hemodialysis, including home nocturnal hemodialysis.

All treatments must be administered under a physician's prescription, and must be performed by a trained and qualified person, considered to be competent in the use of this device by the prescribing physician.

Symbols

Table 1-1: Symbol definitions

	This symbol indicates a warning; consultation of the *User Guide* prior to equipment operation is critical to the safe operation of the device. A warning is a statement that alerts you to the possibility of serious injury, other adverse reactions, or death associated with the use or misuse of the NxStage System One.
	This symbol indicates a precaution. A precaution or caution is a statement that alerts you to the possibility of a problem with the device associated with its use or misuse. Such problems include device malfunction, device failure, damage to the device or damage to other property.
	The ON indication for the cycler.
	The OFF indication for the cycler. The "dot" indicates power is still available to the computer and devices connected to the AC outlet on the back of the cycler.
	This symbol indicates the catalog number.
	This symbol indicates the lot number.
	This symbol indicates the temperature storage limits.
	This symbol indicates the relative humidity range.
	This symbol indicates the Use-by-Date.
Rx Only	This symbol indicates Federal law (USA) restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

Table 1-1: Symbol definitions

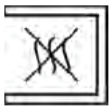
	This symbol indicates do not use if the product sterilization barrier or its packaging is compromised or if the packaging is damaged.
	This symbol indicates that the product is a sterile fluid pathway, sterilized by gamma irradiation.
	This symbol indicates that the product is a non-pyrogenic fluid pathway.
	This symbol indicates that the product is for single use only.
	This symbol indicates do not use a knife or other sharp object to open this product or its packaging.
	This symbol indicates that consultation of the instructions for use (operating instructions) is mandatory prior to use.
	This symbol indicates to consult the instructions for use (operating instructions) prior to use.
	This symbol indicates the product is not made with natural rubber latex.
	This symbol indicates the manufacturer.
	This symbol indicates the authorized representative in the European Community.
	This symbol indicates compliance with the requirements for the European Union.

Table 1-1: Symbol definitions

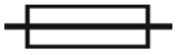
	This symbol indicates the date of manufacture.
	This symbol indicates that the product contains DEHP, which is commonly used to make PVC plastics more pliable. Animal studies indicate that repeated or prolonged DEHP exposure may result in adverse reproductive or developmental effects or both. While there is no conclusive data regarding the adverse effects in humans from DEHP exposure, certain populations such as children and pregnant or nursing women may be at the highest risk. Prior to using this product, consult with your physician for further information.
	This symbol indicates that separate waste collection is required for electrical and electronic equipment.
	This symbol indicates that the device meets the IPX1 "Drip Proof" requirements of IEC 60529.
	This symbol indicates Class II electrical equipment.
	This symbol indicates the device meets the IP22 "Effective against >12.5 mm Objects," and "Drip Proof" requirements of IEC 60529.
	This symbol indicates a fuse.
	This symbol indicates Alternating Current (AC) voltage.
	This symbol indicates Type BF Applied Part. It is provided to tell the operator, patient, or both that the applied part is isolated (floating) from the rest of the device and therefore provides a higher degree of protection against electric shock and allowable leakage currents than a non-isolated applied part.

Table 1-1: Symbol definitions

R	This symbol indicates the date of last service.
	This symbol indicates Radio Frequency (RF) transmitter: Intentional RF transmissions for wireless communications.
	This symbol indicates that the NxStage System One Cycler has been tested by a Nationally Recognized Testing Laboratory (NRTL) per OSHA in the United States and by a Standards Council of Canada Testing Organization (TO) and a Certification Organization (CO) in Canada for conformance to the listed product safety standards.
	This symbol indicates the range of temperatures the equipment must be operated in.

General warnings

A warning alerts you to the possibility of serious injury, other adverse reactions, or death associated with the use or misuse of the NxStage System One. There are additional warnings throughout this guide.

WARNINGS

- Treatment with the NxStage System One should only be done under the responsibility of a physician and performed by a trained and qualified person. A trained and qualified person must observe all treatments so that alarms and harmful conditions can be responded to promptly. Possible harmful conditions include, but are not limited to venous disconnects, inadvertent fluid administration, or excessive ultrafiltration. A patient should not dialyze alone, even if they are trained and qualified.
- All NxStage equipment and disposables must be used as described in the applicable User Guides and Instructions for Use, and in accordance with a physician's prescription. Make sure that all User Guides are carefully read and understood, and are always available to the operator at the treatment location. Improper use may cause injury or death.
- Always follow universal precautions when operating the NxStage System One, cleaning or disinfecting equipment, or observing patient treatment, to avoid infection.
- Weigh the patient before treatment to make sure that the appropriate ultrafiltration volume is calculated. Follow the physician's prescription for maximum volume and rate of fluid to be removed. Removing too much or too little fluid, or removing fluid too quickly, may cause patient injury. In addition, prescribing physicians should be aware that certain patients, such as low weight patients and patients at or near their dry weight, may be unable to tolerate fluid balance variations in amounts less than the total fluid accuracy tolerances of the NxStage System One Cycler and other ancillary fluid delivery devices. These patients must be closely monitored for signs and symptoms of excessive ultrafiltration or fluid overload. Refer to the System One User Guide for additional information on ultrafiltration during dialysis.

WARNINGS

- Hemodialysis may result in significant changes in the blood concentration of electrolytes and glucose and in the patient's volume status. Appropriate monitoring of the patient's hemodynamic, fluid, electrolyte, and acid-base balance should be performed regularly, per physician orders, to ensure appropriate response to therapy. Failure to do so could result in inappropriate therapy for the patient.
- The Dialyzer may remove medications given into the Arterial Patient Line (red clamp). Refer to the medication manufacturer's labeling for clearance characteristics of any medications given into the Arterial Patient Line (red clamp). Follow the policies and procedures of your center for infusing fluid or medications into the blood circuit. Infusing fluids or medication incorrectly may reduce the dose given to the patient or cause harm to the patient.
- When a heart rate monitor is used during treatment, the NxStage System One Cycler's pumps may produce electrostatic discharges that may appear as artifacts on the monitor's screen. The electrostatic discharges produced by the Cycler will not harm the patient. Look at the monitor's screen when the Cycler's pumps are running and when they are stopped to confirm it is the Cycler that is producing these artifacts.
- Observe the patient for allergic reactions, especially if the patient has a history of allergies. If the patient has an adverse reaction, stop the treatment and follow your center's instructions.
- If you are using a Cartridge without a pre-attached Dialyzer, make sure that the Dialyzer you select has a maximum transmembrane pressure (TMP) of at least 500 mmHg or higher. Use of a Dialyzer with a lesser TMP rating increases the risk of a blood leak. NxStage defines TMP as the difference between venous pressure and effluent pressure. Follow the Dialyzer manufacturer's instructions for use for TMP rating.
- Do not use any supplies after their expiration date or Use-by Date, or the supplies may not perform as intended.

WARNINGS

Manual fluid boluses and fluid consumed during treatment are not included in the System One fluid balance calculations. Excessive fluid boluses, whether intentional or unintentional, or failure to account for consumed fluid during treatment, may cause patient injury. Include fluid boluses and the volume of fluid consumed in manual fluid balance calculations. Make sure that the administration lines used for manual bolus or rinseback are clamped after use.

Extreme high or low fluid temperatures may cause injury or death. The NxStage System One Cycler checks for high and low dialysate temperature during normal operation. The temperature of rinseback and manual bolus fluids is not monitored at all. At dialysate rates lower than 5 L/hr, low fluid temperatures are more likely to occur. If System Setting #79 is set to 0 or the Cycler software version is less than 4.9, low temperature monitoring is disabled at all times. In instances of low fluid temperatures, the patient may feel discomfort, which may include but is not limited to shivering. Sedated or comatose patients should be watched carefully when fluid temperature is not monitored.

The NxStage System One disposables are for single use only unless otherwise indicated. Do not reuse or resterilize. Materials used to make the disposables may not withstand reprocessing or reuse or both. Reuse or resterilization of the disposables may result in, but is not limited to, the following problems:

- risk of cross contamination
- material degradation
- biocompatibility issues
- endotoxin reactions
- failure of the disposable to perform as intended.

WARNINGS

The NxStage System One Cycler will automatically remove the rinseback volume when both the System Setting #38 is set to 1 and the Ultrafiltration pump rate (UFR) is greater than 0. Automatic removal of the rinseback volume is not displayed to the operator. Therefore it is important to account for the rinseback volume when calculating the ultrafiltration rate and volume for the treatment. Do not add the rinseback volume to the targeted ultrafiltration volume when the Cycler is set to automatically remove the rinseback volume or excess ultrafiltration will result. For patients that may be unable to tolerate even small fluid balance changes, such as low weight patients and patients at or near their dry weight, the excess ultrafiltration may result in hypotension or hypovolemia which may cause patient injury or death. When automatic removal of the rinseback volume is not desired, System Setting #38 should be set to 0.

In order to avoid electric shock, patients with a central venous catheter must not touch or be in contact with any AC powered electric devices during their treatment. Examples include but are not limited to, electric blankets or heating pads, electric lamps or lights, computers that are plugged into an electrical outlet, and electric powered chairs.

Physicians must ensure that central venous catheters are not placed in the right atrium. The risk of microshock to the patient resulting in fibrillation is increased when the tip of a central venous catheter placed in the right atrium touches the atrium wall during use of the NxStage System One.

Caution should be taken with babies and young children around the System One and PureFlow SL. The disposable lines or bags pose a strangulation hazard. The disposables also contain small parts that pose a choking hazard if swallowed.

The NxStage System One contains alarms that may be configured by the operator. The operator should check that the current alarm settings are correct for the patient. Incorrect settings may cause injury or death.

General precautions

A precaution or caution is a statement that alerts you to the possibility of a problem with the device associated with its use or misuse; such problems include device malfunction, device failure, damage to the device or damage to other property. Additional precautions can be found throughout this guide.

⚠ PRECAUTIONS

⚠ Federal law (USA) restricts this device to sale by or on the order of a physician or properly licensed practitioner.

⚠ The maximum dialysate flow rate for the NxStage System One is 300 ml/min. Consider this when prescribing dialysis.

⚠ Do not use the Cartridge for more than 72 hours or 864 liters of blood processed.

⚠ The NxStage System One has only been studied for up to 4 hours of hemodialysis therapy in the home setting.

⚠ Do not alter any NxStage disposables. Performance of altered disposables cannot be guaranteed.

⚠ Store and transport NxStage disposables and equipment in accordance with applicable Instructions for Use or labeling. Failure to do so may affect performance.

⚠ Follow your center's instructions for steps to take in case of emergency. Each home patient should develop a personal disaster plan with their center to address the actions that they should take in the event of a natural or other disaster affecting their home such as a fire, flood or loss of electrical power.

⚠ PRECAUTIONS

⚠ In a low humidity environment, static electricity can build up and you will produce an Electrostatic Discharge (ESD) to any conductive surface, resulting in a small electric shock. The NxStage System One Cycler and its accessories have conductive surfaces. Static electricity can especially build up when removing the plastic outer wrap from the dialysate bags, therefore it is recommended that you grasp the IV Pole or saline hook to discharge any built up static electricity before hanging the bags.

⚠ Preventive maintenance on NxStage equipment must be performed in accordance with this User Guide or applicable Instructions for Use. When the Cycler displays a Yellow Caution 71, it is time to contact Technical Support or an authorized distributor to schedule maintenance on the Cycler.

⚠ After use, discard all disposables in accordance with local, national and federal regulations as instructed by your center. Use universal precautions when disposing of Cartridges.

⚠ The clamps included on disposables are intended to be used to allow flow when opened and stop flow when closed. They are not intended to be used to control the rate of flow.

⚠ It is the responsibility of the healthcare provider to make sure that the procedures to return the product are followed.

Aseptic technique

Treatment with the NxStage System One requires access to the patient's blood. This may expose patients, caregivers, and observers of the treatment to agents that can cause infection.

Users of the equipment must use aseptic technique to minimize infection. Examples of aseptic technique include washing hands before making connections or disconnecting parts of the equipment or disposables, not touching line connections and inside the lines with caps, keeping supplies in a clean and dry environment.

Universal precautions

Universal precautions are medical procedures to follow when caring for patients to prevent contamination from potentially infectious blood and bodily fluids. Personal protective equipment such as gloves, face shields, and gowns must be worn when opening the blood circuit or accessing the blood or waste. Patients must wear personal protective equipment to prevent contamination to hands and clothes. If you are exposed to blood or bodily fluids, always treat them as potentially infectious.

Emergency backup

Your dialysis center must have an emergency backup plan to provide your dialysis treatment if your equipment needs repair, service, or is not available for use. An emergency backup plan may tell you:

- To go to your center for treatment
- To go to another center that has an agreement with your center for emergency backup
- To receive a machine before your next treatment

Notify your center if problems with your equipment or supplies prevent you from performing your treatment.

Returning your product

PRECAUTION

It is the responsibility of the healthcare provider to make sure that the procedures to return the product are followed.

In the United States and Canada

To return a product to NxStage, you need a return authorization (RA) number. Contact Customer Service or Technical Support to receive an RA number and a returns kit with instructions for packing, labeling, and shipping the product.

Before shipping the NxStage System One, follow the cleaning instructions given in Chapter 6, Maintenance. Always notify your center when you need to return a product to NxStage.

Address for returns

NxStage Medical, Inc.
Attn: Customer Service
350 Merrimack Street Lawrence, MA 01843 USA

Email: customerservice@nxstage.com

Outside the United States and Canada

Contact your local center or distributor for product return procedures.

Disclaimer

NxStage Medical, Inc. is not responsible or liable for any NxStage System One performance failure when the failure is due (in whole or in part) to any misuse of or modification to the system or its operations. This includes, without limitation:

- The failure to have all operating procedures performed by a fully trained and qualified person.
- The failure to maintain proper electrical connections fully compliant with all codes, system specifications, and applicable international electrical standards (IEC) requirements.
- The failure to use the system at all times in accordance with this user guide.
- The failure to use only approved devices with the NxStage System One.

Conventions used in this guide

NxStage uses the following type-style conventions in this guide:

Table 1-2: Conventions

Style	Description	Example
KEYS/KNOBS	References to keys or knobs on the cycler, warmer, and PureFlow SL.	Press the **STOP** key
Modes	References to modes of operation.	The cycler is in Treatment Mode
Cross-reference	Cross-reference to a heading within this documents.	See **Ultrafiltration,** page 2-4.
Title	References to user guides for other NxStage equipment.	*NxStage PureFlow SL User Guide.*

Table 1-3: Important Keys

Key	Name	Actions
	**ADD FLUID**	• In Prime Mode - Begins Prime and Alarm Test • In Rinseback Mode - Returns blood
	**TREATMENT**	• Begins therapy • Continues therapy if it has stopped
	**STOP**	Single press • During treatment - Stops all pumps. • During alarm - Starts alarm recovery. Press and hold for two seconds • In Treatment Mode - Ends treatment • In Rinseback Mode - Ends rinseback
	**MUTE**	Silences alarms and cautions.
	**VOLUME TOGGLE**	• Press once to change the display from rate to volume. • Press again to return to the rate display or wait for the display to return automatically.
	**UP** Adjustment Arrows	• To increase
	**DOWN** Adjustment Arrows	• To decrease

Glossary

See Chapter 8, Glossary for the common terms and their meaning used in this guide.

Pictures

The pictures in this user guide are for example only. Treatment values shown in pictures are for example only. Always use the treatment values from your prescription and your cycler control panel during treatment.

Chapter 2 The NxStage System One

The NxStage System One is for short term (acute) and long term (chronic) renal replacement therapies. The System One and its components work together to deliver your treatment from beginning to end.

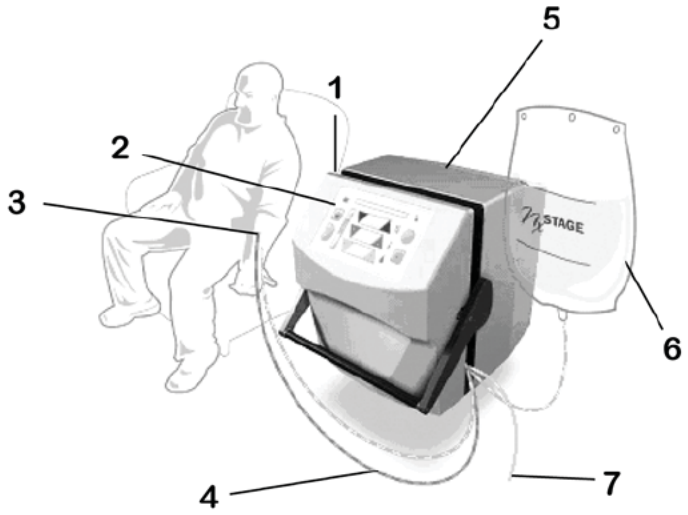
An introduction to dialysis

Dialysis is needed when the kidneys are no longer able to clean the blood of wastes or remove extra fluid. The three types of dialysis are hemodialysis, hemofiltration, and hemofiltration with or without ultrafiltration.

Kidneys have several functions in the body. The most well known function is to make urine. When the kidneys can no longer filter the blood and make urine, there is a buildup of waste products and excess fluid in the blood. Dialysis removes waste and excess fluid from the blood of patients.

A dialyzer filters the blood of waste products and removes excess fluid from the blood. A mix of water and electrolytes, called the dialysate, is pumped through the dialyzer to remove waste products like urea and creatinine from the blood. It does not remove the blood cells, proteins, and important substances the body needs.

Figure 2-1: The therapy system



1	Dialyzer (not shown)	5	Machine
2	Control panel	6	Dialysate
3	Vascular access	7	To drain
4	Blood tubing set		

The vascular access

The vascular access is the site on the patient's body where blood is removed and returned during dialysis. The three types of vascular access for dialysis are the fistula, graft, and catheter. From the vascular access, the blood is pumped through a blood circuit outside the body. The blood goes through the dialyzer where the waste products and excess fluid are removed. The filtered blood is returned to the body through the vascular access.

The dialysis machine

The dialysis machine controls the flow of the dialysate. It also controls the flow of blood while it is outside the body. The dialysis machine has a control panel to enter the treatment settings prescribed by a doctor. The machine also monitors the treatment, which helps keep the patient safe.

Alarms alert patients and caregivers to potential dangers that need prompt attention. To protect the patient, NxStage labeling requires that a trained and qualified person must observe all treatments so that alarms and dangers are recognized and treated promptly. Patients should not dialyze alone. A disconnected blood line, errors in fluid administration, or ultrafiltration errors are examples of potential dangers during treatment.

The dialyzer

The dialyzer is a filter. It has many tiny tubes through which the blood flows. The tubes are made of a very thin membrane with very small holes. The small holes keep blood cells, proteins, and other important substances from passing through the membrane into the dialysate. Smaller waste products in the blood like urea, creatinine, potassium, and extra fluids pass through the membrane.

During dialysis, the dialysate fluid flows along the outside of the tubes. The waste products flow into the dialysate. After the dialysate passes through the dialyzer, it is sent to a drain.

The prescription

The doctor writes a prescription for each patient. A common prescription includes the type of dialyzer to use and the chemical composition of the dialysate. It also includes the frequency and duration of treatment, the rate of blood flow, and the rate and volume of dialysate to use.

Risks of dialysis therapy

Use of the NxStage System One, like all medical devices, involves some risks. Risks may be mild or severe. Common risks during treatment include anxiety, back pain, bleeding, blood clotting, chest pains, cramps, depression, dizziness that could result in fainting, electrolyte imbalance, fluid overload, fatigue, fever, headache, high blood pressure, infection, itching, low blood pressure, low red blood cell count, nausea, shakes and chills, and vomiting.

Less common risks include allergic reaction including severe hives, blockage of a blood vessel by an air bubble, damage to the vascular access, decrease in platelet count, fluid build-up in the lungs, heart rhythm disturbances, heart attack, seizure, shock, stroke, and even death.

To help control the risks of dialysis, check the blood pressure, vital signs, and general well-being of the patient at regular intervals during treatment. Identified early in the treatment, risks can be treated promptly.

Before treatment, review potential risks with your doctor. Review the potential risks given in this user guide.

Ultrafiltration

When the kidneys work well, they remove excess water from the body to maintain body weight without excess fluid. For patients on dialysis, it is necessary to remove this excess water to get the patient back to dry weight. Dry weight is the body weight without excess fluid.

Ultrafiltration is the process of removing excess fluid during dialysis to get the patient back to dry weight. The doctor or center determines the dry weight of each patient. Patients check their weight at the start of each treatment to determine how much fluid to remove during the treatment and to confirm that their dry weight is met at the end of treatment.

At the start of treatment, patients enter into their dialysis machine how much excess fluid to remove. This is called the ultrafiltration volume goal. They also enter how quickly to remove the excess fluid. This is called the ultrafiltration rate. It is important for patients and caregivers to enter the correct volume and rate given by their doctor or center to avoid potential risks and side effects.

Removing too much fluid or removing fluid too fast can affect the body in harmful ways, some life threatening. During and after treatment, it can cause low blood pressure, nausea, vomiting, dizziness, and muscle cramps.

If not enough fluid is removed during treatment, other side effects can occur. Between treatments, excess fluid can cause swelling of ankles, calves, face, or hands, difficulty breathing, coughing, and high blood pressure.

To prevent the risks and complications of ultrafiltration, during each treatment, do the following:

- Enter the ultrafiltration volume goal and rate in the dialysis machine as given by your doctor or center. See Chapter 9, System Settings.
- Remember to add the rinseback volume to the ultrafiltration volume goal if System Setting 38 is set to **0**.
- Do not remove excess fluid faster than the rate set by your doctor or center. Do not remove more fluid than the volume set by your doctor or center. Better yet, distribute the volume to be removed over the duration of the treatment. Be familiar with the symptoms of removing too much fluid or too little fluid.
- Use the correct dry weight. Measure the dry weight in kilograms, not pounds, to calculate the ultrafiltration volume goal. Use a digital medical scale that reads kilograms.
  - Weight yourself three times and average the three numbers. Each weight should be within 0.1 kg of each other. Disregard any weight above this number and average the remaining weights.
  - Do not eat or drink after measuring your pre-dialysis weight or during dialysis. You will gain weight if food or fluid is consumed during dialysis. If you drink after measuring your pre-dialysis weight or during treatment, add the amount you drank to the ultrafiltration volume goal.
- You should not drink for at least 30 minutes before or during the treatment, unless you have symptoms that suggest you need fluid. If you have symptoms (for example, you feel weak, very thirsty or dizzy) ask your center for guidance.

NOTE

At the end of treatment, determine the weight removed from the patient by comparing the patient's weight before and after dialysis. This value may be different from the ultrafiltration volume goal. Weight calculation or scale errors, food and drink taken during treatment can explain this difference. Sweating and breathing can also result in a small weight loss. The dialysis machine tolerances may also explain the difference in weight.

For more information, go to the National Kidney Foundation www.kidney.org and to the American Association of Kidney Patients www.aakp.org.

The NxStage System One

The NxStage System One is a complete system designed to provide many types of renal replacement therapies.

The system includes:

- A cycler to control your treatment
- A cartridge to route your blood and the dialysate
- A dialyzer attached to the cartridge to filter the blood
- Dialysate to clean the blood of waste products. Dialysate may be pre-mixed or made by the PureFlow SL.
  - Pre-mixed dialysate is commonly available in 5-liter bags
  - The PureFlow SL is an option to make your own dialysate instead of using pre-mixed solutions
- A warmer to warm the dialysate to a comfortable temperature

Some additional supplies that are needed to complete your treatment are listed on page 2-23.

The cycler is available with two maximum dialysate flow rates, see Table 2-1.

Table 2-1: Cycler Models

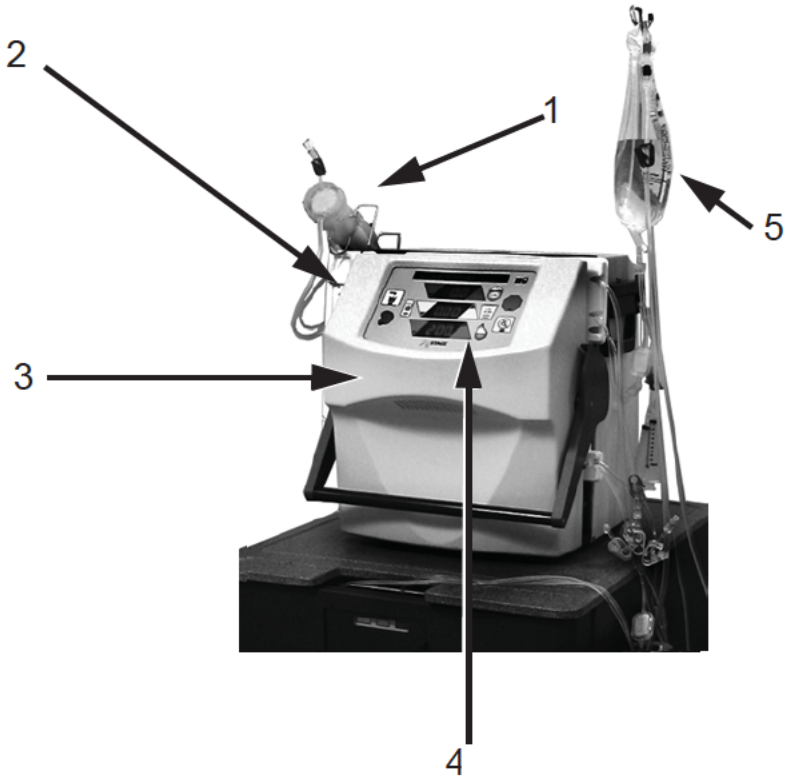
Brand Name	Part Number	Model Number	Max Dialysate Flow Rate
NxStage System One	CYC-D2E	NX1000-1	12 L/hour
NxStage System One S	CYC-D2E	NX1000-3	18 L/hour
NxStage System One S		NX1000-4	18 L/hour

The System One CYC-D2E (NX1000-1) cycler delivers up to 12 liters of dialysate per hour. The System One S CYC-D2E (NX1000-3) and the NX1000-4 deliver up to 18 liters of dialysate per hour.

To deliver higher flow rates with the CYC-D2E (NX1000-3) cycler or the NX1000-4 cycler, you must set up the system for high flow rate. See **High flow configuration**, page 3-10. When using a warmer, the dialysate rate must never exceed 12 liters per hour.

If your treatment calls for dialysate flow rates above 12 liters per hour, you cannot use a pre-mixed dialysate. In its place, you must use a dialysate prepared with the PureFlow SL. Contact your center to receive a PureFlow SL if your treatment calls for flow rates above 12 liters per hour.

Figure 2-2: The NxStage System One



1	Dialyzer (shown pre-attached)	Filters waste fluid, toxins, and electrolytes without removing blood cells or significant blood protein.
2	Cartridge (shown inside the cycler)	A single-use disposable containing all fluid pathways.
3	Cycler	Contains all pumps, sensors, and control to administer therapy.
4	Control panel	Allows operator to control and monitor therapy.
5	Fluids	*Priming/Bolus/Rinseback*: Sterile saline solution to prepare circuit for use and to administer intravenously to patient. *Therapy (dialysate or replacement):* Used to deliver prescribed therapy.

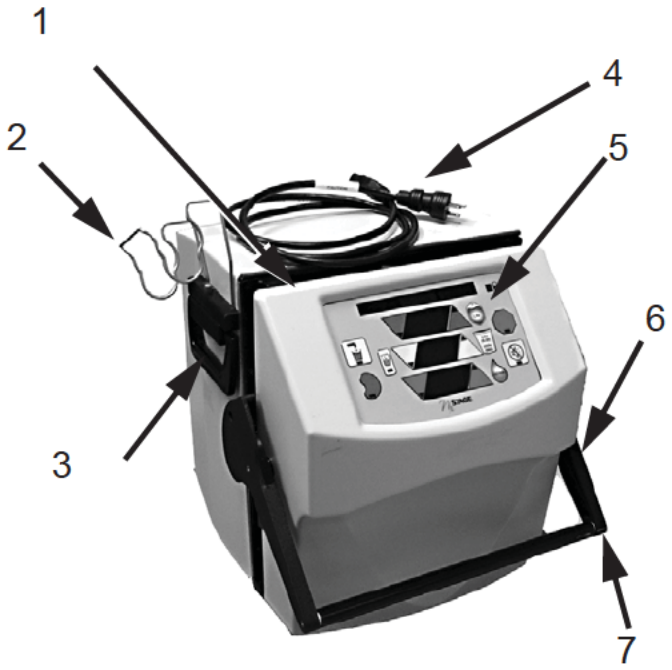
Cycler

The cycler controls the blood pump, the treatment, and monitors the safety systems.

NOTES

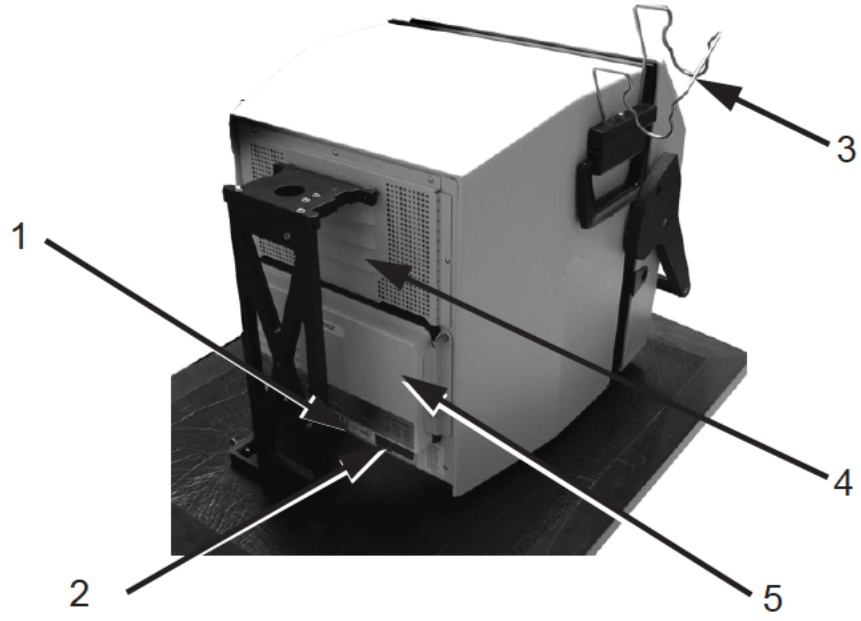
- The CYC-D2E (NX1000-1 and NX1000-3) cyclers have a power cord with a three-prong plug, with ground.
- The NX1000-4 cycler has a power cord with two prongs, no ground.

Figure 2-3: Front View (shown with AC power cord)



1	Serial Number Label	5	Control Panel
2	Filter Holder	6	Access Pressure Connection Point
3	Lift/Carry Handle: One on each side	7	Cycler Door Handle: Lift to Open, Push Down to Close
4	AC Power Cord		

Figure 2-4: Back View (Shown with table top stand)



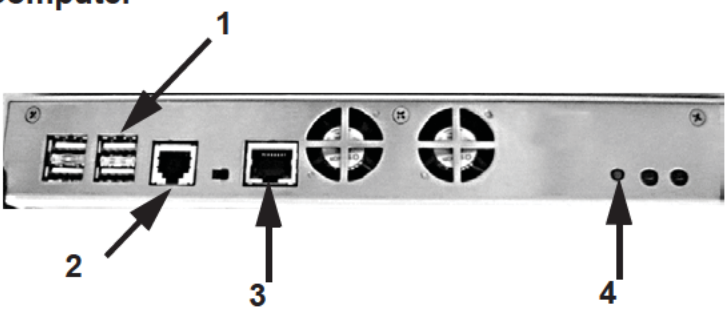
1	Serial Number Label	4	Cooling Fan
2	Power Input and Power Switch	5	Jewel Box or ConNxBox Computer (Jewel Box shown)
3	Filter Holder		

Figure 2-5: Power Indicator

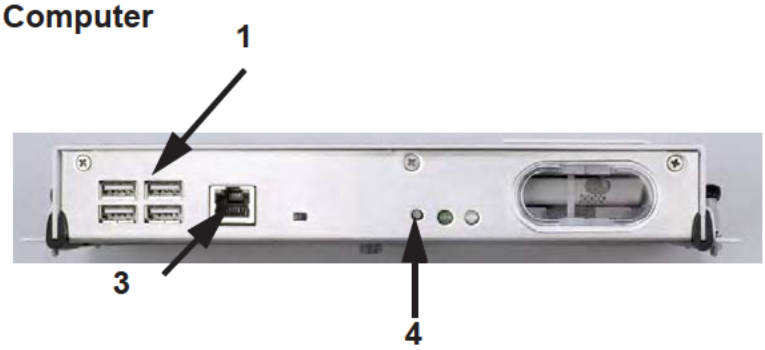
On	▮
Off	○

Figure 2-6: Underside of computer

Jewel Box Computer



ConNxBox Computer

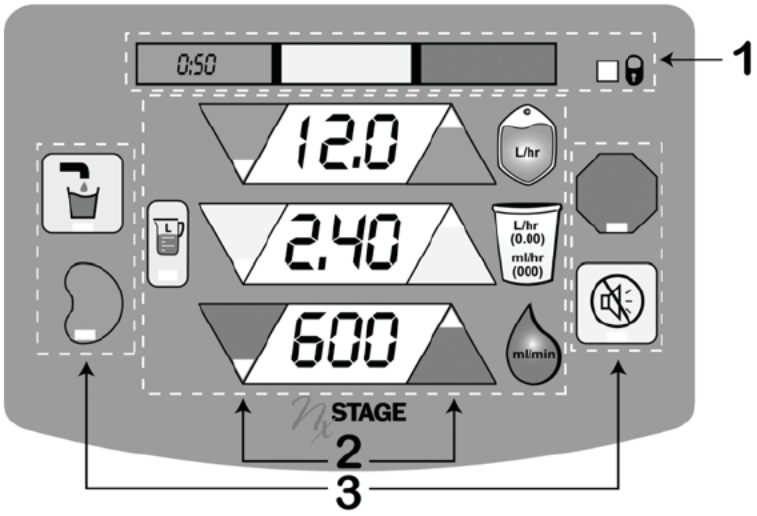


1	USB Ports	3	Network Connection
2	Telephone Connection (Jewel Box only)	4	Reset Button

Control panel

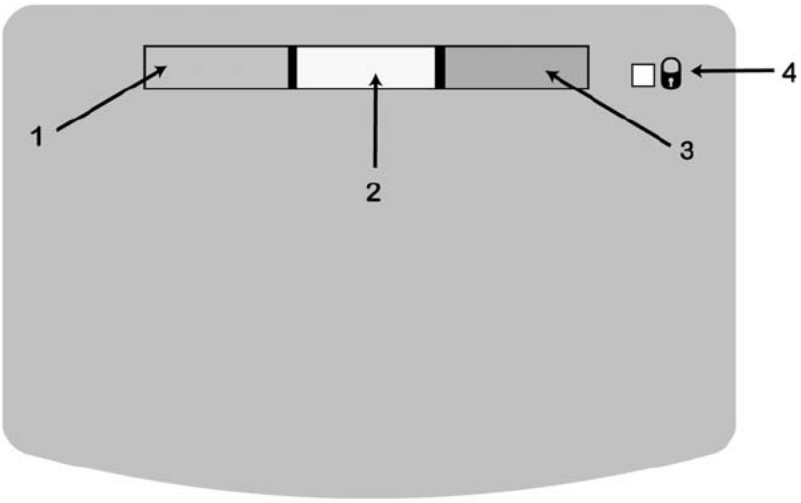
The control panel allows you to set and adjust your treatment parameters, and monitor the treatment.

Figure 2-7: The control panel



1	Status Window
2	Rate/Volume Controls
3	Treatment Keys

Figure 2-8: Status window

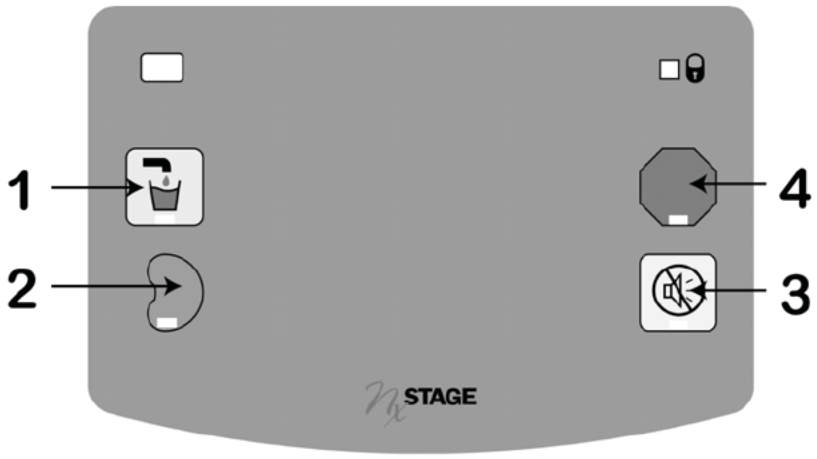


1	Green Operating	• Safe operating condition • No action required Also displays: – Time left in Prime – Time left in Treatment – Venous pressure – Effluent pressure – Flow fraction – Access pressure (optional)
2	Yellow Caution	• Caution event • Action may be required, see Chapter 5, Troubleshooting
3	Red Alarm	• Alarm event • Action will be required, see Chapter 5, Troubleshooting
4	Door Lock	When lit, door is locked

Treatment keys

The treatment keys allow you to adjust your treatment. Treatment keys light up when they are available for use. When the pumps are running, the **STOP** key is available for use.

Figure 2-9: Treatment keys and functions

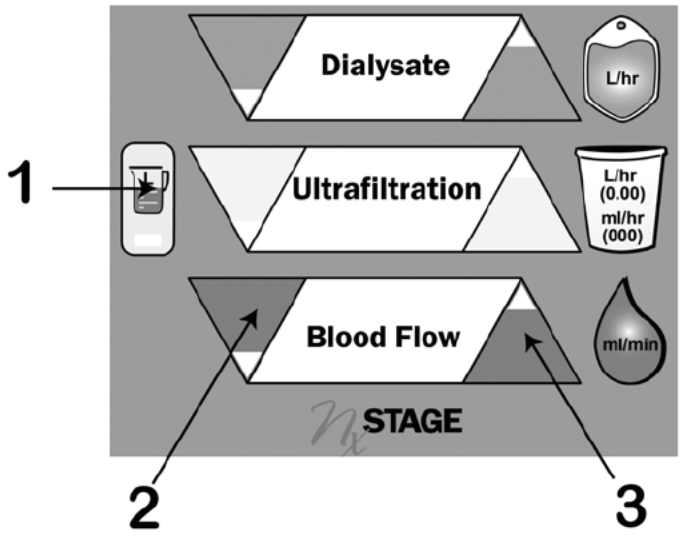


1	**ADD FLUID**	• Prime – Begins Prime and Alarm Test • Rinseback – Returns blood
2	**TREATMENT**	• Begins therapy or continues therapy if it has stopped
3	**MUTE**	• Silences alarms and cautions
4	**STOP**	• Single press – Stops all pumps (during treatment) or initiates alarm recovery (during alarm) • Press and hold (for two seconds) – Enters end of Treatment or end of Rinseback

Rate and volume keys

The rate and volume keys allow you to adjust the rate and volume for the dialysate, ultrafiltration, and blood flow. The rate and volume keys light up when they are available for use. The rate and volume keys are toggle-keys.

Figure 2-10: Rate/Volume controls and functions



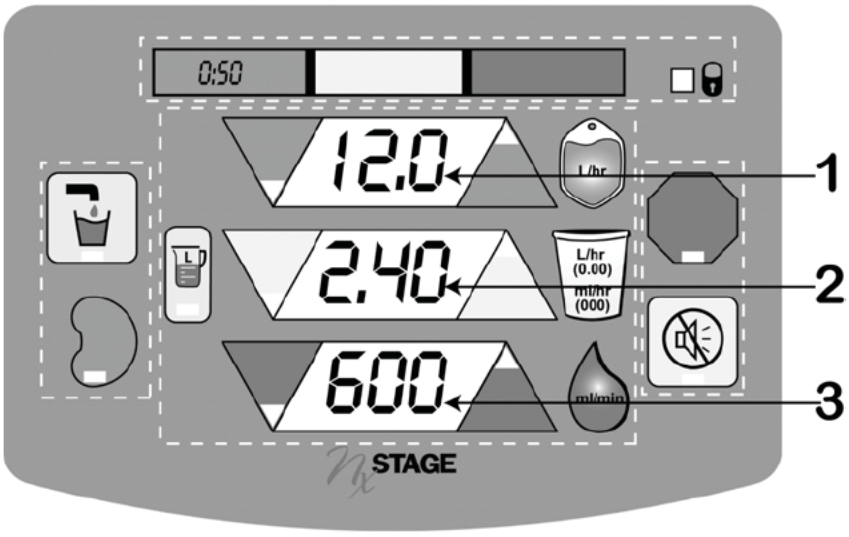
1	VOLUME TOGGLE	Changes window from rate to volume when the key is pressed.
2	DOWN ADJUSTMENT ARROWS	To decrease rate or volume
3	UP ADJUSTMENT ARROWS	To increase rate or volume

NOTE

Press the **VOLUME TOGGLE** key to change the windows from **rate** to **volume**. The volume windows returns automatically to the rate windows after a period of time, based on the cycler software version and your System Settings. See Chapter 9, System Settings.

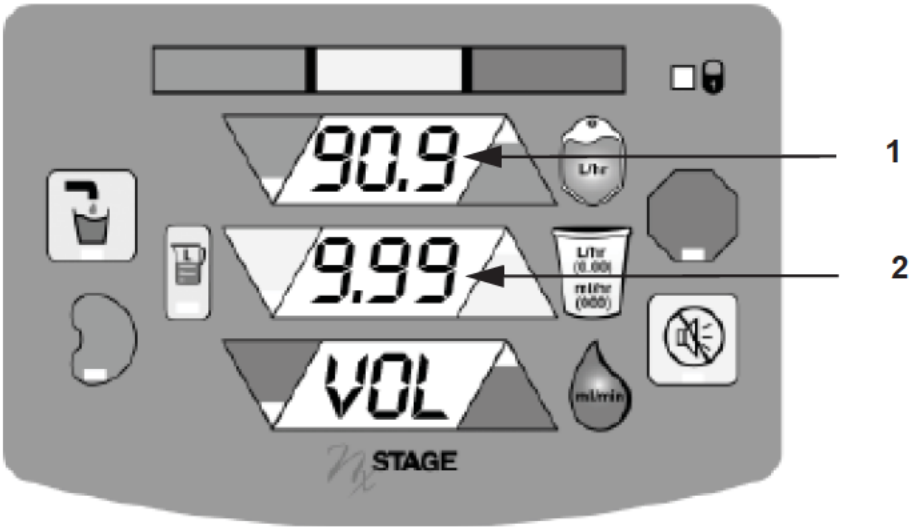
Rate and volume windows will show different information when the **VOLUME TOGGLE** key is pressed.

Figure 2-11: The rate window



1	Dialysate	Shows the flow of dialysate in liters per hour (L/hr).
2	Ultrafiltration	Shows how fast excess fluids are removed from the patient, in liters per hour (L/hr). See Chapter 9 for details.
3	Blood flow	Shows how fast the blood flows through the cartridge, in milliliters per minute (ml/min).

Figure 2-12: The volume window



1	Dialysate	Shows the volume of prescribed dialysate left to exchange, in liters.
2	Ultrafiltration	Shows the excess fluid left to remove, in liters. See Chapter 9.

Pump ON indicator

The pump ON indicator is a red dot in the lower right corner of each rate and volume window. It indicates which pumps are running during treatment or automatic rinseback. See Chapter 9 for details.

NOTE

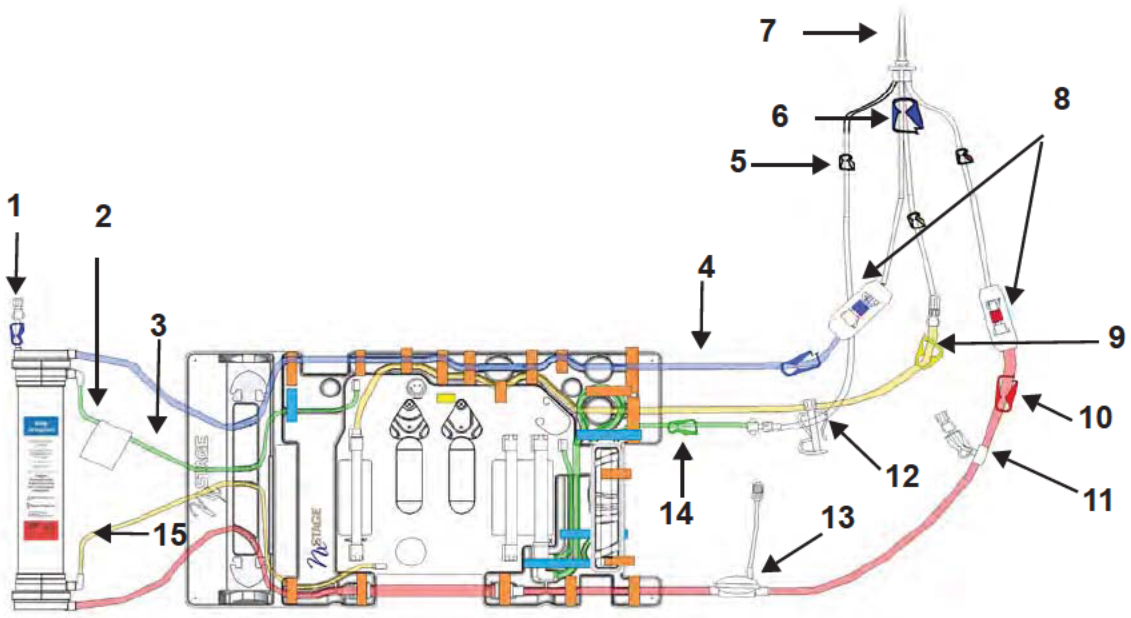
You can turn off the pump ON indicator. See System Setting 55.

Figure 2-13: Pump ON indicator location

Cartridge

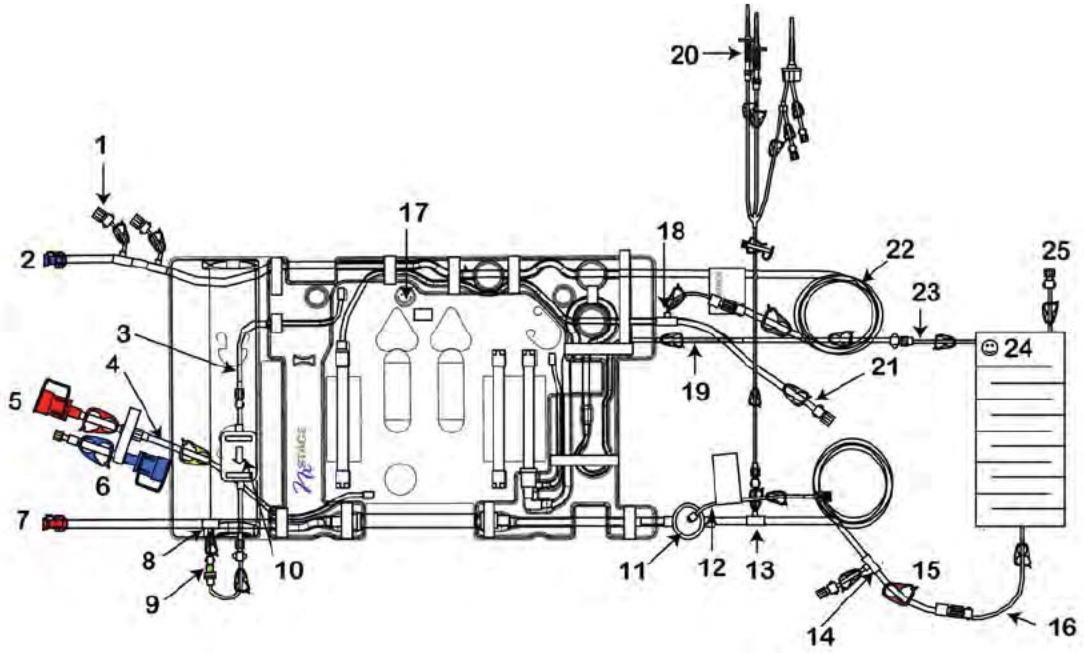
The cartridge is a single-use disposable. It includes a blood circuit and a fluid circuit. NxStage cartridges are available with or without a pre-attached dialyzer. The pictures in this chapter are examples of both kinds of NxStage cartridges. For other cartridges, check their instructions for use. This guide uses the NxStage cartridges with a pre-attached dialyzer for all examples.

Figure 2-14: Cartridge with a pre-attached dialyzer (priming configuration)



1	Post-dialyzer port (blue clamp)	9	Waste line (yellow clamp)
2	Cartridge information label	10	Arterial blood line (red clamp)
3	Dialysate outlet line	11	Saline "T" (white clamp)
4	Venous blood line (blue clamp)	12	Female-female connector
5	Saline line (white clamp)	13	Access pressure pod
6	Waste & Venous Line (Dual Line) clamp (blue clamp)	14	Dialysate inlet line (green clamp)
7	Priming spike	15	Effluent line
8	Connector tabs		

Figure 2-15: Cartridge without a pre-attached dialyzer (priming configuration)



1	Post-filter "T"	14	Pre-pump arterial "T"
2	Venous filter line (blue cap)	15	Arterial blood line (red clamp)
3	Therapy fluid line	16	Warmer inlet
4	Effluent line	17	Smiling face
5	Red Hansen connector	18	Waste "T"
6	Blue Hansen connector	19	Therapy fluid inlet
7	Arterial filter line (red cap)	20	Priming line (white clamps)
8	Pre-filter "T"	21	Waste line
9	Check valve	22	Venous blood line (blue clamp)
10	Air filter	23	Warmer outlet
11	Access pressure pod	24	Air trap
12	Access pressure pod monitoring line	25	Air vent
13	Saline "T"		

NxStage cartridges have two flow circuits: one for the blood and one for the dialysate.

Figure 2-16: Blood circuit (Cartridge loaded)

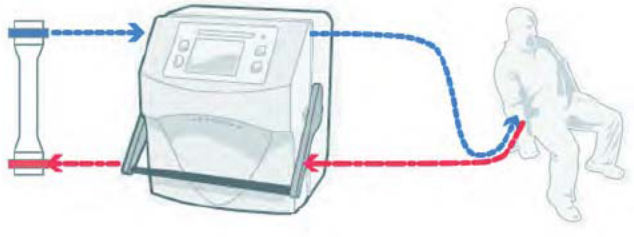
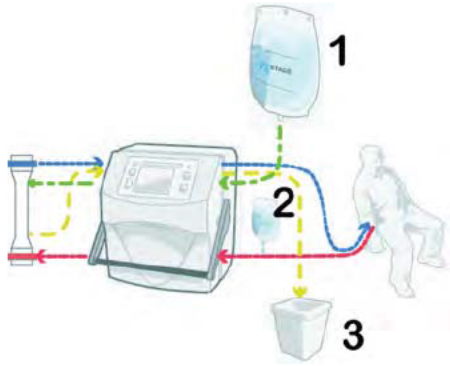


Figure 2-17: Fluid circuit (Cartridge loaded)

1	Dialysate
2	Saline
3	Waste

Figure 2-18: Blood and fluid circuits (Cartridge loaded)



1	Dialysate
2	Saline
3	Effluent

Supplies

Supplies for your treatment must be compatible with the NxStage System One. To use these supplies, check the instructions for use from the manufacturer.

The basic treatment supplies include:

- A dialyzer, if your cartridge does not have a pre-attached dialyzer
- Bags of pre-mixed dialysate
- Bags of sterile saline
- A digital scale
- A set of luer-lock syringes
- An anticoagulant prescribed by your doctor
- A female-to-female adapter (Molded Product Part MPC-150) or equivalent

WARNINGS

Use only physiologic fluids prescribed by a physician with the NxStage System One. Fluids must meet the requirements of local regulations, standards, or laws. Refer to fluid labeling for complete instructions. Fluids for hemofiltration, priming, bolus, and rinseback must be indicated for infusion. Dialysate fluids must be used for hemodialysis. The use of incorrect fluids may cause patient injury or death.

Do not use any fluid delivery devices that have a post-pump drip chamber or a maximum output pressure of less than 600 mmHg. Using these devices may cause blood loss, undesired fluid delivery, inaccurate flows, leaks, and other failure of the fluid delivery device to perform its intended function.

Do not connect to the accessory electrical outlet on the back of the Cycler any electrical items that are not specified as part of, or approved for use with, the NxStage System One Cycler. Unapproved or incompatible electrical items can create an electrical hazard.

Make sure only compatible devices are used with the NxStage equipment. Non-compatible devices may not perform as intended.

Sterile saline

Use the sterile normal saline:

- to prime and flush the cartridge and the dialyzer before treatment.
- to rinse back the blood.
- to give a bolus during treatment. Your doctor prescribes the amount of bolus needed for your treatment.
- to re-circulate the cartridge circuits after returning the blood. See **temporary disconnection,** page 4-50.

Digital scale

Use a digital scale to weight the patient before and after treatment. A medical-grade digital scale is preferred. Calibrate and set the scale to display the weight in kilograms (kg). Measuring the weight in kilograms prevent errors from converting pounds into kilograms.

Dialysate

WARNINGS

When using pharmacy-compounded fluids, the physician should make sure that the potential exposure to endotoxins does not exceed the USP/EP guideline levels for the prescribed therapy. If you are not sure, consult a pharmacist. If the potential exposure exceeds the guideline levels, use endotoxin-reducing IV filters with a working pressure higher than 15 psi. Using an IV filter with a working pressure lower than 15 psi may increase IV filter failure and may lead to a pyrogenic reaction. Refer to the *NxStage System One User Guide* for tables and conversions for endotoxins.

Physicians should take extra care when prescribing dialysate for patients with an increased level or an impaired metabolism of lactate ions, as in severe hepatic insufficiency.

PRECAUTION

Make sure that premixed dialysate is at room temperature before using. If it is not at room temperature, outgassing of air may occur as the fluid is warmed, which may cause NxStage System One Cycler air alarms.

The dialysate cleans waste products from the blood. It also helps keep electrolytes at normal levels in the blood. Dialysate comes in pre-mixed bags. The dialysate can also be prepared with the NxStage PureFlow SL by mixing water and concentrates. The prescription written by your doctor includes the type and volume of dialysate to use, the number of dialysate bags, and the administration rate.

Figure 2-19: NxStage PureFlow Solution

NOTES

- Store pre-mixed dialysate bags with lactate at room temperature between 15°C–30°C, as labeled. The International Conference on Harmonization (ICH) has verified by tests that dialysate stored at slightly higher or lower temperatures is safe to use. The ICH guidelines also allow that frozen bags of dialysate that have been thawed can be used safely for treatment. However, do not freeze dialysate bags. When frozen, the bag material becomes brittle and may leak.
- Dialysate bags kept at up to 40°C for a few days are safe to use after bringing them back to the recommended room temperature. The bag material may be discolored but it does not affect the quality of the dialysate.

Dialyzer

If using a cartridge without a pre-attached dialyzer, check the instructions from the dialyzer manufacturer for the maximum transmembrane pressure. Check the cartridge instructions for how to use the cartridge with the dialyzer.

WARNING

If you are using a Cartridge without a pre-attached Dialyzer, make sure that the Dialyzer you select has a maximum transmembrane pressure (TMP) of at least 500 mmHg or higher. Use of a Dialyzer with a lesser TMP rating increases the risk of a blood leak. NxStage defines TMP as the difference between venous pressure and effluent pressure. Follow the Dialyzer manufacturer's instructions for use for TMP rating.

Other supplies

Other supplies include:

- 20 ml luer-lock syringes
- Anticoagulant (prescribed by your doctor)
- Female-to female connector (Molded Product Part MPC-150), or equivalent
- IV air removal filter (Churchill Medical Part AMS 423-1) or equivalent (for hemofiltration)

WARNING

When an IV filter is used during treatment, a check valve is required. Failure to put the check valve between the blood path and IV filter may damage the IV filter.

This page intentionally left blank.

Chapter 3 Preparing for Use

Before starting your treatment, you need to set up the NxStage System One and prepare for treatment.

WARNINGS

A trained person must install and test the NxStage System One. Improper installation and testing could lead to malfunction or damage, which may cause patient injury or death.

Unless specifically recommended by NxStage, non-medical electrical equipment should not be used within 1.8 meters (6 feet) of the System One. Use of such equipment may affect patient safety.

Do not use NxStage equipment in the presence of a Flammable Anesthetic Mixture with Air, a Flammable Anesthetic Mixture with Oxygen, or a Flammable Anesthetic Mixture with Nitrous Oxide or in an oxygen-enriched or explosive atmosphere.

To avoid injury, the NxStage System One Cycler must be plugged into a properly grounded outlet, except for Cyclers with the model number NX1000-4. Ask a qualified electrician to check your outlet if you are not sure that it is properly grounded. Cyclers with the model number NX1000-4 do not require a grounded outlet for their safe operation; the model number is located at the rear of the Cycler.

Use only routers, switches, or other data networking equipment that comply with IEC 60950 if they are used to connect the computer on the back of the NxStage System One Cycler to a wired-data network. The use of equipment that does not comply with IEC 60950 may result in electric shock to the patient or operator.

Do not connect printers or other equipment to the computer on the back of the NxStage System One Cycler to reduce the risk of electrical shock to the patient or operator. USB thumb drives or USB connections from the PureFlow SL are the only devices than can be connected to the computer on the back of the Cycler.

WARNINGS

The NxStage System One Cycler weighs approximately 34 kilograms (75 pounds). To avoid injury, two people must lift and carry the Cycler. Close and lock the door of the Cycler before lifting and carrying it. Do not lift and carry the Cycler by the door handle. Use the grip points under the Cycler or the handles included on some models.

The maximum fluid volume for transporting the NxStage System One Cycler using the mobile base with the ComfortMate Fluid Warmer is 10 liters of fluid. Do not transport the Cycler with fluid using the mobile base if using the Express Fluid Warmer. The maximum fluid volume for stationary use of the Cycler with an IV pole is 29 liters of fluid when using the ComfortMate Fluid Warmer or 21 liters of fluid when using the Express Fluid Warmer. Fluid volume must not be exceeded and fluid must be evenly distributed on the IV pole to prevent accidental tipping of the Cycler.

Make sure that the NxStage System One Cycler and its ancillaries are attached securely to its mobile stand or placed on a table sturdy enough to hold the weight of the Cycler, its ancillaries, and fluid bags. Check the bolts on the mobile stand regularly to make sure that they are fastened securely, especially before moving the Cycler. If the bolts are not fastened securely, the Cycler, its ancillaries, or the fluid bags may fall and cause injury.

Use only the power cords supplied by NxStage or its authorized distributors. Do not connect portable multiple-socket outlets or extension cords to any NxStage equipment. Non-authorized or incompatible electrical power cords and outlets can create an electrical hazard.

Do not connect to the accessory electrical outlet on the back of the Cycler any electrical items that are not specified as part of, or approved for use with, the NxStage System One Cycler. Unapproved or incompatible electrical items can create an electrical hazard.

⚠ PRECAUTIONS

⚠ If too many devices are plugged into the same electrical circuit, the circuit may become overloaded. The NxStage System One Cycler does not require a dedicated electrical outlet, however, to avoid overloading the circuit, plug the Cycler into a circuit separate from other devices.

⚠ Inspect all NxStage System One Cycler components for damage before use. If product is damaged, follow the procedures to return the product included in this User Guide.

⚠ Do not alter the factory-set height of the IV pole. The height of the IV pole is important to maintain adequate fluid flow. Altering the height of the IV pole may negatively impact system performance and result in nuisance alarms.

⚠ Refer to Electromagnetic Compatibility (EMC) specifications in this User Guide to make sure that the equipment is being operated within these specifications.

⚠ Keep all equipment out of direct sunlight to prevent the device from overheating.

⚠ Keep children and pets away from all equipment to prevent damage that may lead to poor system performance.

Treatment environment

WARNINGS

In order to avoid electric shock, patients with a central venous catheter must not touch or be in contact with any AC powered electric devices during their treatment. Examples include but are not limited to, electric blankets or heating pads, electric lamps or lights, computers that are plugged into an electrical outlet, and electric powered chairs.

Physicians must ensure that central venous catheters are not placed in the right atrium. The risk of microshock to the patient resulting in fibrillation is increased when the tip of a central venous catheter placed in the right atrium touches the atrium wall during use of the NxStage System One.

The NxStage System One must be used in a treatment area that is safe, secure, and well organized. The treatment area is an area of 1.8 m (6 feet) around the equipment and patient. A safe treatment area includes keeping household pets away from the area to reduce the risk of injury or infection. Be careful if non-trained people, children, other family members or friends enter the treatment area.

The minimum requirements for a safe treatment area are:

- A clean, well-lit room with a temperature between 15°C and 37°C (59°F and 99°F)
- A properly grounded 100–120/230 VAC, 50/60 Hz electrical outlet
- A table or cart on which to place the system and that can hold at least 68 kg (150 lbs), is at least 45 cm wide and 60 cm deep (18 inches wide x 24 inches deep), and is non-tipping
- A clean and dry space for storing supplies
- A digital scale, preferably medical grade, as required by your center
- A hand washing sink close to the treatment area
- A telephone
- Other supplies to measure vital signs, as required by your center
- Access to an emergency kit, as required by your center
- At least 1.8 meters (6 feet) of distance from any electronic device, for example, a television set. Do not touch the NxStage System One and another electronic device (such as a television set) at the same time. In addition, no other person should touch any electronic devices and the patient at the same time.

Unpacking and initial test

PRECAUTION

Allow the Cycler to adjust to a room temperature between 15°C and 37°C (59°F and 99°F) for at least one hour before use.

NOTE

Save the box and packing material for future use.

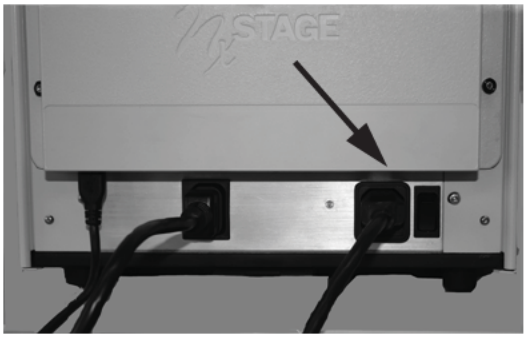
Figure 3-1: The cycler and the filter holder

To unpack your cycler and prepare for the initial tests:

1. Carefully remove the cycler from the box. If the box or cycler is damaged, call Customer Service.
2. Set up the cycler on a firm, stable surface. Set up other devices (fluid warmer and PureFlow SL) as instructed in their user guides. Leave at least 15 cm (6 inches) of space around the back of the cycler for air to cool the cycler.

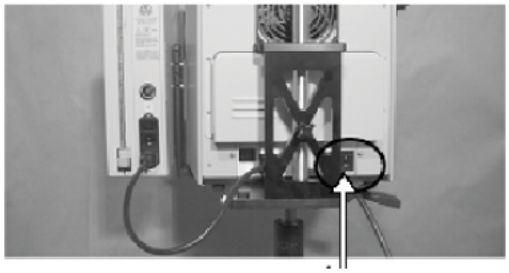
3. Plug the power cord into the power input on the back of the cycler. Align the pins on the power cord with the holes on the power input.

Figure 3-2: Power input for the cycler



4. Turn off the cycler power switch.

Figure 3-3: Power switch for the cycler



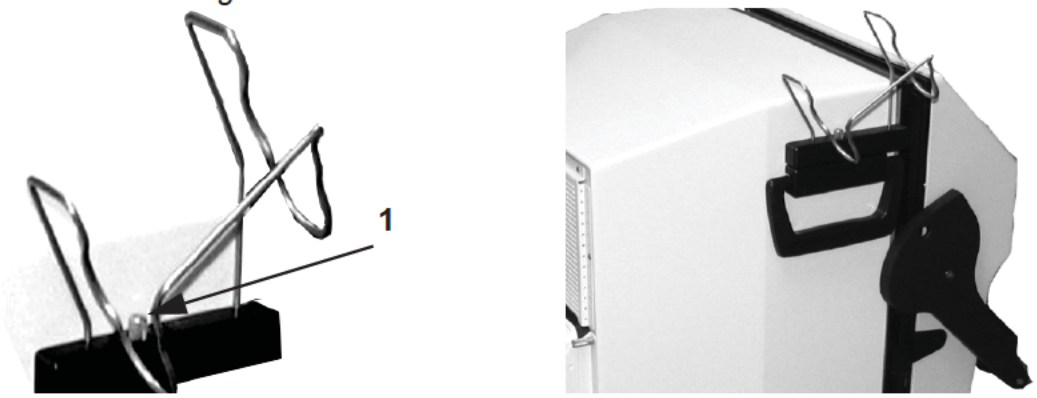
5. Plug the cycler power cord into an electrical wall outlet. Cycler models CYC-D2E (NX1000-1) and CYC-D2E (NX1000-3) must be plugged into a wall outlet with a ground.

NOTE

If you need to disconnect the cycler from power, unplug the power cord from the back of the cycler or unplug the power cord from the electrical wall outlet.

6. Facing the control panel, attach the filter holder to the handle on the left side of the cycler. Line up the thumbscrew with the hole in the handle and tighten the screws.

Figure 3-4: Attaching the filter holder



1	Thumbscrew

7. Turn the cycler on to test the power connection. Make sure the control panel lights up and flashes. The software version appears in the rate/volume window. After 25 seconds, the cycler is ready to use.
8. Turn off the cycler.
9. Enter the system settings as given by your center. See **Changing system settings**, page 9-2. Confirm the settings.

NOTES

- If using the CYC-D2E (NX1000-3) cycler for dialysate flows rates higher than 12 liter per hour, be sure to set the System Setting 0 (CAR Type) to 8 (CAR-170 and 172) or 9 (CAR-171), and the System Setting 1 to your prescribed flow fraction.
- You must turn off the cycler before going to the next step.

10. Open the door of the cycler. To open, lift up the front handle until it clicks and pull the door toward you.
11. Turn on the cycler. The switch is at the back of the cycler. The control panel lights up and performs a system check. If the system passes the self-test, load the cartridge. See **Loading the cartridge**, page 4-8.

    If there is an alarm that cannot be resolved, contact Technical Support.

High flow configuration

If your treatment calls for a dialysate flow rate higher than 12 liters per hour:

- Check the part number on your cycler. It must be part number CYC-D2E (NX1000-3) or higher.
- Set the System Setting 0 to 8 (CAR-170 and 172) or 9 (CAR-171).
- Set the System Setting 1 to the exact flow fraction determined by your center.
- Make sure the software version of your PureFlow SL is version 1.15 or higher.
- Make sure your SAKs are the 400 series
- Select the correct SAK type on your PureFlow SL control unit. From the user maintenance menu on the control unit, select the settings menu to enter the SAK type.

If your setup does not meet these requirements, contact Customer Service. You cannot run dialysate flow rates higher than 12 liters per hour if your setup does not meet these requirements, alarms will occur. See Chapter 5, Troubleshooting. Refer also to the troubleshooting section of the *PureFlow SL User Guide*.

Network or telephone line connection

All cyclers come with a Jewel Box or a ConNxBox computer attached to the back of the cycler to communicate with your center or NxStage.

- ConNxBox communicates with your center over cellular air waves. If cell coverage is poor and your home has a wired network, connect the ConNxBox to the network using the cable specified by NxStage.
- Jewel Box communicates with the NxStage server. You can connect the computer to:
  - a wired network in the home with CAT5 cable.
  - a telephone line with a telephone cable (US only).

Figure 3-5: Network connection on the computer

Connecting to the network (Jewel Box or ConNxBox)

To connect the computer to a network:

1. Connect one end of the network cable to the 10/100 LAN connection on the computer.
2. Connect the other end of the network cable to your network router.

NOTES

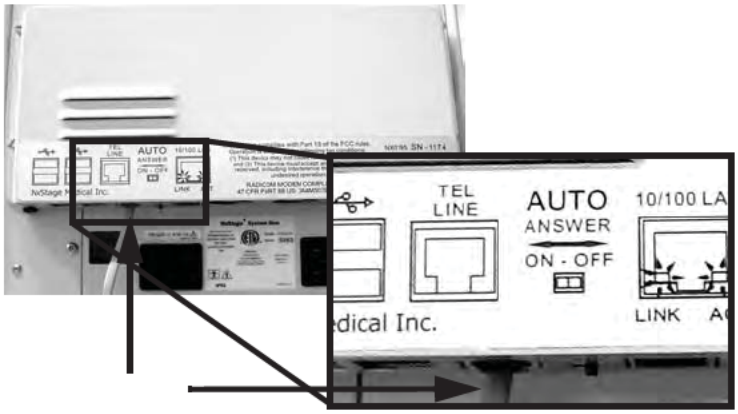
- For the connection to work, plug the cycler into the electrical wall outlet. It is not necessary to turn on the cycler for the connection to work.
- The transfer of data starts as soon as your treatment ends.

Connecting to the telephone line (Jewel Box in the US only)

To connect the computer to the telephone line:

1. Connect one end of the telephone cable to the telephone line (TEL LINE) connection on the computer.

Figure 3-6: Telephone line connection

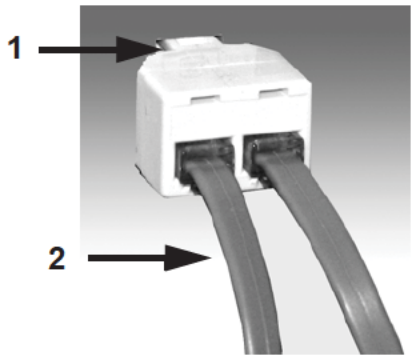


NOTE

Set the auto-answer to off unless Technical Support asks you to turn it on.

2. Connect the other end of the telephone cable to a telephone jack. A line splitter lets you connect your cycler and your telephone to the same jack.

Figure 3-7: Line splitter



1	Wall jack
2	One line to your telephone and the other to your cycler

NOTES

- Your line splitter may look different from the one shown in the illustration. The connection and function are the same.
- For the connection to work, plug the cycler into the electrical wall outlet. It is not necessary to turn on the cycler for the connection to work.
- The transfer of data starts at 2:00 am eastern standard time (EST).

Transport and storage

Before traveling with your cycler, contact Customer Service for packing instructions and information for having supplies shipped to your destination.

Your cycler and its components must be transported and stored at temperatures between 0°C and 50°C (32°F and 90°F).

PRECAUTION

Allow the Cycler to adjust to a room temperature between 15°C and 37°C (59°F and 99°F) for at least one hour before use.

Chapter 4 Hemodialysis

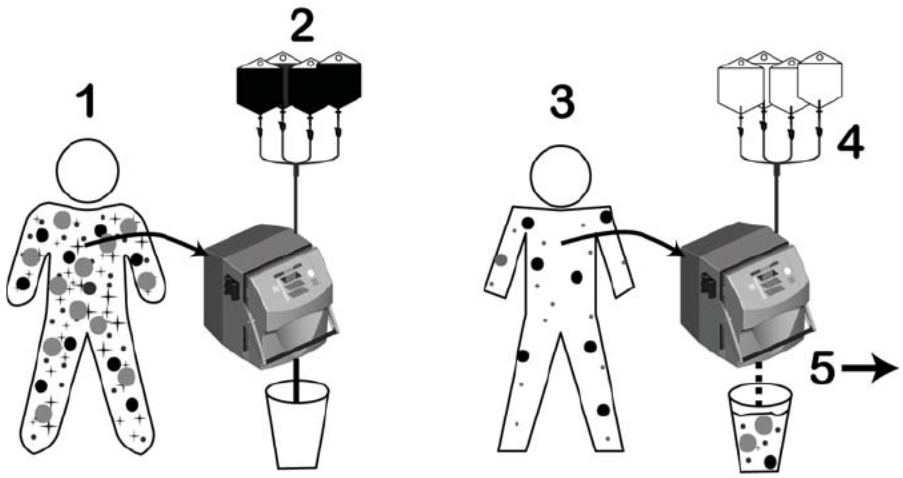
The NxStage System One uses a cartridge with a pre-attached dialyzer set up for hemodialysis. Other cartridges are available. Check with your doctor.

Overview

Using the same cartridge and cycler, the NxStage System One performs hemodialysis with or without ultrafiltration.

During hemodialysis, the blood flows on one side of the dialyzer fibers or small tubes. The dialysate flows on the other side of the dialyzer fibers or small tubes. Waste products and excess fluid pass from the blood and into the dialysate. Needed electrolytes pass from the dialysate into the blood. This process is called diffusion.

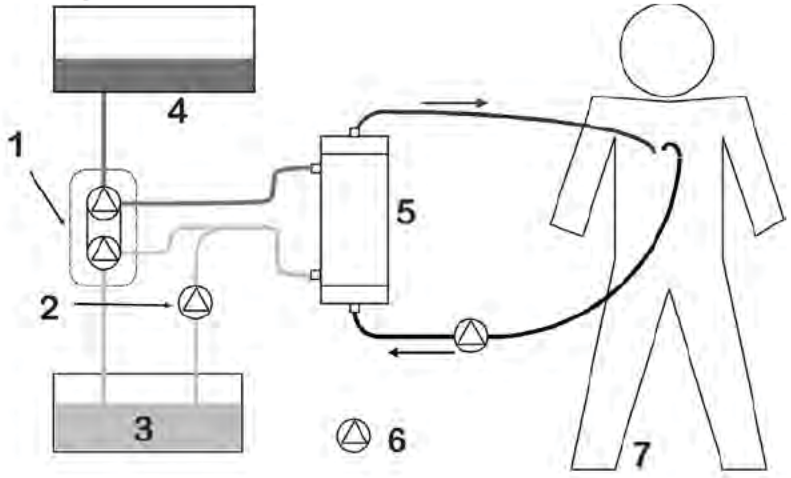
Figure 4-1: Hemodialysis and ultrafiltration therapies



1	Before treatment	3	After treatment
2	Dialysate going in	4	Bags empty of dialysate
		5	Waste and excess fluid going out

With ultrafiltration, excess fluid is removed from the blood through the dialyzer. Ultrafiltration can be done during dialysis or separately. When ultrafiltration is done separately to remove extra fluid from the body, it typically does not use dialysate.

Figure 4-2: Hemodialysis and ultrafiltration connections



1	Exchange balancing	5	Dialyzer
2	Ultrafiltration (removal of excess fluid)	6	Pump symbol
3	Waste	7	Patient
4	Dialysate		

Preparing for treatment

To prepare for treatment:

- Get all the supplies. See page 4-7.
- Load the cartridge. See page 4-8.
- Perform the prime and alarms tests. See page 4-12.
- Make the cartridge connections. See page 4-22

WARNINGS

Always visually inspect the package and product before use. Do not use any disposables if the package is open, damaged, or if any of the connector's protective caps are loose, disconnected, or missing. These disposables may no longer be sterile and may cause patient infection.

Do not touch surfaces of any disposable covered by protective caps. This includes connectors and needleless access sites. Always use aseptic technique when handling connections. Touching these surfaces may make them non-sterile, which may cause patient infection.

Do not use excessively cold dialysate. Under certain conditions, including but not limited to patient weight, dialysate flow rates and treatment durations, some patients may develop hypothermia when exposed to excessively cold dialysate.

Do not use a knife or other sharp instrument to open any shipping carton or case containing disposables because it may cut or damage the contents. Do not use any disposables from a shipping carton or case that has been opened with a knife or other sharp instrument. Damage to disposables may cause blood or air leaks, causing patient injury or death.

Do not use any fluid delivery devices that have a post-pump drip chamber or a maximum output pressure of less than 600 mmHg. Using these devices may cause blood loss, undesired fluid delivery, inaccurate flows, leaks, and other failure of the fluid delivery device to perform its intended function.

WARNINGS

Do not use ultrasound gel, or any gel-like substances around the air detectors. These substances may prevent the detection of air in the blood lines. If air cannot be detected it may cause an air embolism in the patient.

The maximum fluid volume for transporting the NxStage System One Cycler using the mobile base with the ComfortMate Fluid Warmer is 10 liters of fluid. Do not transport the Cycler with fluid using the mobile base if using the Express Fluid Warmer. The maximum fluid volume for stationary use of the Cycler with an IV pole is 29 liters of fluid when using the ComfortMate Fluid Warmer or 21 liters of fluid when using the Express Fluid Warmer. Fluid volume must not be exceeded and fluid must be evenly distributed on the IV pole to prevent accidental tipping of the Cycler.

Do not attach ancillary devices that can restrict blood flow, such as stopcocks, to the patient lines. Restrictions in the blood circuit can cause hemolysis.

Do not use a Cartridge with kinked blood lines. Always inspect the blood lines for kinks before and during use, particularly around Dialyzer connections. Kinked blood lines may cause hemolysis.

The risk of blood clotting in the Cartridge and Dialyzer is higher during long treatments, when no anticoagulation is used, in certain patients who are more prone to excess clotting, or any time when the blood flow stops, including when the NxStage System One Cycler loses power or during an unrecoverable alarm. The risk of blood clotting increases the longer treatment continues and the longer blood flow is stopped. To reduce the risk of blood clotting and identify the early signs of clotting:

- Follow your center's instructions to give and monitor anticoagulant.
- During treatment, regularly check the Cartridge and Dialyzer for clotting by looking closely at the Cartridge and Dialyzer, and periodically flushing the Dialyzer with a manual fluid bolus.

Failure to respond to blood clotting in the Cartridge and Dialyzer or administering medication through the Post-dialyzer port when clotting is present in the dialyzer venous header may result in a blood clot being released into the patient's bloodstream and causing a blockage (thromboembolism). Failure to respond to clotting may also lead to sustained high pressures in the blood circuit and cause a dialyzer blood leak or hemolysis. These conditions may cause serious injury or death if not responded to promptly and appropriately. Regularly check the Dialyzer for

any evidence of a leak. Do not return the blood if the blood flow is stopped for a long time. Discard the Cartridge and Dialyzer if they are clotted.

PRECAUTIONS

⚠ Allow the Cycler to adjust to a room temperature between 15°C and 37°C (59°F and 99°F) for at least one hour before use.

⚠ Allow the Cartridge to adjust to a room temperature between 15°C and 37°C (59°F and 99°F) for at least one hour before use.

⚠ Make sure that premixed Dialysate is at room temperature before using. If it is not at room temperature, outgassing of air may occur as the fluid is warmed, which may cause NxStage System One Cycler air alarms.

⚠ Use caution when handling any Disposable Set to avoid tearing and puncturing.

⚠ The default value for System Setting #9 is zero (0) for hemodialysis which disables the automatic bolus feature. In certain geographic areas outside of the US, additional labeling provides more information on using the NxStage System One to deliver an automatic fluid bolus.

⚠ Do not alter any NxStage disposables. Performance of altered disposables cannot be guaranteed.

Getting the supplies

As you prepare for treatment, make sure you have the following supplies:

- Dialysate bags and disposables
- A hemodialysis cartridge set
- Saline bags
- Personal protection supplies for universal precautions. Check with your center to know which protection supplies you need.
- Other supplies for use during treatment. Check with your center to know which other supplies you need.

Before starting your treatment:

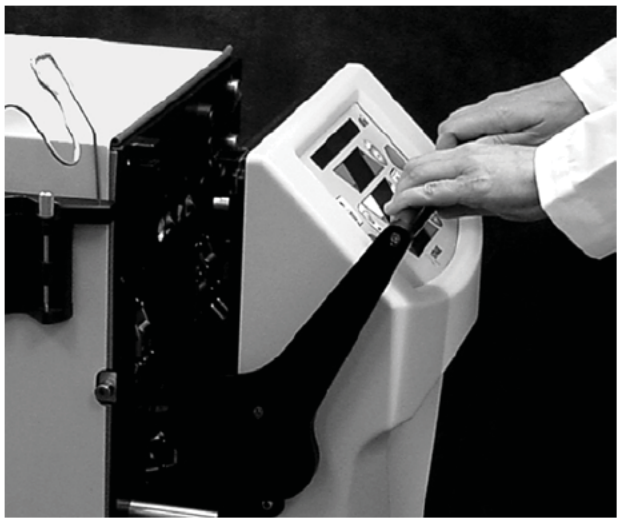
- Make sure your center gives you a list of all the non-NxStage supplies you need.
- Check all supplies for damage or missing parts.
- Read the instructions for use given with the supplies.
- Check that all your supplies match your prescription. If they do not match your prescription, call your center.
- Make sure the cycler's power supply is attached to the back of the cycler and plugged into an electrical outlet.
- Check your prescription and cartridge IFU for the System Settings information.

Loading the cartridge

To open the cycler:

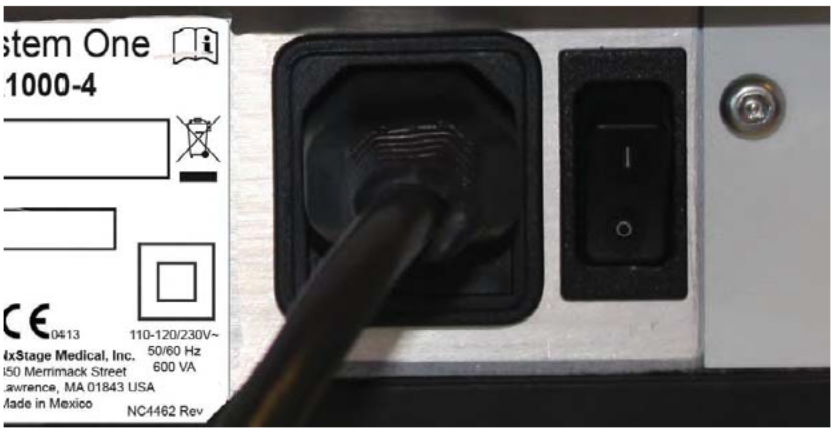
1. Open the door of the cycler. To open, lift up the front handle until it clicks and pull the door toward you.

Figure 4-3: Open the cycler door



2. Turn on the cycler. The switch is at the back of the cycler. The control panel lights up and performs a brief system check.

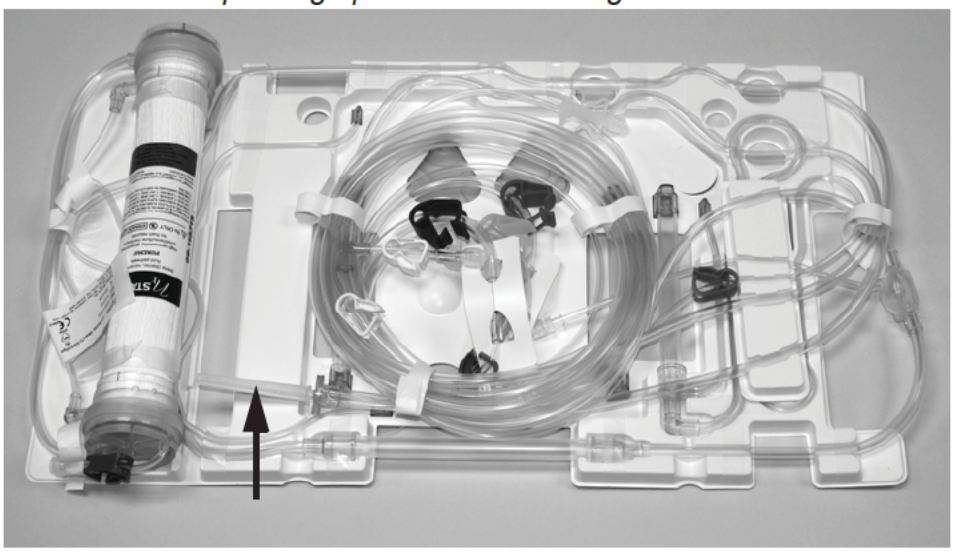
Figure 4-4: The cycler power switch



To unpack the cartridge:

1. Remove the cartridge from its package carefully. Look for the blood line connections with red and blue luer connections on the priming spike and tighten them. Tighten all caps and luer connections on the lines, saline "T" and post-dialyzer port.
2. Lift the priming spike carefully out of the cartridge.

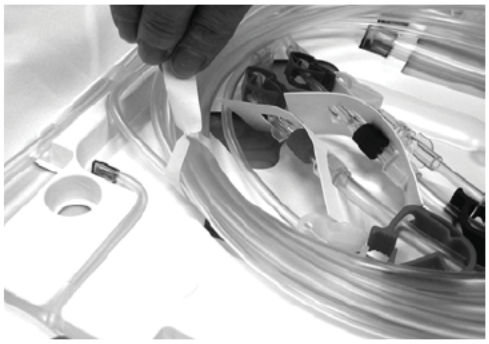
Figure 4-5: Locate the priming spike on the cartridge



3. Remove the connector tabs and paper tape.

Figure 4-6: Remove the connector tabs

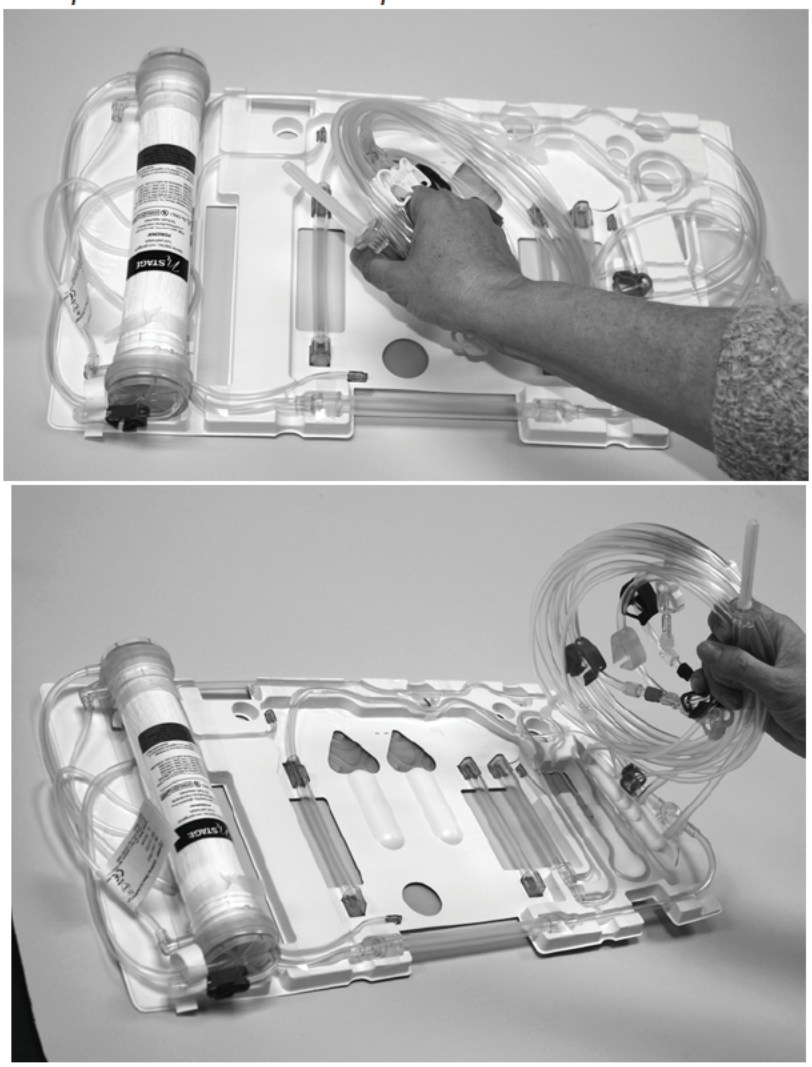
Pinch



Tear

4. Hold the coiled lines in one hand and pull the lines out of the line organizer.

Figure 4-7: .Grasp the coiled lines and pull



5. Remove the line organizer from the cartridge and throw it away.

Figure 4-8: Remove the line organizer

6. Check the lines for any kinks or dents. Do not use any blood tubing that is dented or flattened by more than one-third.

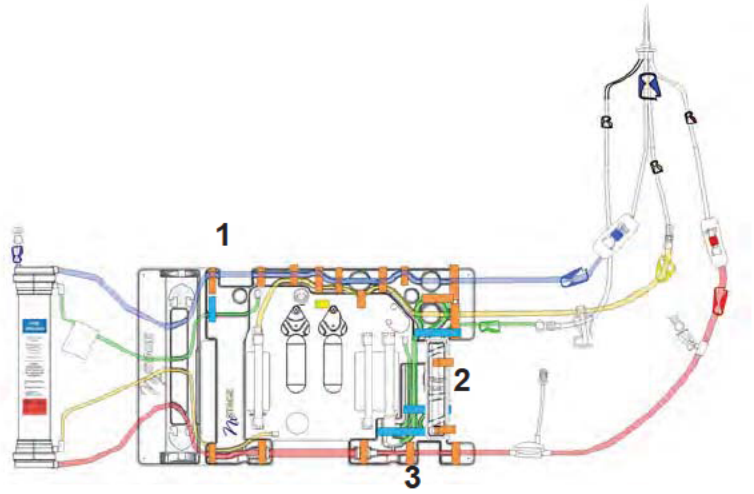
NOTE

You can also keep the tabs in place until you connect the arterial and venous blood lines to the vascular access.

To load the cartridge:

1. Place the cartridge into the cycler. Press the lines into the three air detectors:
   - the venous blood line in the top left corner
   - the dialysate line in the middle right corner
   - the arterial blood line at the bottom right corner.

Figure 4-9: Location of cartridge air detectors



1	Venous Air Detector
2	Dialysate Air Detector
3	Arterial Air Detector

2. Make sure that all lines, clamps, and caps are away from the door handle, including the luggage tag on the cartridge.

3. Close the door of the cycler. Push down the door handle until it clicks to lock it.

Figure 4-10: Close the cycler door

WARNING

To avoid injury when closing the Cycler door, make sure to keep fingers and other body parts away from the door opening.

Prime and alarms test

Before treatment is possible, the cartridge lines and dialyzer must be flushed with saline to eliminate all air. This is called priming the cartridge. The cycler and cartridge must also test the safety systems.

WARNINGS

Only spike the saline bag after loading the Cartridge and closing the door of the NxStage System One Cycler. Failure to do so may cause Cartridge leaks or a misalignment of the Cartridge, resulting in compromised treatment, injury, or death.

Never connect the patient to the Cartridge before you see the treatment parameters in the NxStage System One Cycler's window, which indicates that the Prime and Alarms Test is completed. Some safety systems are not active during the Prime and Alarms Test. Connecting the patient at any time before completion of the Prime and Alarms Test may cause serious injury or death.

PRECAUTIONS

⚠ After use, discard all disposables in accordance with local, national and federal regulations as instructed by your center. Use universal precautions when disposing of Cartridges.

⚠ If you do not pass the NxStage System One Cycler's Prime and Alarms Test, repeat the test. If you do not pass again or you do not pass the Display Tests, do not connect the patient to the Cartridge. Call Technical Support.

⚠ Remove accumulated air as instructed prior to making patient connections to minimize the chance of NxStage System One Cycler air alarms after making patient connections.

Priming the cartridge:

1. Put on gloves. Remove the protective cap from the priming spike.
2. Insert the priming spike into a 1-liter bag of saline using a twisting motion. Insert the spike as far as you can until the saline outlet is flush with the disk on the priming spike.

Figure 4-11: Fully insert the priming spike into the saline bag

- When the tip is fully inserted into the bag when you can see the tip inside the bag. If the tip is not fully inserted, air may enter the cartridge.
- Make sure that the cartridge is loaded and the door is locked before inserting the spike into the saline bag. If not, the cartridge may not load or be damaged. It may impair the performance of the system.

- The size of the administration port on the saline bags may be different from one manufacturer to another. As a result, you may have to use more or less force to insert the spike into the saline bag.

Connecting the access pressure pod monitoring line:

If your cartridge has an access pressure pod monitoring line, connect it now.

1. Hold the line behind the locking collar.
2. Insert the tip of the line into the connector on the right side of the cycler, next to the front handle.

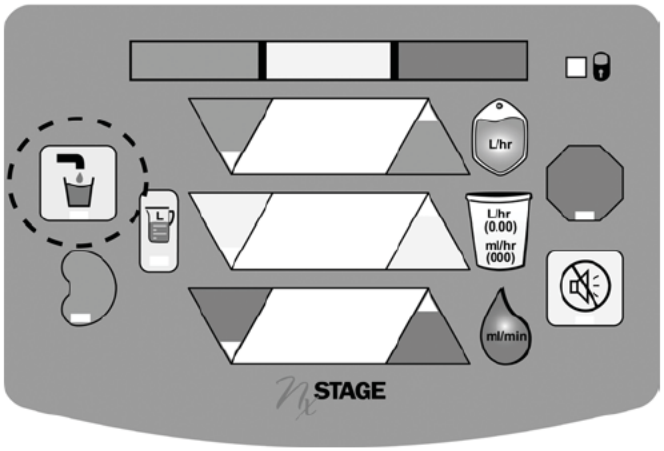
Figure 4-12: Connect the access pressure pod monitoring line

3. Press the monitoring line into the connector. Twist the tip a quarter turn to the left to seal the connection.
4. Tighten the locking collar.

To prime the system:

1. Press the **ADD FLUID** key to prime the system.

Figure 4-13: Location of the ADD FLUID key



During prime:

- The cycler pumps the saline into the cartridge to remove air.
- The Green Operating window shows the time left to prime the system. It takes about 15 minutes to prime the system.
- The top window shows the priming step. The bottom window shows the alarm tests.

NOTE

If the cycler fails to prime or if an operator error occurs, see **Re-priming a cartridge**, page 4-44.

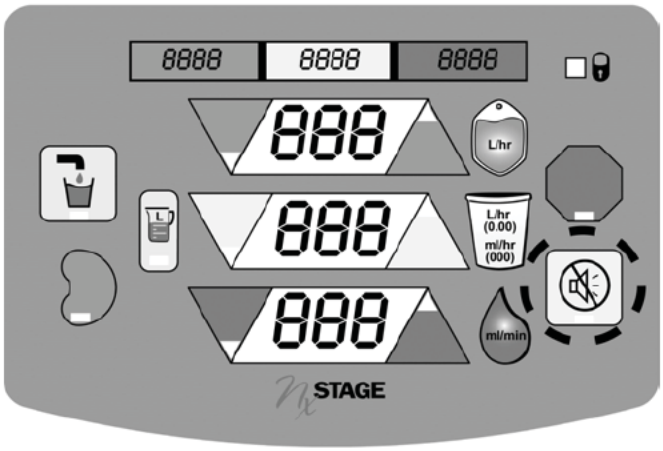
2. Prepare the dialysate source.
   - If using a ComfortMate Fluid Warmer or Express Fluid Warmer, follow the instructions to set-up the pre-mixed dialysate.
   - If using a PureFlow SL, follow the instructions to prepare the SAK dialysate.

End of the prime and alarms test

When the prime and alarms test ends, note the first display test:

1. Check that the control panel displays the number eight in all the windows.
2. Listen for the audible alarm sound.
3. Check that all light segments are turned on.
4. Press the **MUTE** key. All lights segments are turned off.

Figure 4-14: First display test and MUTE key



5. When the first display test is successful, note the second display test. Make sure the windows on your control panel are exactly as shown here. Press the **MUTE** key to continue.

Figure 4-15: Second display test and MUTE key

6. The numbers and letters displayed must be exactly as shown in this example:

   The top status window of the control panel shows:

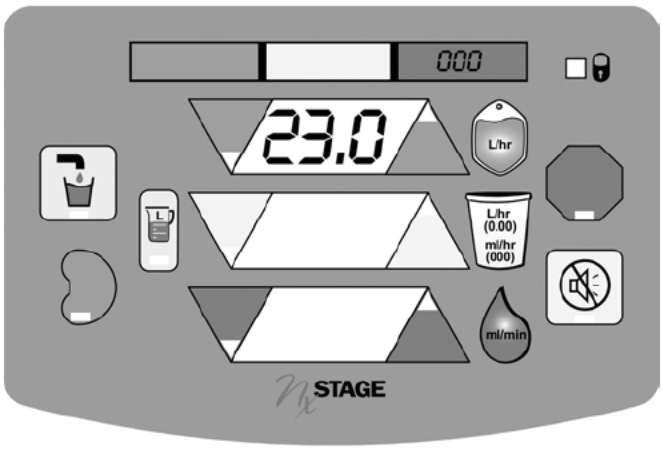
   - 1234 and a-h from left to right:

   The three rate and volume windows show:

   - 9-1 from top to bottom:

7. Check for the number **23.0** in the top window. This number tells you that the system is in Recirculation Mode. During recirculation, the blood and fluid pumps are running. The pumps circulate fluid through the cartridge and saline bag.

Figure 4-16: Top window during recirculation



Do **not** press the **STOP** key. Do **not** close the clamps. Do not disconnect the lines. Instead, do one of the following:

- If you are not moving your cycler to another location, go to **Removing air from the blood circuit**, page 4-19.
- If you are moving your cycler, you can turn off the cycler during the priming step 23.0. Move the cycler to the new location.
- Turn on the cycler power. When you turn on the cycler within the time specified in your System Setting 33, the number **40** appears in the Yellow Caution window and the **TREATMENT** key lights up. System Setting 33 is the cartridge life timeout.
- Press the **TREATMENT** key. The number **20.0** appears in the top window and changes to **23.0** meaning that the balancing system was checked a second time.
- Do **not** press the **STOP** key. Do **not** close the clamps. Do **not** disconnect the lines.
- When the number **23.0** appears in the top window, the cycler is back in recirculation. Go to **Removing air from the blood circuit**, page 4-19.

Removing air from the blood circuit

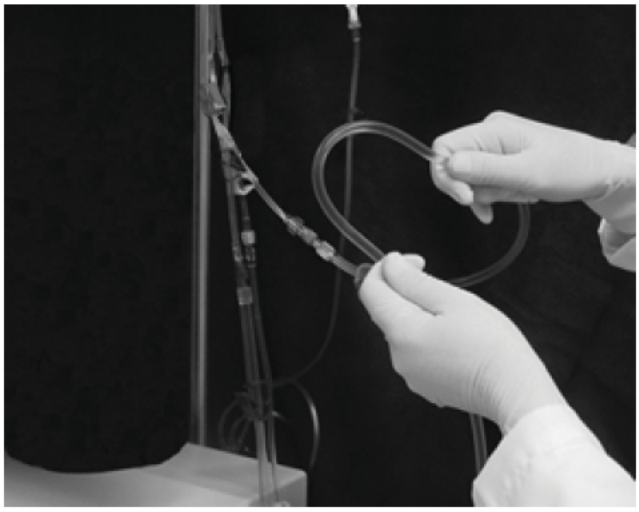
PRECAUTION

Remove accumulated air as instructed prior to making patient connections to minimize the chance of NxStage System One Cycler air alarms after making patient connections.

To remove air from the blood circuit:

1. Start at the red port on the priming spike. Snap and tap the arterial blood line (red clamp). Observe the air moving to the cycler.

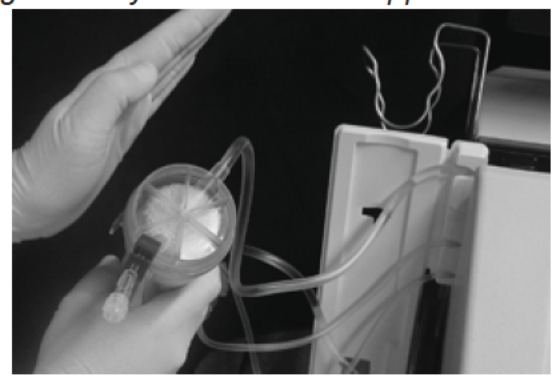
Figure 4-17: Removing air from the blood circuit



2. Pull out the dialyzer from the left side of the cartridge. Turn the dialyzer upside down so that the venous blood line is up. This lets air out of the dialyzer. Be careful not to twist the lines.

3. Tap the dialyzer a few times against the palm of your hand to remove trapped air. You can also tap the dialyzer on a padded surface.

Figure 4-18: Tapping the dialyzer to remove trapped air



WARNING

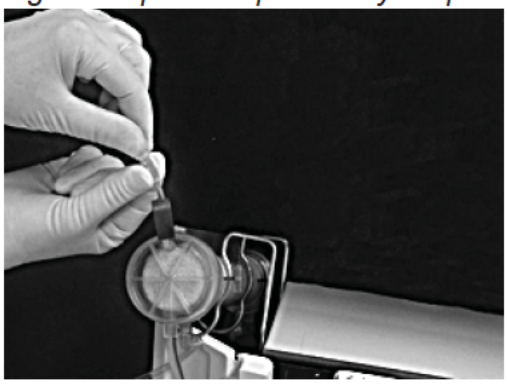
Do not tap the Dialyzer against a hard surface, such as the NxStage System One Cycler. This may damage the Dialyzer and may cause a blood or fluid leak, causing patient injury or death.

4. Place the dialyzer into the filter holder so that the post-dialyzer port is up.

To prime the post-dialyzer port

1. Loosen the cap on the post-dialyzer port to remove air.
2. Tighten the post-dialyzer port cap and close the clamp securely.

Figure 4-19: Loosening the cap of the post-dialyzer port



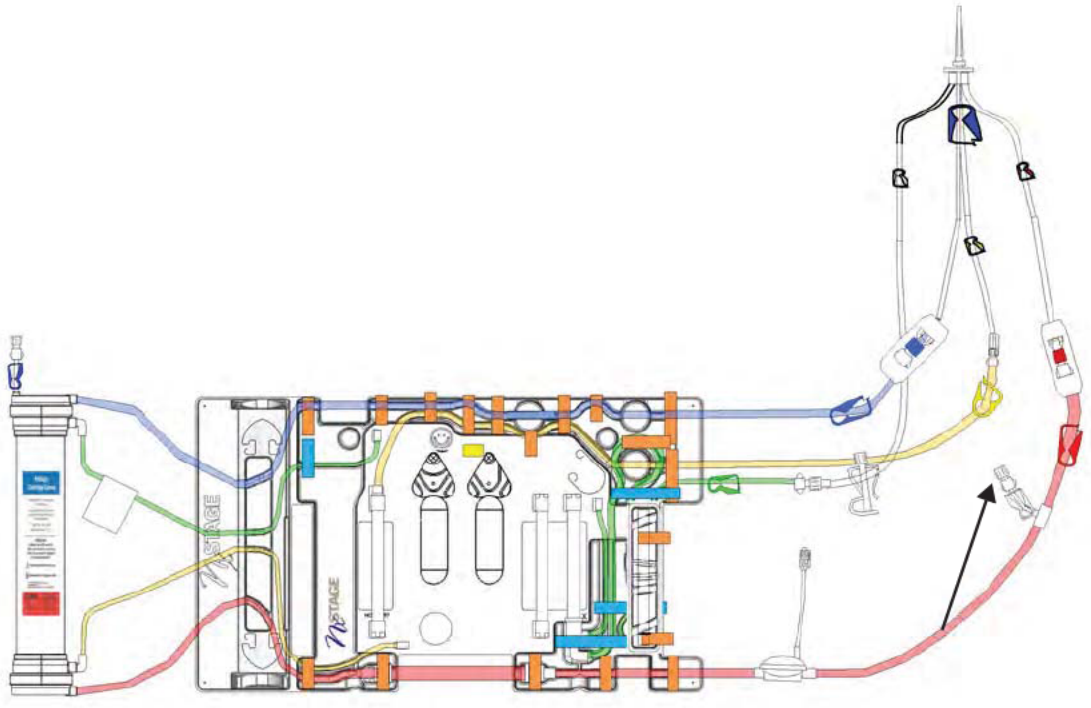
- You can attach a 20 milliliter syringe with a luer lock to the port.
- Make sure there are no kinks in the blood line when placing the dialyzer in the filter holder.

NOTE

Do not administer fluid or medication through the post-dialyzer port.

3. Follow the blood circuit to the right side of the cycler. Snap and tap the venous blood line (blue clamp). Observe the air moving to the saline bag.
   - Repeat the steps to remove air from the blood circuit, to make sure there is no air left in the blood circuit.
   - Check the blood lines carefully a second time to make sure there is no air in the lines. If there is air or if the cycler is left in recirculation, repeat the steps to remove air from the blood circuit. If the cycler is left in recirculation, you will need to repeat steps for air removal again.
4. Press the **STOP** key.
5. Check that the default treatment rates for the patient appear in the windows.
6. Prime the saline "T" (white clamp). Loosen the cap on the saline "T" to remove air. Tighten the cap. Close the white clamp on the saline "T."

Figure 4-20: Location of the saline "T"



Making the cartridge connections

After the prime and alarms and display tests, make the non-patient connections to the cartridge.

WARNINGS

The Cartridge has multiple connection points. Failure to make the proper connections may cause compromised treatment, blood loss, injury or death. Make sure mated luer-connectors are secure but do not over-tighten, especially when connections are wet.

Manually prime any administration “T”s and ports, if present, even if they are not used, to prevent air from entering the patient blood lines. Secure caps and close clamps after priming, and after each use to prevent blood loss or air entering the patient blood lines.

Do not touch surfaces of any disposable covered by protective caps. This includes connectors and needleless access sites. Always use aseptic technique when handling connections. Touching these surfaces may make them non-sterile, which may cause patient infection.

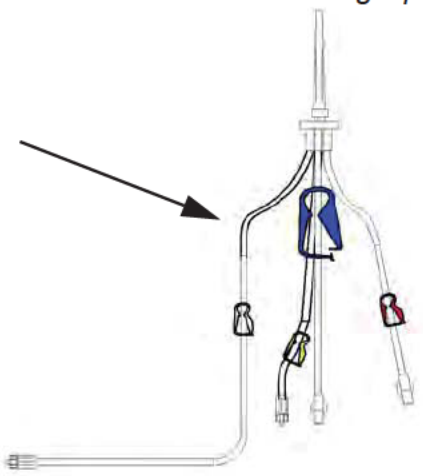
PRECAUTION

Remove accumulated air as instructed prior to making patient connections to minimize the chance of NxStage System One Cycler air alarms after making patient connections.

To make the cartridge connections:

1. At the priming spike, look for the start of the saline line. The saline line is the only line with no clamp near the spike. Follow the saline line to the white and green clamps.

Figure 4-21: Location of Saline Line on the Priming Spike



2. Close the green clamp on the dialysate inlet line.
3. Close the white clamp on the saline line.
4. Disconnect both the dialysate and saline lines. Keep the connections sterile.
5. Remove the cap from the saline "T." Connect the saline line to the saline "T." **Do not open the white clamps.**
6. Remove the cap from the dialysate source line. Connect the dialysate inlet line to the dialysate source line. Both lines have green clamps. Open both green clamps.
7. Close the yellow clamp on the priming spike. Close the yellow clamp on the cartridge waste line. Disconnect both lines.
8. Make the cartridge waste line connections.
   - If you are using bagged dialysate, connect the cartridge waste line to the waste line extension. Place the other end of the waste line extension into an appropriate plumbing drain, such as a tub or sink. Open the yellow clamps on the cartridge waste line and the waste line extension.
   - If you are using the NxStage PureFlow SL, connect the cartridge waste line to the PureFlow Control Unit Waste Line Adapter. Make sure the yellow clamps on the cartridge waste line and the waste line adapter are open.

Performing treatment

WARNING

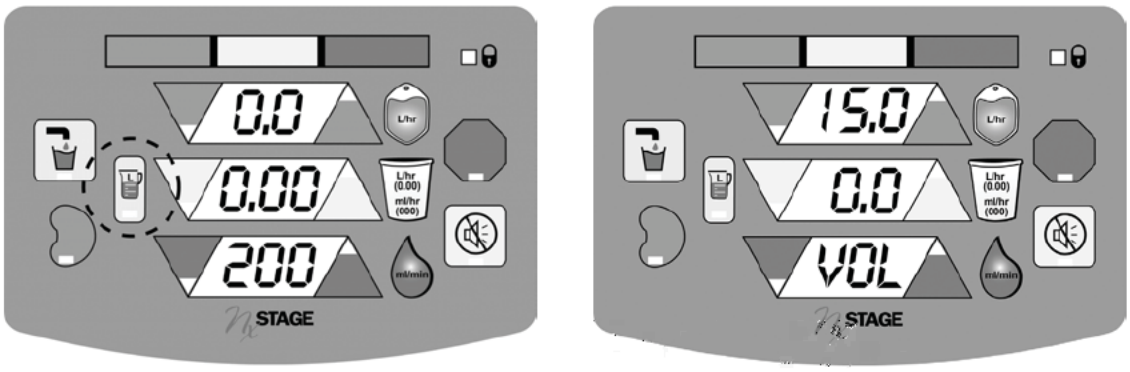
The NxStage System One Cycler will automatically remove the rinseback volume when both the System Setting #38 is set to 1 and the Ultrafiltration pump rate (UFR) is greater than 0. Automatic removal of the rinseback volume is not displayed to the operator. Therefore it is important to account for the rinseback volume when calculating the ultrafiltration rate and volume for the treatment. Do not add the rinseback volume to the targeted ultrafiltration volume when the Cycler is set to automatically remove the rinseback volume or excess ultrafiltration will result. For patients that may be unable to tolerate even small fluid balance changes, such as low weight patients and patients at or near their dry weight, the excess ultrafiltration may result in hypotension or hypovolemia which may cause patient injury or death. When automatic removal of the rinseback volume is not desired, System Setting #38 should be set to 0.

Entering the treatment settings

To enter the treatment settings:

1. Press the **VOLUME TOGGLE** key. VOL appears in the bottom window.

Figure 4-22: Volume toggle changes between rate and volume windows

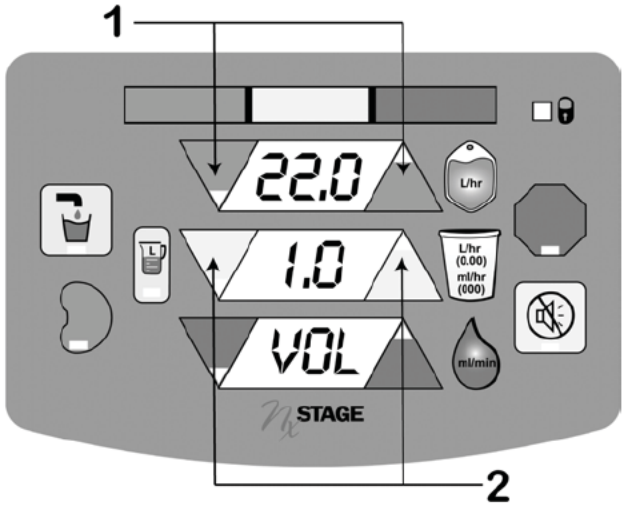


Rate Window **Volume Window**

2. Press the **ADJUSTMENT ARROWS** keys to enter the dialysate volume goal.

3. Press the **ADJUSTMENT ARROWS** keys to enter the ultrafiltration volume goal.

Figure 4-23: Location of dialysate and ultrafiltration adjustment arrows



1	Dialysate volume • Top window, green arrows
2	Ultrafiltration volume (weight to remove) • Middle window, yellow arrows

NOTE

Make sure you have the correct patient weight before entering the ultrafiltration volume. See **Ultrafiltration**, page 2-4.

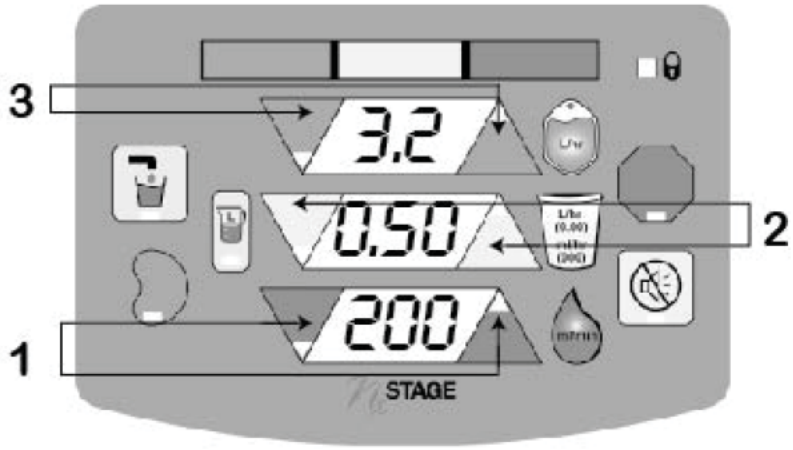
4. Press the **VOLUME TOGGLE** key to return to the rate window.

NOTE

The volume window returns automatically to the rate window after a period of time that is determined by the software version of your cycler and your system settings. See Chapter 9, System Settings.

5. Note the blood flow rate. Adjust the ultrafiltration rate and the dialysate rate. Press the **ADJUSMENT ARROWS** keys to enter rate changes.

Figure 4-24: Location of adjustment arrows



1	Blood flow rate • Bottom window, red arrows
2	Ultrafiltration rate • Middle window, yellow arrows
3	Dialysate rate • Top window, green arrows

NOTES

- If your cycler is model CYC-D2E (NX1000-1), the maximum dialysate rate you can enter is 12 liters per hour. If your cycler is model CYC-D2E (NX1000-3) or NX1000-4, the maximum dialysate rate you can enter is 18 liters per hour.
- To avoid an unexpected large or sudden decrease in blood pressure from removing fluid too fast, remove the ultrafiltration fluid gradually over the length of your treatment. See **Ultrafiltration**, page 2-4.

Starting and monitoring the treatment

After priming the cartridge and entering your treatment settings, make the patient connections. Always use universal precautions and aseptic technique as taught by your center when connecting the vascular access and blood lines and when making patient connections.

Treatment starts when you press the **TREATMENT** key. During treatment, you can monitor the treatment and change treatment settings on the cycler control panel, as needed.

WARNINGS

Do not adjust the vascular access while the Blood Pump is running. Adjusting the vascular access while the Blood Pump is running increases the likelihood of needle dislodgement, which may result in a significant blood loss.

The risk of blood clotting in the Cartridge and Dialyzer is higher during long treatments, when no anticoagulation is used, in certain patients who are more prone to excess clotting, or any time when the blood flow stops, including when the NxStage System One Cycler loses power or during an unrecoverable alarm. The risk of blood clotting increases the longer treatment continues and the longer blood flow is stopped. To reduce the risk of blood clotting and identify the early signs of clotting:

- Follow your center's instructions to give and monitor anticoagulant.
- During treatment, regularly check the Cartridge and Dialyzer for clotting by looking closely at the Cartridge and Dialyzer, and periodically flushing the Dialyzer with a manual fluid bolus.

Failure to respond to blood clotting in the Cartridge and Dialyzer or administering medication through the Post-dialyzer port when clotting is present in the dialyzer venous header may result in a blood clot being released into the patient's bloodstream and causing a blockage (thromboembolism). Failure to respond to clotting may also lead to sustained high pressures in the blood circuit and cause a dialyzer blood leak or hemolysis. These conditions may cause serious injury or death if not responded to promptly and appropriately. Regularly check the Dialyzer for any evidence of a leak. Do not return the blood if the blood flow is stopped for a long time. Discard the Cartridge and Dialyzer if they are clotted.

WARNINGS

Never try to open the door of the NxStage System One Cycler when the door lock symbol is on. If the door is opened by force, all safety systems will no longer be active, which may cause patient injury or death. If the door must be opened while the patient is connected, press the STOP key, immediately clamp all fluid and blood lines, turn the power switch OFF on the Cycler, and then open the door of the Cycler.

When a Yellow Caution is displayed, some safety systems may not be active. Monitor the system and the patient until the Green Safe Operating condition returns. Failure to do so may cause patient injury or death.

Manual fluid boluses and fluid consumed during treatment are not included in the System One fluid balance calculations. Excessive fluid boluses, whether intentional or unintentional, or failure to account for consumed fluid during treatment, may cause patient injury. Include fluid boluses and the volume of fluid consumed in manual fluid balance calculations. Make sure that the administration lines used for manual bolus or rinseback are clamped after use.

Weigh the patient before treatment to make sure that the appropriate ultrafiltration volume is calculated. Follow the physician's prescription for maximum volume and rate of fluid to be removed. Removing too much or too little fluid, or removing fluid too quickly, may cause patient injury. In addition, prescribing physicians should be aware that certain patients, such as low weight patients and patients at or near their dry weight, may be unable to tolerate fluid balance variations in amounts less than the total fluid accuracy tolerances of the NxStage System One Cycler and other ancillary fluid delivery devices. These patients must be closely monitored for signs and symptoms of excessive ultrafiltration or fluid overload. Refer to the System One User Guide for additional information on ultrafiltration during dialysis.

Before starting treatment, check the patient blood lines for air. Check again before and during rinseback. Follow the instructions to remove air before starting treatment or rinseback. Failure to remove air from the patient blood lines may cause an infusion of air, which may lead to an embolism.

Do not disconnect and reverse patient blood lines during treatment. This may cause an infusion of air into the patient blood lines, which may lead to an embolism.

WARNING

The NxStage System One Cycler may not detect slow fluid or blood leaks from loose connections, faulty components, venous access disconnection, vascular needle dislodgement, or other potential causes. Leaking fluids may cause blood loss, injury, or death. Leaking fluids on the floor may also cause a person to slip or fall.

To reduce the risk of fluid or blood leaks, or accidental disconnections:

- Keep vascular access sites and all Cartridge connections visible throughout the treatment. Do not cover sites or connections with a blanket, or clothing, or any objects that block the view of the site and connections.
- Before starting treatment, make sure all manual connections are secure and fluid-tight, but not over-tight.
- A trained and qualified observer must check the system for blood and fluid leaks during treatment and pay close attention to the blood line and access connections, especially when the patient is connected and disconnected. If any leaks are found and cannot be stopped, end the treatment and rinse back the patient's blood, unless the center gives instructions not to rinse back. Do not rinse back the patient’s blood if there are clots or air in the blood circuit or in the patient blood lines. Do not rinse back if the blood is hemolyzed.
- Before connecting the patient, make sure that there is no blood or other lubricious fluid on the Cartridge connectors and mating connectors, such as on vascular access devices. Lubricious fluids, including but not limited to blood, silicone oil, and povidone iodine-based disinfectants on mated luer-connections may significantly increase the chance of accidental disconnections.
- Strictly follow the center’s procedure for taping the blood lines and access device connections to the patient. Check all connections and secure taping again, if necessary, when the patient changes position, when changing the dressing of the catheter, or if there is stress on the Cartridge tubing or blood access device.
- Use only Dialyzers, catheters or AVF needles, and other devices that have locking connectors in compliance with ISO 594 parts 1 and 2 and ISO 8638 when connected to the Cartridge. With repeated patient treatments, a temporary or permanent catheter’s connectors may change shape and no longer comply with ISO 594 parts 1 and 2 and become incompatible with the Cartridge. Using incompatible connectors with the Cartridge may cause blood loss, patient injury, or death. Contact the device manufacturer for all compliance questions.

WARNING

Manually prime any administration “T”s and ports, if present, even if they are not used, to prevent air from entering the patient blood lines. Secure caps and close clamps after priming, and after each use to prevent blood loss or air entering the patient blood lines.

PRECAUTIONS

Do not disconnect any Cartridge pressure pod monitoring line from the NxStage System One Cycler after priming the Cartridge, unless directed to do so in the Troubleshooting section of this guide. Doing so may result in inaccurate pressure readings and may lead to false cautions and alarms or failure of appropriate cautions and alarms to occur.

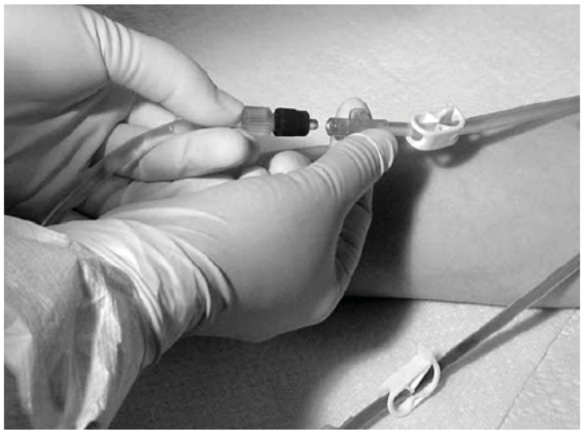
Do not allow fluid or blood to contact the NxStage System One Cycler's pressure sensor connection points. If this happens, return the Cycler for service. This is a preventive measure to make sure that the pressure readings are accurate. It also eliminates the potential for cross contamination.

To connect the patient:

1. Close the red and blue clamps on the priming spike, arterial blood line and venous blood line.
2. Using aseptic technique, disconnect the arterial blood line and the venous blood line from the priming spike.

3. Connect the arterial blood line and venous blood line to the vascular access.

Figure 4-25: Connect the blood lines to the patient's vascular access



4. Open the red and blue clamps on the blood lines and the clamps on the vascular access lines.
5. Connect a luer-lock syringe to the red and blue ports on the priming spike to keep them sterile.

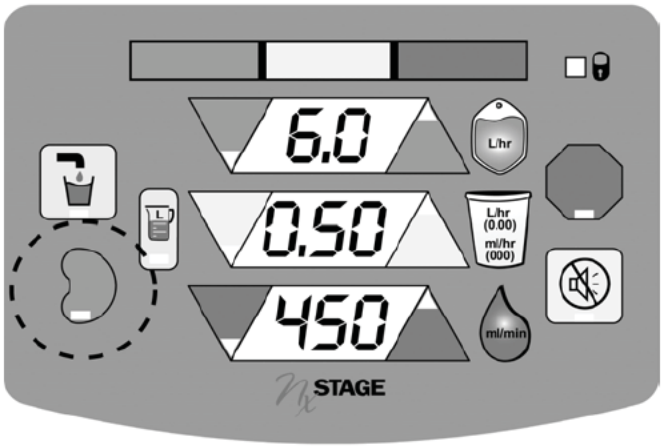
Before starting the treatment, check the following:

- The dialyzer is in the filter holder with the post-dialyzer port upright.
- The waste line on the cartridge is connected to the drain line. Both lines have yellow clamps. The clamps should be open.
- The blood lines are visible, free of kinks and connected to the vascular access and all clamps are opened.
- The white clamps on the saline line and saline "T" are closed.
- The dialysate source is connected and ready to use.
- The clamps from the dialysate source are open.

To start the treatment:

1. Press the **TREATMENT** key.

Figure 4-26: Location of the TREATMENT key



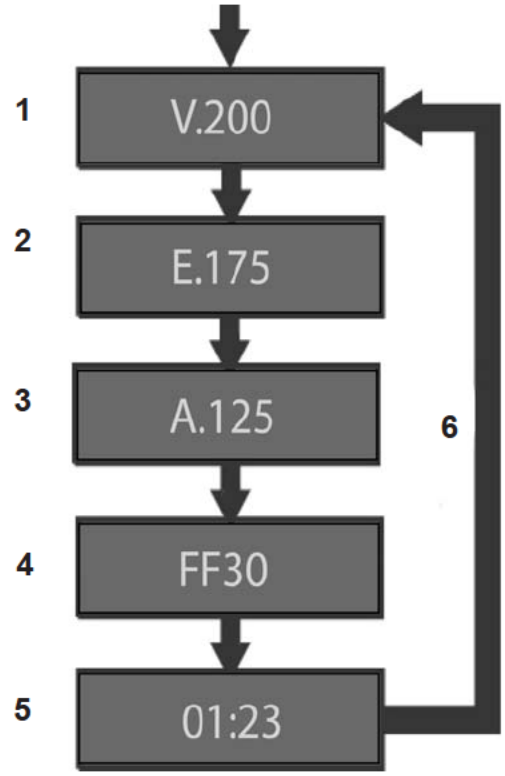
- Monitor the arterial and venous pressures while increasing the blood flow rate to the prescribed rate. Increase the dialysate flow rate until it stops.
- Check for air in the venous blood line (blue clamp).
- Check for air in the arterial blood line (red clamp). Small air bubbles in the arterial blood line may appear if the blood flow rate is set too high.
- Monitor the arterial and venous pressures. Watch for pressures outside normal ranges. A normal arterial pressure is between -50 and -200 mmHg. A normal venous pressure is between 20 and 300 mmHg. If pressures are outside the range, it may be necessary to adjust the blood flow rate to obtain a good access flow. Check the recommendations given by your center to re-adjust the blood flow rate.
- If the access flow is poor, check for kinks and clots in the blood lines. Check to make sure all clamps are open.
- Monitor the control panel until the Green Safe Operating condition occurs.

NOTE

The cycler displays the arterial access pressure without the negative sign. Therefore, when the arterial pressure decreases (more negative), the arterial pressure displayed on the cycler shows a higher number indicating a more restricted flow.

2. Monitor the treatment values as they scroll through the Green Operating window.

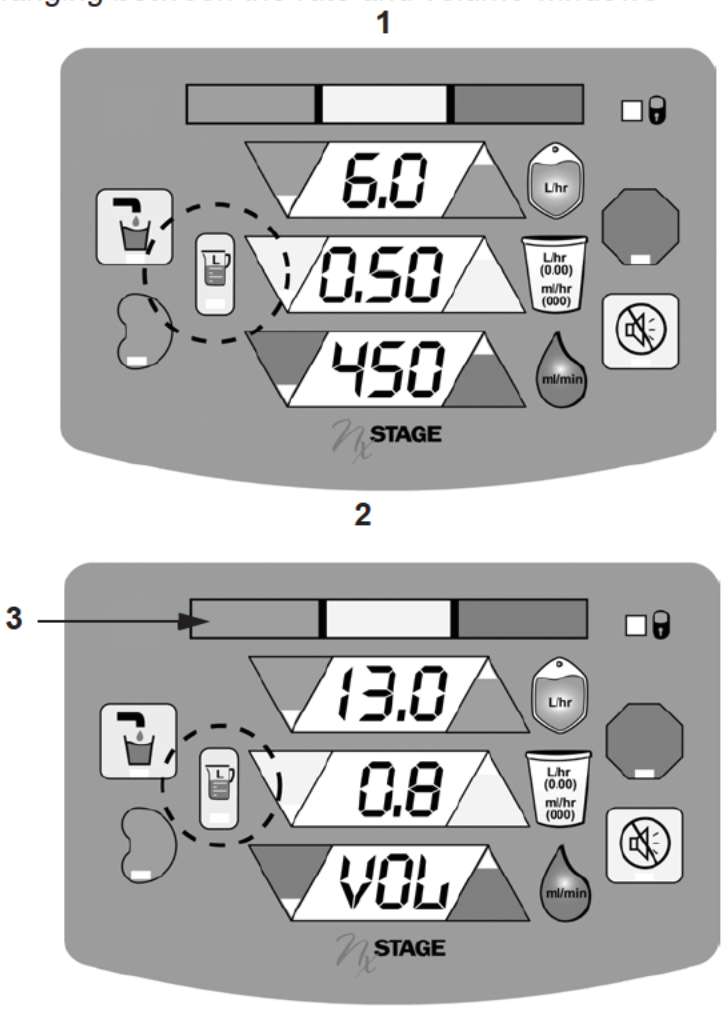
Figure 4-27: Treatment values



1	Venous Pressure
2	Effluent Pressure
3	Access Pressure (Optional)
4	Flow Fraction
5	Time Remaining
6	Repeat Cycle

3. Press the **VOLUME TOGGLE** key to determine how much of the treatment is left.

Figure 4-28: Changing between the rate and volume windows

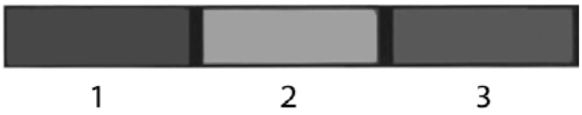


1	Rate window: Shows current rates
2	Volume window: Shows volumes of remaining dialysate to exchange and ultrafiltration to remove
3	Elapsed treatment time shown in Green Operating window

4. Press the **VOLUME TOGGLE** key a second time to show the rate window. You can also wait for the rate window to appear automatically, after a short delay. The delay is determined by the software version of your cycler and your system settings. See Chapter 9, System Settings.

5. Note alarms and cautions in the status windows. Correct all alarm and caution conditions as necessary.

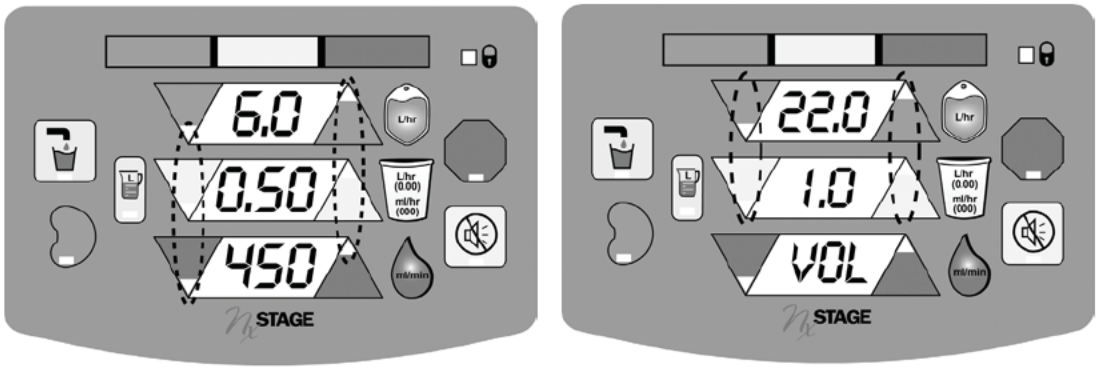
Figure 4-29: The status windows



1	Green Operating Window
2	Yellow Caution Window
3	Red Alarm Window

- If a red alarm or yellow caution appears, see the **List of alarms and cautions**, page 5-19 for alarms procedures.
- All red alarms require immediate attention.
- It is normal for some yellow cautions to appear during treatment.

6. Press the **ADJUSTMENT ARROWS** to change the fluid rate and volume targets if needed.



Rate Window **Volume Window**

7. Monitor your treatment:
   - Respond immediately to all alarms and cautions.
   - Make sure the blood lines are visible and secured to the vascular access.
   - Monitor the vital signs to determine response to treatment.
   - Monitor the arterial and venous pressures. Watch for any values outside normal ranges. The normal arterial pressure is between -50 and -200 mmHg; the normal venous pressure is between 20 and 300 mmHg. If pressures are outside the ranges, it may be necessary to adjust the blood flow rate to obtain a good access flow. If the access flow is good, check for kinks, clotting, or other obstruction.

NOTE

The cycler displays the arterial access pressure without the negative sign. Therefore, when the arterial pressure decreases (more negative), the arterial pressure displayed on the cycler shows a higher number indicating a more restricted flow.

WARNING

Do not disconnect and reverse patient blood lines during treatment. This may cause an infusion of air into the patient blood lines, which may lead to an embolism.

- If the cartridge has an access pressure pod, check that the pod is pulsing. If the pod does not pulse, reset it (see page 4-46) and check that the access pressures are within the expected range.
- If using a warmer, confirm that the dialysate bags drain evenly.
- Check that the saline line is primed with both white clamps closed to prevent the infusion of fluid or air by accident.
- Check for air in the venous header on the dialyzer. If there is air, remove the air from the post-dialyzer port with a 20 ml luer lock syringe. Flush the port with 3 ml of saline to clear the blood and then close the clamp.
- Check for clots in the blood circuit. You can check for clots by giving a manual bolus of fluid while closing the red clamp on the arterial blood line. See the instructions on page 4-49.

End of treatment

At the end of the treatment, you rinse back your blood from the cartridge.

WARNINGS

- Never try to open the door of the NxStage System One Cycler when the door lock symbol is on. If the door is opened by force, all safety systems will no longer be active, which may cause patient injury or death. If the door must be opened while the patient is connected, press the STOP key, immediately clamp all fluid and blood lines, turn the power switch OFF on the Cycler, and then open the door of the Cycler.

- Follow your center's instructions for rinsing back blood at the end of treatment. Blood that is left in the blood lines after rinseback will result in blood loss.

- Before starting treatment, check the patient blood lines for air. Check again before and during rinseback. Follow the instructions to remove air before starting treatment or rinseback. Failure to remove air from the patient blood lines may cause an infusion of air, which may lead to an embolism.

The treatment ends automatically when:

- The prescribed volume of dialysate has been delivered to the patient.
- The prescribed ultrafiltration volume has been removed from the patient.
- All alarm conditions have been cleared.

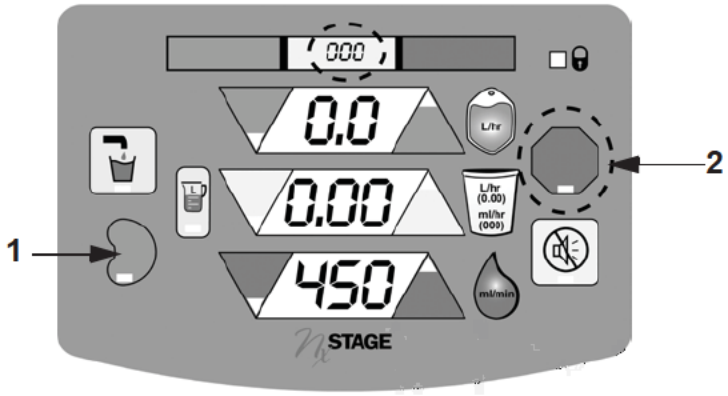
You can also end the treatment before reaching the volume goals.

1. To end the treatment, press the **STOP** key for two seconds.

NOTE

If you need to resume treatment at previous rates, press the **TREATMENT** key.

Figure 4-30: Location of STOP and TREATMENT buttons



1	**TREATMENT** key
2	**STOP** key

At the end of the treatment:

- Three zeros (**000**) appear in the Yellow Caution window
- The dialysate and ultrafiltrate rates go to zero (**0**)
- The blood pump continues to run

Do not press the **STOP** key until you are ready to rinse back the blood.

NOTE

All alarm conditions must be cleared before **000** End of Treatment can occur. If an alarm cannot be cleared or if the power fails, refer to **manual rinseback** on page 4-52.

Do not try to rinse back the blood manually:

- if the blood circuit is clotted or hemolyzed,
- if you see air in the blood circuit or blood lines, or
- if your center tells you differently.

Automated rinseback

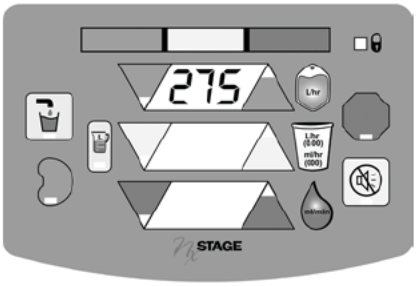
Before rinsing back the blood:

1. Make sure there is enough saline to rinse back the blood.

Figure 4-31: Checking saline level in bag

- The bag should have between 300 and 500 ml of saline left in the bag. If not, hang a fresh bag of saline.
- To prevent air entering the blood circuit, make sure that the saline line is primed.

2. Press the **STOP** key to stop the blood pump.
3. Check that the rinseback volume is shown in the top window of the control panel. For example, **275**.



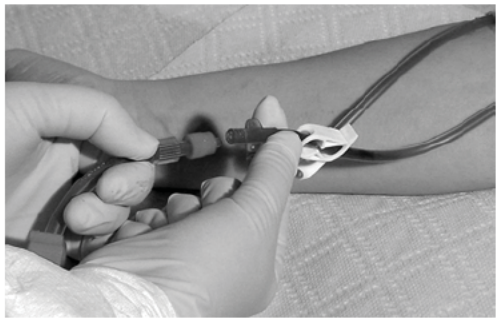
NOTE

The volume number shown in the picture is for example only. Your cycler may show a different number based on your System Settings 12 and 13.

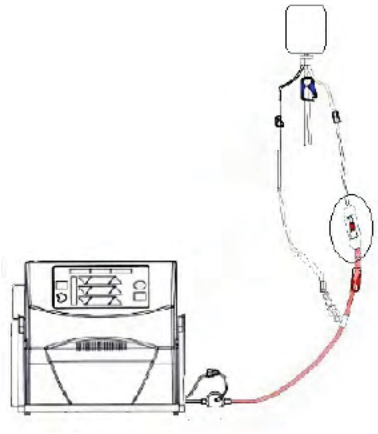
4. Close the red clamp on the arterial blood line and the clamp on the vascular access, using aseptic technique.

5. Disconnect the arterial blood line.
6. Connect the arterial blood line to the priming spike (red clamp).

Figure 4-32: Disconnect the arterial blood line and reconnect to the priming spike



Disconnecting



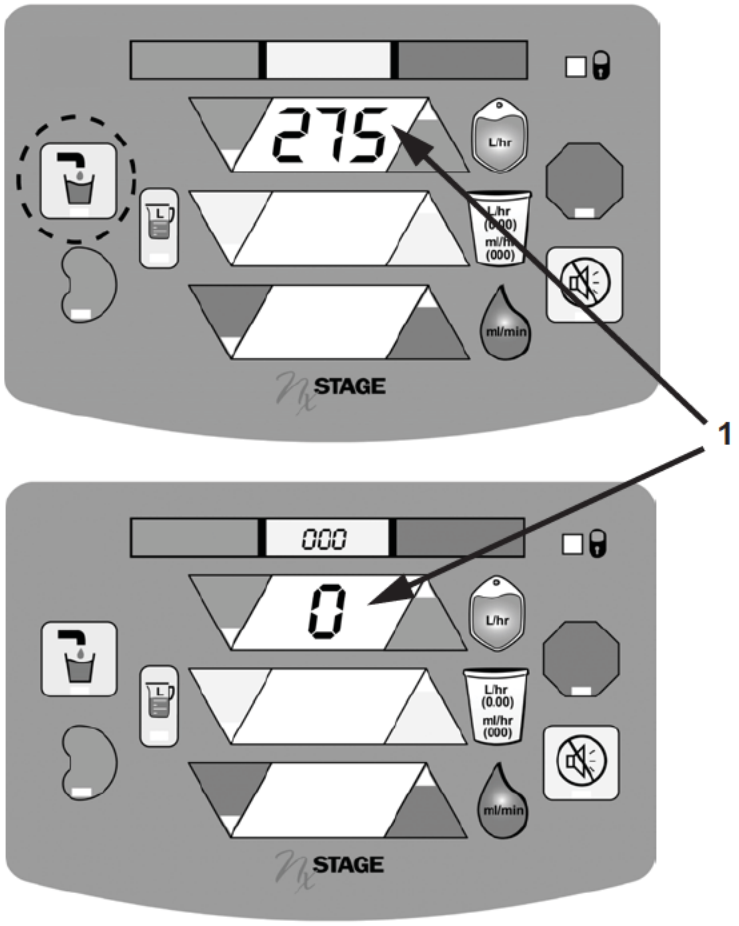
Reconnecting

7. Open the red clamps on the arterial blood line and priming spike.

To rinseback the blood:

1. Press the **ADD FLUID** key. The rinseback volume number (**275**) drops to zero (**0**).
2. Monitor the venous blood line (blue clamp) for air.

Figure 4-33: Top window counting down for Rinseback



1	Top window counts down as saline is used to rinse back. Rinseback is complete when top window reads **0** and Yellow Caution window reads **000**.

3. If needed, press the **ADD FLUID** key again until all blood lines are clear.

   If you administer extra fluid during rinseback, the ultrafiltration volume shown in the middle window increases as this extra fluid is given back to the patient.

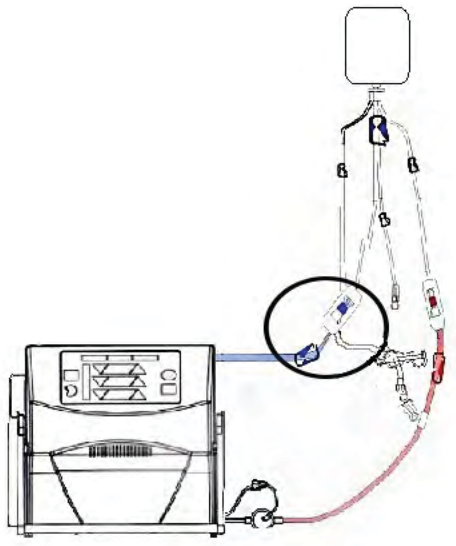
NOTE

A low venous pressure alarm (Yellow Caution 20, 21) may occur during rinseback due to a change in the fluid thickness. Press the **MUTE** key to clear the alarm.

At the end of rinseback:

1. Close the blue clamp on the venous blood line and the clamp on the vascular access.
2. Disconnect the venous blood line (blue clamp) from the vascular access.
3. Connect the venous blood line to the priming spike (blue clamp).

Figure 4-34: Attaching the venous blood line to the priming spike

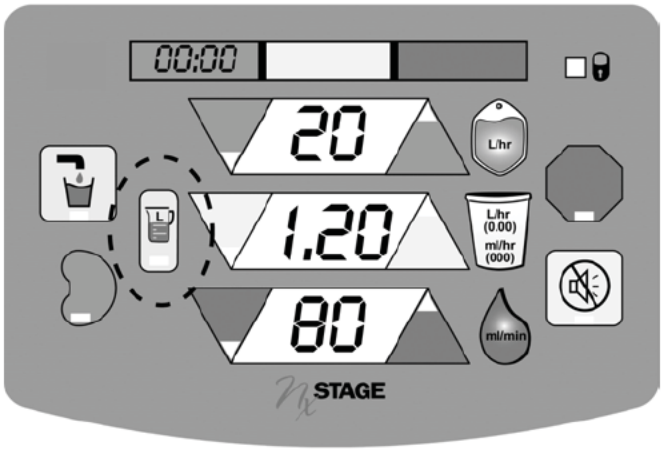


4. Press the **VOLUME TOGGLE** key to see the treatment summary.

   The treatment summary shows (from top to bottom):

   - the total treatment time.
   - the amount of dialysate used.
   - the ultrafiltration volume.
   - the amount of blood processed, in liters.

Figure 4-35: Example of treatment summary



NOTE

When you turn off the cycler, the treatment summary disappears.

5. Turn off the cycler.

To remove the disposables:

1. Disconnect the access pressure pod from the cycler.
2. Close the green clamps on the dialysate inlet line and dialysate source. Disconnect the dialysate inlet line from the dialysate source.
3. Close the yellow clamps on the waste line and drain line. Disconnect both lines.
4. Open the door of the cycler. To open, lift up the front handle until it clicks and pull the door toward you.
5. Remove the saline bag and cartridge.
6. Throw away the saline bag, cartridge, and other disposables as appropriate.

Common procedures

Re-priming a cartridge

The troubleshooting steps may ask you to re-prime the cartridge.

To re-prime the cartridge:

1. Turn off the cycler.
2. Lower the saline bag below the cycler.
3. Open the cycler door. Let the saline flow back completely into the bag.
4. Disconnect the access pressure pod. Remove the cartridge.
5. Turn on the cycler. Keep the door open and the handle up.
6. When the Yellow Caution window flashes two bars, insert the cartridge and press the lines into the three air detectors.
7. Close the door of the cycler.
8. Connect the access pressure pod and hang the saline bag.
9. Press the **ADD FLUID** key to re-prime the cartridge.

⚠ PRECAUTION

⚠ Do not reprime a Cartridge that has been used on a patient. Failure to follow the instructions for repriming a Cartridge may cause damage to the Cartridge or misloading, and may impact system performance.

Flushing the priming fluid before treatment

WARNING

Do not touch surfaces of any disposable covered by protective caps. This includes connectors and needleless access sites. Always use aseptic technique when handling connections. Touching these surfaces may make them non-sterile, which may cause patient infection.

The center may ask you to flush the priming fluid from the cartridge before starting the treatment and before connecting the blood lines to the vascular access.

Before flushing the cartridge:

1. Prepare the patient's vascular access.
2. Insert the priming spike in a fresh 1-liter bag of saline.
3. Close the blue clamps on the priming spike and venous blood line. Disconnect the venous blood line.
4. Place a luer lock syringe on the priming spike line with the blue clamp to maintain sterility. Be sure to leave the arterial blood line with the red clamp connected to the priming spike.
5. Hold the venous blood line over a clean container. Open the blue clamp.

To flush the cartridge:

1. Press the **TREATMENT** key. Drain the amount of saline determined by your center.
2. Press the **STOP** key.

After flushing the cartridge:

1. Close the blue clamp on the venous blood line. Connect the venous blood line to the vascular access.
2. Close the red clamps on the priming spike and arterial blood line. Using aseptic technique, disconnect both lines.
3. Connect the arterial blood line to the vascular access.
4. Open the red and blue clamps on the arterial and venous blood lines and the clamps on the vascular access.

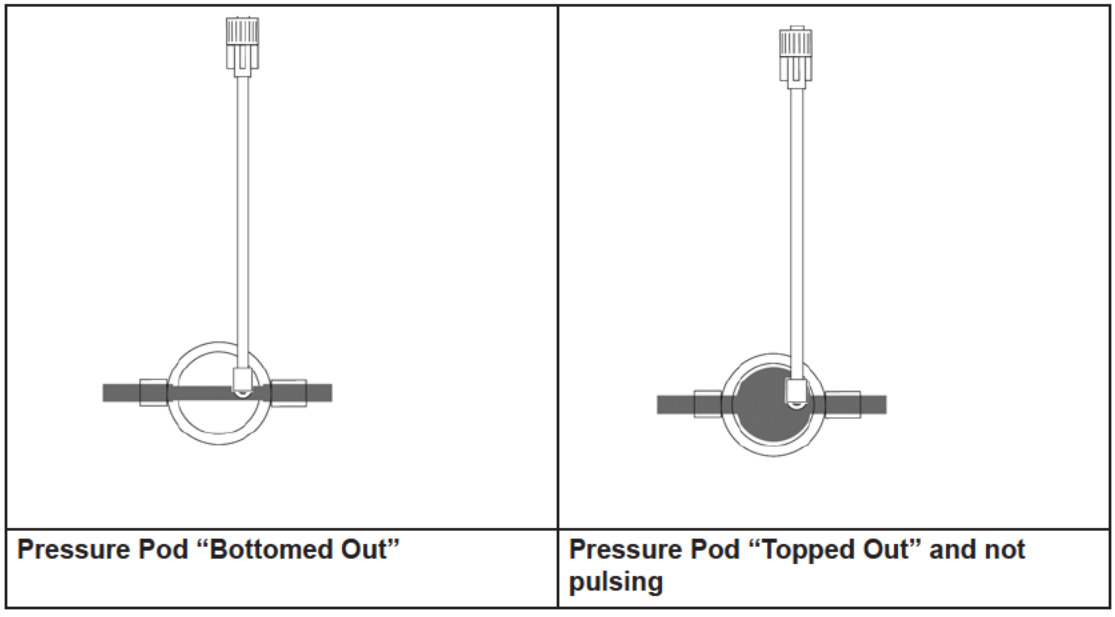
5. Place a luer lock syringe on the priming spike to maintain sterility.
6. Check that the system is ready.
7. Press the **TREATMENT** key to start treatment.

Resetting the access pressure pod

You need to reset the access pressure pod when:

- the pod is full of blood and not pulsing.
- there is no blood in the pod.
- there is no access pressure reading.

Figure 4-36: Reset access pressure pod when it tops out or bottoms out



Pressure Pod "Bottomed Out"	Pressure Pod "Topped Out" and not pulsing

To reset the access pressure pod:

1. Disconnect the access monitoring line from the cycler. The access pressure pod deflates.
2. Press the **STOP** key. If the pod fills immediately with blood, go to the procedure: **To connect the access monitoring line to the access pressure pod,** page 4-47.

If the pod does not fill immediately with blood:

1. Close the red clamp on the arterial blood line.

2. Open the white clamps on the saline line and saline "T." The pod fills with blood.
3. Close the white clamps on the saline line and saline "T."
4. Open the red clamp on the arterial blood line.

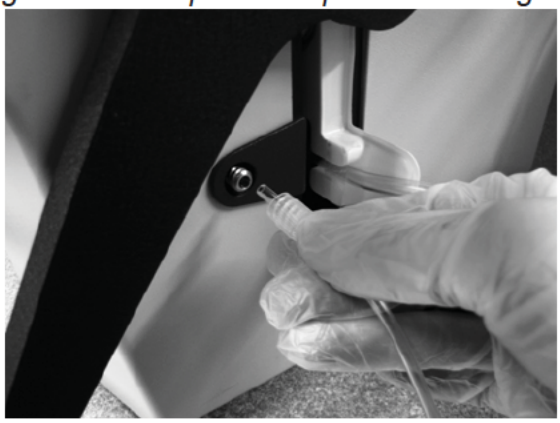
To connect the access monitoring line to the access pressure pod:

1. Hold the monitoring line behind the locking collar.
2. Insert the end of the monitoring line into the cycler. The connection is below the handle on the right side of the cycler.
3. Press the monitoring line into the connector. Twist a quarter turn to the left to seal the connection.
4. Tighten the locking collar.

To complete resetting the access pressure pod:

1. Press the **TREATMENT** key.
2. Check that the arterial pressures are within range.

Figure 4-37: Attaching the access pressure pod monitoring line



Treating low blood pressure (hypotension)

Unexpected low blood pressure may occur during treatment for a number of reasons. It may occur when the ultrafiltration is too fast or when the ultrafiltration goal is too high.

To treat low blood pressure, you can do one or both of the following:

- Deliver a manual fluid bolus.
- Stop the ultrafiltration.

Review your ultrafiltration rate and goal to determine the causes for low blood pressure during treatment. Reduce your ultrafiltration rate or goal or both if needed.

Delivering a manual fluid bolus

To deliver a manual fluid bolus:

1. Make sure there is enough saline in the saline bag for a fluid bolus.
2. While the blood pump is running, open the white clamps on the saline "T" and saline line.
3. Give the desired fluid volume.
   - Use only saline to give a fluid bolus.
   - Make sure the saline line is primed before delivering the fluid bolus.
   - Look at the markings on the saline bag to give the correct fluid volume.

Figure 4-38: Checking saline level in bag

4. Close the white clamps on the saline line and saline "T" after delivering the fluid bolus.
   - A low-pressure caution (Yellow Caution 20 or 21) may occur briefly when delivering a bolus. After delivering the bolus, the caution stops.
   - The cycler does not account for the volume of fluid given manually. You must determine if it is appropriate to add the bolus volume to the goal. Include any bolus volume not removed by ultrafiltration when you compare the weights before treatment and after treatment.

WARNING

Manual fluid boluses and fluid consumed during treatment are not included in the System One fluid balance calculations. Excessive fluid boluses, whether intentional or unintentional, or failure to account for consumed fluid during treatment, may cause patient injury. Include fluid boluses and the volume of fluid consumed in manual fluid balance calculations. Make sure that the administration lines used for manual bolus or rinseback are clamped after use.

Stopping the ultrafiltration

To stop the ultrafiltration, press and hold the **STOP** key for two seconds. The dialysate and ultrafiltration rates go to zero. The Yellow Caution window shows three zeros (**000**). The blood flow rate is not changed.

After the first treatment of low blood pressure

1. Check the patient's response to the manual bolus and stopping ultrafiltration.
2. Give another fluid bolus if needed to support the blood pressure.
3. If the blood pressure is good, continue treatment. Press the **TREATMENT** key to return to the first dialysate and ultrafiltration rates. Consider decreasing the ultrafiltration rate and volume.
4. If the blood pressure continues to be a concern, end the treatment and call your home training nurse.

NOTE

See **Ultrafiltration**, page 2-4.

Checking the dialyzer for clots

To check the dialyzer for clots by giving a manual fluid bolus with 100 to 200 milliliters of saline, follow **delivering a manual fluid bolus**, page 4-48.

The best way to check the dialyzer for clots while delivering a manual fluid bolus is to do the following:

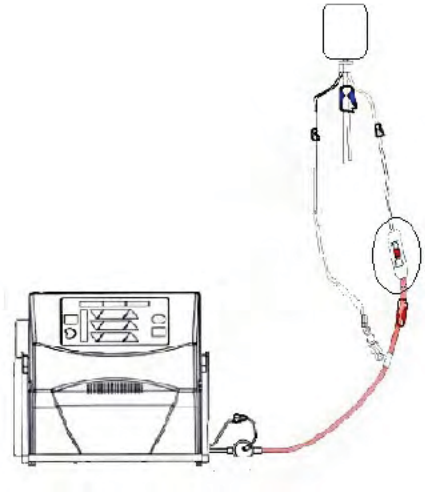
1. Press the **TREATMENT** key if the cycler is not in Treatment Mode.
2. Close the red clamp on the arterial blood line near the saline "T" (white clamp) while saline is infusing with the blood pump running.
3. Check the venous header and the arterial header for dark spots or patches. Dark spots or patches in headers are an indication of blood clotting.
4. After flushing the dialyzer, open the red clamp on the arterial blood line.
5. Close the white clamps on the saline "T" and saline line.

Temporary disconnection

To recirculate the blood circuit after rinsing back the blood:

1. After rinsing back the blood, keep the arterial blood line with the red clamp connected to the red port on the priming spike.
2. If you see clotting, throw away the cartridge.

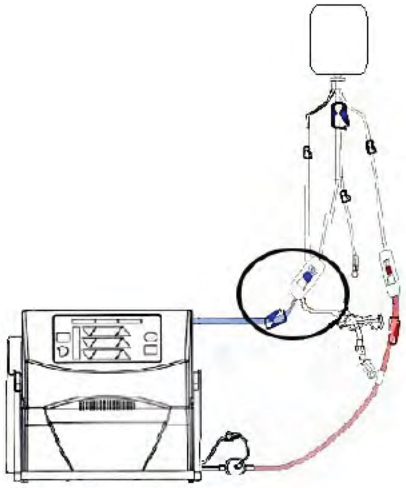
Figure 4-39: Connect the arterial blood line to the priming spike



3. Close the clamp on the venous vascular access line.
4. Close the blue clamp on the venous blood line. Disconnect it from the vascular access using aseptic technique.
5. Connect the venous blood line to the priming spike. Both have blue clamps.

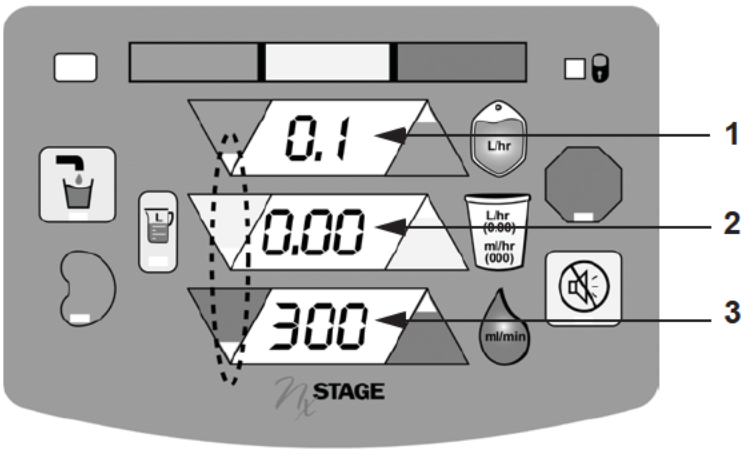
6. Open the blue clamps on the venous blood line and priming spike.

Figure 4-40: Attach the venous blood line to the priming spike



7. Press the **TREATMENT** key to recirculate the blood circuit with saline.
8. Immediately, press the **ADJUSTMENT ARROWS** keys to set the rates to the values shown in Figure 4-41.

Figure 4-41: Set the rates with the Adjustment Arrows keys



1	Dialysate rate, green arrows (top window): 0.1
2	Ultrafiltration rate, yellow arrows (middle window): 0
3	Blood flow rate, red arrows (bottom window): 300–350

Follow the instructions from your center to determine the recirculation time allowed for a temporary disconnection. If you see clotting in the blood circuit, throw away the cartridge.

To reconnect the patient after recirculation:

1. Press the **STOP** key.
2. Close the clamps on the blood lines.
3. Disconnect the blood lines from the priming spike.
4. Re-connect the blood lines to their original configuration on the vascular access.
5. Open the clamps on the blood lines and vascular access.
6. Press the **TREATMENT** key. Enter the treatment settings to resume treatment.

Manual rinseback

There are times when you can rinse back the blood manually, for example during a power failure, a recurring alarm, or any other problem that cannot be resolved. Check with your center if you are authorized to rinse back the blood manually.

Before rinsing back the blood manually, make sure that the blood circuit is not clotted or hemolyzed. Make sure there is no air in the blood circuit or blood lines.

WARNINGS

During a manual rinseback, do not apply excessive pressure or use devices that apply pressure on the saline bag (for example, blood pressure cuffs). The use of excessive pressure or a device that applies pressure to the saline bag may cause an infusion of air into the patient blood lines, which may lead to an embolism.

When performing manual rinseback, the NxStage System One Cycler door is open, which deactivates all safety systems. The operator must visually monitor for air in the patient blood lines, to prevent an infusion of air, which may lead to an embolism.

Follow your center's instructions for rinsing back blood at the end of treatment. Blood that is left in the blood lines after rinseback will result in blood loss.

Before rinsing back the blood:

1. Hang a fresh 1-liter bag of saline.
2. Make sure the saline line is primed and free of air.

NOTE

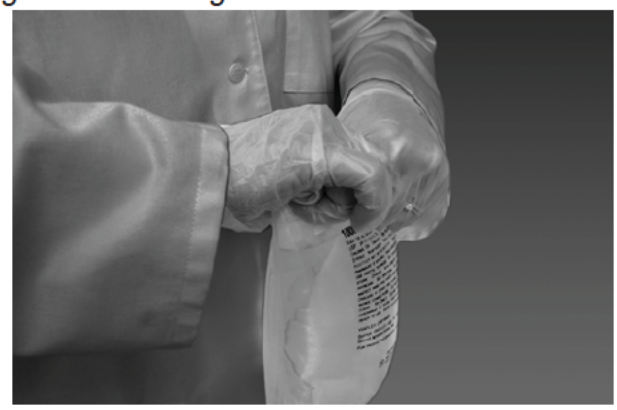
During a manual rinseback, air may enter the blood lines when squeezing a bag that is only partially filled with saline.

3. Turn off the cycler.
4. Close the yellow clamp on the waste line.
5. Close the green clamp on the dialysate inlet line to the cartridge.
6. Close the clamp on the patient's arterial vascular access line.
7. Close the red clamp on the arterial blood line. Using aseptic technique, disconnect it.
8. Connect the arterial blood line to the priming spike. Both have red clamps.

Rinsing back the blood:

1. Open the red clamps on the blood line and priming spike.
2. Open the door of the cycler. To open, lift up the handle until it clicks, then pull it toward you.
3. Squeeze the saline bag until the blood lines are clear of blood.
4. If there is pressure or resistance in the blood lines, or if there is air in the venous blood line, **do not try** to rinse back the blood.

Figure 4-42: Squeezing the saline bag for rinseback



After rinsing back the blood:

1. Close the clamp on the venous vascular access line.
2. Close the blue clamp on the venous blood line, using aseptic technique. Disconnect it from the vascular access.
3. Connect the venous blood line to the priming spike. Both have blue clamps.
4. Disconnect the access pressure pod from the cycler.
5. Close the green clamps on the dialysate inlet line and dialysate source. Disconnect the dialysate inlet line from the dialysate source.
6. Close the yellow clamps on the waste line and drain line. Disconnect both lines.
7. Remove the saline bag and the cartridge.
8. Throw away the saline bag, the cartridge, and other disposables, as appropriate.

Emergency rinseback

There are times when you need to rinse back the blood quickly. Before rinsing back the blood in an emergency, make sure that the blood circuit is not clotted or hemolyzed. Make sure there is no air in the blood circuit and blood lines.

To rinse back the blood quickly:

1. Make sure there is enough saline to rinse back the blood. You will need between 300 and 500 milliliters of saline.
2. Open the white clamps on the saline line and saline "T." Check the flow of saline.
3. Close red clamp on the arterial blood line.
4. Let saline infuse the blood lines to return the blood to the patient.

After returning the blood:

1. Press the **STOP** key on the cycler when the venous blood line (blue clamp) is clear of blood.
2. Close the clamps on the arterial and venous vascular access lines.
3. Close the blue clamp on the venous blood line. Disconnect it from the vascular access using aseptic technique.
4. Close the red clamp on the arterial blood line. Disconnect it from the vascular access using aseptic technique.
5. Connect the arterial blood line (red clamp) and venous blood line (blue clamp) to the red and blue clamps on the priming spike.
6. Turn off the cycler.
7. Open the door of the cycler. To open the door, lift up the handle until it clicks, then pull it toward you.

To remove the disposables:

1. Disconnect the access pressure pod from the cycler.
2. Close the green clamps on the dialysate inlet line and dialysate source line. Disconnect the dialysate inlet line from the dialysate source.
3. Close the yellow clamps on the waste line and drain line. Disconnect both lines.
4. Remove the saline bag and cartridge from the cycler.
5. Throw away the saline bag, cartridge and other disposables, as appropriate.

This page intentionally left blank.

Chapter 5 Troubleshooting

The NxStage System One cycler delivers safe, smooth, and comfortable treatment. The cycler has features that monitor for safe operation. Alarms and cautions alert you of problems or potential problems to help you maintain safe treatments. Always have your care partner help you troubleshoot blood lines.

WARNINGS

The risk of blood clotting in the Cartridge and Dialyzer is higher during long treatments, when no anticoagulation is used, in certain patients who are more prone to excess clotting, or any time when the blood flow stops, including when the NxStage System One Cycler loses power or during an unrecoverable alarm. The risk of blood clotting increases the longer treatment continues and the longer blood flow is stopped. To reduce the risk of blood clotting and identify the early signs of clotting:

- Follow your center's instructions to give and monitor anticoagulant.
- During treatment, regularly check the Cartridge and Dialyzer for clotting by looking closely at the Cartridge and Dialyzer, and periodically flushing the Dialyzer with a manual fluid bolus.

Failure to respond to blood clotting in the Cartridge and Dialyzer or administering medication through the Post-dialyzer port when clotting is present in the dialyzer venous header may result in a blood clot being released into the patient's bloodstream and causing a blockage (thromboembolism). Failure to respond to clotting may also lead to sustained high pressures in the blood circuit and cause a dialyzer blood leak or hemolysis. These conditions may cause serious injury or death if not responded to promptly and appropriately. Regularly check the Dialyzer for any evidence of a leak. Do not return the blood if the blood flow is stopped for a long time. Discard the Cartridge and Dialyzer if they are clotted.

Manual fluid boluses and fluid consumed during treatment are not included in the System One fluid balance calculations. Excessive fluid boluses, whether intentional or unintentional, or failure to account for consumed fluid during treatment, may cause patient injury. Include fluid boluses and the volume of fluid consumed in manual fluid balance calculations. Make sure that the administration lines used for manual bolus or rinseback are clamped after use.

When a Yellow Caution is displayed, some safety systems may not be active. Monitor the system and the patient until the Green Safe Operating condition returns. Failure to do so may cause patient injury or death.

During a manual rinseback, do not apply excessive pressure or use devices that apply pressure on the saline bag (for example, blood pressure cuffs). The use of excessive pressure or a device that applies pressure to the saline bag may cause an infusion of air into the patient blood lines, which may lead to an embolism.

WARNINGS

Before starting treatment, check the patient blood lines for air. Check again before and during rinseback. Follow the instructions to remove air before starting treatment or rinseback. Failure to remove air from the patient blood lines may cause an infusion of air, which may lead to an embolism.

There are no operator or customer technician serviceable parts in any NxStage equipment. Unless otherwise instructed or authorized, NxStage or its agent must perform all maintenance and repair. No changes or modifications to any NxStage equipment are allowed without NxStage's authorization. Unauthorized changes or modifications to equipment may impact performance which may lead to patient or operator injury or death.

Re-priming the cartridge

The troubleshooting steps may ask you to re-prime the cartridge.

To re-prime the cartridge:

1. Turn off the cycler.
2. Lower the saline bag below the cycler.
3. Open the cycler door. Let the saline flow back completely into the bag.
4. Disconnect the access pressure pod. Remove the cartridge.
5. Turn on the cycler. Keep the door open and the handle up.
6. When the Yellow Caution window flashes two bars, insert the cartridge and press the lines into the three air detectors.
7. Close the door of the cycler.
8. Connect the access pressure pod and hang the saline bag.
9. Press the **ADD FLUID** key to re-prime the cartridge.

PRECAUTION

Do not reprime a Cartridge that has been used on a patient. Failure to follow the instructions for repriming a Cartridge may cause damage to the Cartridge or misloading, and may impact system performance.

Manual fluid bolus

The troubleshooting steps may ask you to give a manual fluid bolus.

To give a manual fluid bolus:

1. Make sure there is enough saline in the saline bag for a fluid bolus.
2. While the blood pump is running, open the white clamps on the saline "T" and saline line.
3. Give the desired fluid volume.
   - Use only saline to give a fluid bolus.
   - Make sure the saline line is primed before delivering the fluid bolus.
   - Look at the markings on the saline bag to give the correct fluid volume.

Figure 5-1: Checking saline level in bag

4. Close the white clamps on the saline line and saline "T" after delivering the fluid bolus.
   - A low-pressure caution (Yellow Caution 20 or 21) may occur briefly when delivering a bolus. After delivering the bolus, the caution stops.
   - The cycler does not account for the volume of fluid given manually. You must determine if it is appropriate to add the bolus volume to the goal. Include any bolus volume not removed by ultrafiltration when you compare the weights before treatment and after treatment.

General alarm events

Treatment time displays 99:99

Probable cause

System Setting 38 is set to one (**1**) and the treatment ultrafiltration rate is set to zero (**0**). The cycler cannot remove the rinseback volume if the ultrafiltration rate is set to zero (**0**) and the cycler is not able to calculate the treatment time.

Action required

Set the ultrafiltration rate to 0.5 L/hr to remove the rinseback volume. The estimated treatment time will be shown in the window. This time is based upon the dialysate rate and volume.

Cycler will not turn on

Probable cause

1. There is no AC power to the cycler.
2. The cycler is in a power protection state.

Action required

1. Make sure one end of the power cord is fully plugged into a working electrical outlet and the other end to the cycler. Make sure the cycler power switch is turned on.
2. Unplug the power cord from the electrical outlet. Wait five minutes. Plug the power cord back into the electrical outlet and turn on the cycler.

   If the recommended action does not resolve the problem, call Technical Support.

Continuous beep. Nothing on screen

Probable cause

1. Power loss.
2. Service required.

Action required

1. Check the connections of the power cord to the wall outlet and to the power input on the cycler.
2. If the recommended action does not resolve the problem, call Technical Support.

Clotting in the dialyzer or blood circuit

Blood clotting in the dialyzer or blood circuit can be a very serious risk for the dialysis patient. When the blood clots, it cannot be returned to the body and the dialysis patient loses blood. Risks from returning blood that is clotted to the patient include heart attack, stroke, and pulmonary embolism. Clotting in the cartridge can restrict the blood flow and cause damage to the red blood cells, called hemolysis.

Probable cause

Blood clotting in the dialyzer and blood circuit can occur at any time during treatment while the blood is outside the body. Access flow, blood flow rate, not enough anticoagulation and other events may cause blood clotting.

- Clotting in the dialyzer or blood circuit starts to happen as soon as the blood pump is turned off.
- Patients and their caregivers should carefully follow the instructions from their doctor or center on the use of an anticoagulant, for example heparin, as part of their treatment.
- Potential for clotting increases every time the blood flow stops, after multiple alarms, and with prolonged alarm recovery times.

Action required

- Look at the blood circuit. Make sure the blood flows freely.
- Remove air promptly from the blood circuit and dialyzer.
- Respond to all alarms promptly.
- Seek help if unable to clear multiple alarms.
- Check the dialyzer and blood circuit regularly for early signs of clotting.

When there is clotting in the blood lines, the color of the blood is very dark. If the blood stops pulsating in the access pressure pod, it is a sign of clotting in the access pressure pod.

You can check the dialyzer for clotting by giving a manual fluid bolus. See **manual fluid bolus**, page 5-5.

The best way to check the dialyzer for clotting is to do the following:

1. Press the **TREATMENT** key if the cycler is not in Treatment Mode.
2. Close the red clamp on the arterial blood line near the saline "T" (white clamp) while saline is infusing with the blood pump running.
3. Check the venous header and the arterial header for dark spots or patches. Dark spots or patches in the headers are signs of blood clotting.
4. Open the red clamp on the arterial blood line after flushing the dialyzer.
5. Close the white clamps on the saline "T" and the saline line.

WARNING

Manual fluid boluses and fluid consumed during treatment are not included in the System One fluid balance calculations. Excessive fluid boluses, whether intentional or unintentional, or failure to account for consumed fluid during treatment, may cause patient injury. Include fluid boluses and the volume of fluid consumed in manual fluid balance calculations. Make sure that the administration lines used for manual bolus or rinseback are clamped after use.

- Watch closely for any changes in venous or effluent pressure. Unless the blood lines are kinked, blocked, disconnected or the clamps are closed, changes in venous or effluent pressure are signs of blood clotting in the blood circuit.

- Check for clotting in the dialyzer or blood circuit when any of the following alarms occur:
  - Red Alarms 33 and 34 (Check Dialyzer: High TMP)
  - Red Alarm 62 (Check Dialyzer for Clotting: Arterial Pressure Unstable)
  - Red Alarms and Yellow Cautions 20 and 21 (Low Venous Pressure) and 22 (Effluent Pressure)
- If there is clotting in the dialyzer or blood circuit, end the treatment and do **not** rinse back the blood.
- If any of the following events occur, contact your center to determine if anticoagulation needs to be changed or other steps to take before the next treatment:
  - Clotting appears to occur more often.
  - There is a large amount of clotting.
  - The patient loses blood.

Arterial access flow

During hemodialysis, the cycler pulls the blood from the arterial vascular access at the set blood pump rate. If the arterial access does not have sufficient blood flow for the set blood pump rate, alarms may occur.

NOTE

The cycler displays the arterial access pressure without the negative sign. Therefore, when the arterial access pressure decreases (more negative), the arterial access pressure shown on the cycler has a higher number indicating a more restricted flow.

When the cycler tries to pull more blood from the arterial access than it can deliver, it lowers the arterial access pressure (more negative) and pulls small bubbles of air out of the blood. The more negative the arterial access pressure, the higher is the arterial pressure number reading on the cycler. A high arterial access pressure number indicates an insufficient blood flow.

WARNINGS

- Do not disconnect and reverse patient blood lines during treatment. This may cause an infusion of air into the patient blood lines, which may lead to an embolism.
- Do not adjust the vascular access while the Blood Pump is running. Adjusting the vascular access while the Blood Pump is running increases the likelihood of needle dislodgement, which may result in a significant blood loss.

Probable cause

Poor blood flow at the arterial access.

Action required

- Follow the instructions from your center on how to assess the blood flow from the arterial access.
- If there is not enough blood flow for the cycler to pump the blood at the set rate, an alarm occurs:
  - Caution and Alarm 24 usually occur first if the arterial access pressure decreases (becomes more negative).
  - Alarm 11 occurs when air is pulled out of the blood. This alarm also indicates poor blood flow or an occlusion.
  - Caution and Alarm 21 occurs when the venous pressure is low. This alarm may also occur when the blood flow is low at the arterial access because the blood reaching the venous pressure sensor has less pressure.
  - Alarm 22 (Low Effluent Pressure) may occur when there is not enough blood in the dialyzer to produce the positive effluent pressure needed to finish the treatment.

NOTE

For the complete list of alarms and how to clear the alarms see page 5-19.

To prevent arterial access flow problems:

- Follow the instructions from your center on how to insert, position, adjust, and tape the needles at the vascular access.
- Before starting your treatment, check the cartridge arterial blood line for kinks or loose connections that would prevent blood flow. Make sure that all the clamps on the line are opened or closed properly.
- When starting your treatment, watch for any signs of poor blood flow. Check and adjust the arterial vascular access:
  - If you see bubbles of air in the arterial blood line when the cycler pumps the blood.
  - If the access pressure is different from the expected range when the cycler starts pumping the blood.

When it is necessary to check and adjust the arterial access:

- Use a luer lock syringe on the access line and draw a small amount of blood to check that the blood draws easily.
- If the access needle requires more than a minor adjustment, or if it needs to be replaced, rinse back the blood unless otherwise directed by the center, as long as the blood circuit is not clotted or hemolyzed and air is not seen in the blood circuit or in the patient blood lines. Remember, clotting starts when the blood pump is off.
- After rinseback, you can either temporarily disconnect the patient and recirculate the cartridge (see page 4-50) or prime a new cartridge.

- During treatment, monitor for changes in blood circuit pressures, alarms, and cautions. These are signs of insufficient blood flow.

Observation of pink waste fluid

Hemolysis is the destruction of red blood cells. When red blood cells are destroyed, the hemoglobin inside them is released into the blood plasma. Pink-tinged effluent or waste fluid without a Blood Leak Alarm 60 may be due to hemolysis.

Destroying red blood cells releases potassium into the bloodstream. A high potassium level can lead to muscle weakness and changes in the heart rhythm and may eventually lead to cardiac arrest and possibly death. The destruction of the red blood cells may also cause low hemoglobin levels and anemia.

Identifying and responding to the risks, causes, and symptoms of hemolysis may prevent further hemolysis.

NOTE

Clinical symptoms of hemolysis include back pain, shortness of breath, burning in the venous access, and tightness of the chest. These symptoms indicate a medical emergency. Follow the guidelines from your center for help and treatment.

Probable cause

1. A medical condition or medication can cause hemolysis or change the color of the effluent fluid.
2. Hemolysis as the result of treatment occurs under the following conditions:
   - The red blood cells are forced through a narrowed, severely kinked, or obstructed catheter, blood line or needle.
   - The blood pump starts and stops frequently.
   - The pump runs when there is clotting in the dialyzer or blood lines.

Action required

1. Contact your health care provider to discuss medical conditions and medication that may cause hemolysis
2. Follow the instructions from your center on how to test for blood in the effluent fluid.
   - If the test shows blood in the effluent fluid, press the **STOP** key to end the treatment. Perform a manual rinseback to rinse back the blood, unless otherwise instructed by your center. You can rinse back the blood as long as there is no clotting, hemolysis, or air in the blood circuit and blood lines. **See manual rinseback**, page 4-52.
   - If the test does not show blood in the effluent fluid but hemolysis is still suspected, end your treatment and **do not** rinse back the blood.

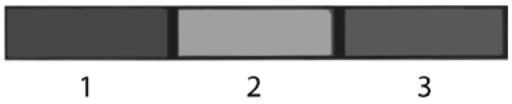
To prevent hemolysis:

1. Check every cartridge for kinks in the bloodlines. Do not use a cartridge with kinked bloodlines.
2. Follow your prescription settings from your doctor for needle size, blood flow rate and blood circuit pressures.
3. Monitor the system for clotting. **Do not try** to rinse back the blood if the blood circuit is clotted. Clotting in the dialyzer and blood line starts as soon as the blood pump is turned off.
   - If you cannot clear an alarm promptly, after two or three attempts, end your treatment. Perform a manual rinseback to rinse back the blood, unless otherwise instructed by your center. You can rinse back the blood as long as there is no clotting, hemolysis, or air in the blood circuit and blood lines. **See manual rinseback**, page 4-52.

Alarm system overview

The alarm system includes a red alarm and a yellow caution. During a red alarm, a red alarm number appears in the red alarm window. During a yellow caution, a yellow caution number appears in the yellow caution window. See Figure 5-2.

Figure 5-2: The Status Windows



1	Green Operating
2	Yellow Caution
3	Red Alarm

During a red alarm, the cycler stops the blood pump. The risk of blood clotting in the circuit and blood lines increases the longer the blood pump is stopped. Multiple alarms and long delays in alarm clearance increase the risk of clotting. To avoid clotting, it is important to identify and clear alarms promptly.

Standard response to red alarms

To respond to a red alarm:

1. Check the alarm number in the red alarm window.
2. Press the **MUTE** key to silence the alarm.
3. Look up the alarm number in the list of alarms and cautions that begins on **page 5-19**.
4. Follow the instructions in the table to identify the cause of the alarm.
5. Press the **STOP** key to clear the alarm.
   - If the red alarm occurs during treatment, press the **TREATMENT** key to continue.
   - If the red alarm occurs during the Prime or Rinseback Mode, press the **ADD FLUID** key to continue.

If you cannot correct the cause of an alarm promptly, after two or three attempts, end your treatment. Perform a manual rinseback to rinse back the blood, unless otherwise instructed by your center. You can rinse back the blood as long as there is no clotting, hemolysis, or air in the blood circuit and blood lines. **See manual rinseback**, page 4-52.

Contact your center if you cannot continue your treatment.

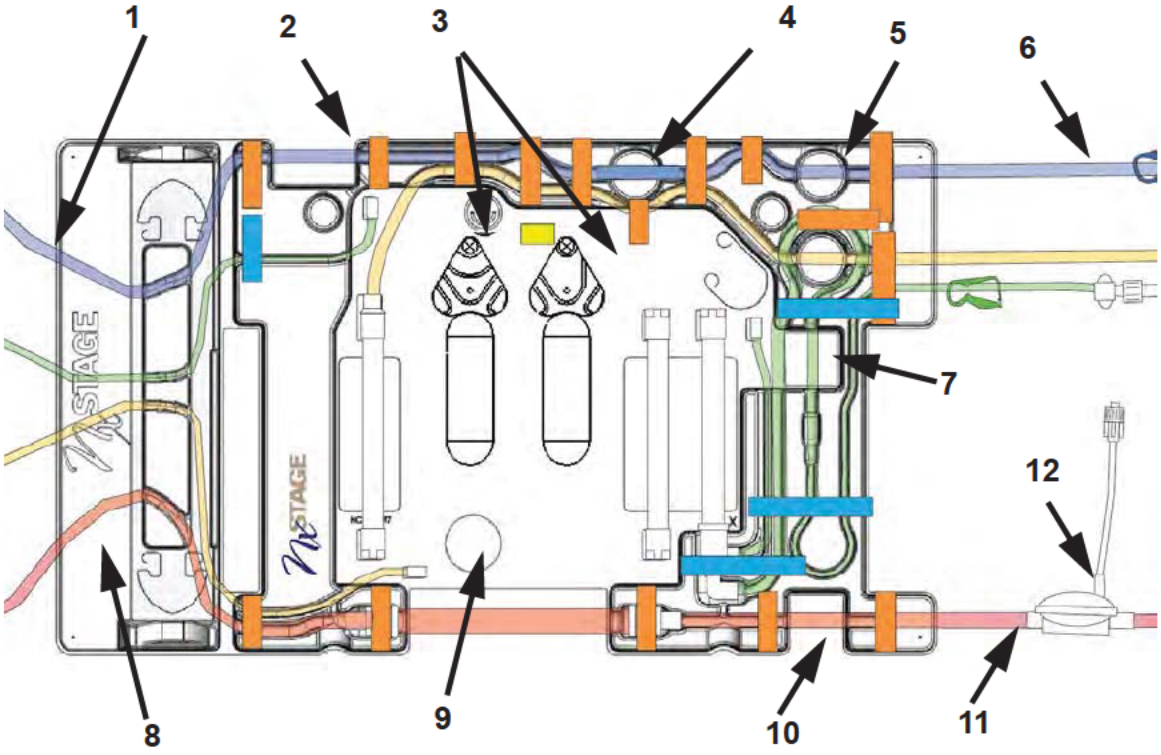
Overview of safety and control systems

Your cycler with the cartridge installed, includes the following safety and control systems:

- Air detection in the arterial and venous blood lines, and in the dialysate lines
- Balance chamber pressure sensor
- Blood leak detection
- Pressure sensors in the arterial and venous blood lines, effluent, waste bag, and in the dialyzer membrane (TMP)
- Temperature sensor

As soon as you load the cartridge into the cycler, the safety and control systems become active.

Figure 5-3: Safety and control system interfaces (location on cartridge)



1	From Dialyzer	7	Dialysate Air Detector
2	Venous Air Detector	8	To Dialyzer
3	Balance Chamber, Waste Line pressure monitoring	9	Effluent Pressure Detector, Blood Leak Detector
4	Venous Pressure Detector	10	Arterial Air Detector
5	Venous Clamp	11	From Arterial Blood Line (red clamp)
6	To Venous Blood Line (blue clamp)	12	Access Pressure Pod

Alarm types

All red alarms and yellow cautions produced by the cycler are related to the equipment or system only. The NxStage System One does not produce any alarms or cautions related to the medical condition of the patient.

Table 5-1: Alarm types include:

Change of status	**Red Alarm 000** **Yellow Caution 000** The cycler is at the end of an operational mode. Press the **STOP** key to go to the next mode of operation. Example: to go from Prime to Treatment.
Information	**Yellow Caution 1, 2, 3, 4, 5, 6, 7, 8, 9,72** This is a system status. Some events require intervention.
Air	**Red Alarm 10, 11, 13** **Yellow Caution 12, 14** Air detected in one of three locations: • in the arterial blood line (red clamp) • in the venous blood line (blue clamp) • in the dialysate inlet line (green clamp) Air must be removed to clear the alarm.
Pressure	**Red Alarm 20*, 21*, 22*, 23, 24, 30, 31, 33*, 34, 35, 62*** **Yellow Caution 20*, 21*, 23, 24, 25, 27, 30, 32** Detected pressures are higher or lower than expected. The cause must be identified and the alarm cleared before continuing the treatment. * When these alarms happen several times, it may indicate that the blood circuit or dialyzer is clotting.
Balancing system	**Red Alarm 36, 37, 38, 39, 90, 91, 92, 99** The fluid balancing system is not performing as expected or there may be a leak in the system. Check the cartridge for a leak before continuing the treatment.
Power failure	**Red Alarm 41** **Yellow Caution 40** Indicates a loss of power to the machine and whether the treatment may be started again.

Temperature	**Red Alarm 50** **Yellow Caution 51, 52, 53, 54** • The dialysate temperature has reached its alarm point. • Status of the cool down or warm up process. • Monitoring status for low temperature.
Blood leak detector	**Red Alarm 60, 61** Lets you know when to check the effluent for blood. Lets you know when the machine may not work due to a dirty detector.
Maintenance	**Yellow Caution 70, 71** Lets you know when the cartridge life has expired. Lets you know when the preventive maintenance is due.
Startup/ priming	**Red Alarm 13, 85, 86, 87, 88, 89, 92** **Yellow Caution 80, 81, 88, 93** Lets you know of the steps you are required to take during the prime and alarms test.
System	**Red Alarm between 100-999 (Except 715 and 721)** **Yellow Caution 999** Lets you know of a system error. Lets you know of a communication error. Lets you know of an incorrect setup. If these events occur, contact Technical Support.
Power loss	Within five seconds of power loss, the machine sounds an alarm tone and the control panel goes blank.

Alarm and caution priorities

Alarm and caution priorities are based on the types and if user intervention is required.

Table 5-2: Alarm priorities

Priority	Alarm type	Intervention required	Alarm/caution number
High	Red alarm	Yes	All red alarm numbers
Medium	Yellow caution	Yes	Caution 4, 6 All caution numbers above number 10
Low	Yellow caution	No	Cautions 000, 1, 2, 3, 5, 7, 8, 9, 70, and 72

The following pages list all red alarm and yellow caution events. Each alarm or caution is identified by its number, probable cause, and actions required to clear the alarm or caution. If an alarm or caution has more than one probable cause, the list gives the number for each cause and the steps to clear the alarm or caution.

NOTE

When using the list of alarms and cautions, make sure you check the next page. Some alarms and cautions have more than one cause and resolution to clear them.

List of alarms and cautions

000 - End of TREATMENT/RINSEBACK (Yellow Caution)

000 - Alarm Test Passed (Red Alarm)

Priority

- Yellow Caution - Low
- Red Alarm - High

Alarm Event

The system has reached the end of a process.

Probable Cause	Action Required
The system has successfully reached the end of a major process (Prime, Treatment, Rinseback).	None required. Press the **STOP** key if you want to go to the next mode, such as: • From Prime to Treatment • From Treatment to Rinseback

1 - Infusing Fluid Bolus (Yellow Caution)

Priority

- Yellow Caution - Low

Alarm Event

The user has pressed the **ADD FLUID** key during the treatment and an automated fluid bolus is underway.

Probable Cause	Action Required
This feature is only active when System Setting 9 is set to a value greater than **0**. System Setting 9 determines the volume of fluid bolus (see **Changing system settings**, page 9-2).	None required, or press the **STOP** key to stop infusing bolus.

PRECAUTION

The default value for System Setting #9 is zero (0) for hemodialysis which disables the automatic bolus feature. In certain geographic areas outside of the US, additional labeling provides more information on using the NxStage System One to deliver an automatic fluid bolus.

2 - Fluid Balance System Check Underway (Yellow Caution)

Priority

- Yellow Caution - Low

Alarm Event

The system is conducting a normal automated fluid balancing system check, which takes approximately two minutes.

Probable Cause	Action Required
The fluid balancing system check is performed at an interval determined by System Setting 43.	None required. If check fails, a balancing system red alarm will appear.

3 - Parameter Limit Exceeded (Yellow Caution)

Priority

- Yellow Caution - Low

Alarm Event

A setting is too low or too high.

Probable Cause	Action Required
The user has attempted to input a setting (for example, flow rate) that is too low or high.	Confirm the system settings. See **System Settings**, page 9-6 for allowable settings.

4 - Blood Pump Off Caution (Yellow Caution)

Priority

- Yellow Caution - Low

Alarm Event

The blood pump is stopped.

Probable Cause	Action Required
The user pressed the **STOP** key during Treatment Mode and the blood pump is stopped. Blood flow rate equals zero (**0**).	• Press the **TREATMENT** key to continue during Treatment Mode. • Press the **ADD FLUID** key to continue during Rinseback Mode. Clotting risk increases if the blood pump is stopped for a long time.

5 - Target Volume Achieved (Yellow Caution)

Priority

- Yellow Caution - Low

Alarm Event

The target volume has been achieved.

Probable Cause	Action Required
Dialysate or ultrafiltration volume target reached.	Reset target volumes (if necessary). Press the **MUTE** key to clear caution.

6 - Blood Circulation Only (Yellow Caution)

Priority

- Yellow Caution - Medium

Alarm Event

No therapy is being delivered but the target volume has not been reached.

Probable Cause	Action Required
The dialysate rate and the ultrafiltration rates are set to zero (**0**), but at least one target volume is non-zero. Blood is flowing through the cartridge, but no therapy is being delivered.	Reset rates or end the treatment and perform an automated rinseback, page 4-39, as appropriate.

7 - Alarms Overridden Caution (Yellow Caution)

Priority

- Yellow Caution - Low

Alarm Event

System is stabilizing.

Probable Cause	Action Required
One or more alarms are temporarily overridden as the system stabilizes, such as after a change in commanded flow rates.	Monitor treatment closely until a Green Operating Condition returns.

8 - Pressure Limits Not Locked (Yellow Caution)

Priority

- Yellow Caution - Low

Alarm Event

System adjusting to commanded change in flow rates.

Probable Cause	Action Required
The user has changed flow rates using the **ADJUSTMENT ARROWS** keys and the adjustable pressure limit windows have not yet "locked" (see Chapter 9, System Settings).	Monitor treatment closely until a Green Operating Condition returns.

9 - Automated High Pressure Recovery (Yellow Caution)

Priority

- Yellow Caution - Low

Alarm Event

Pressure-related alarm recovery.

Probable Cause	Action Required
Alarm reset condition after pressure-related alarm condition (Red Alarm 20–39).	None required. Do **not** press the **STOP** key during the alarm recovery process.

NOTE

TREATMENT key remains lit during high pressure recovery.

10 - Check for Venous Air During PRIME, Not including recirculation Step 23.0 (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

Air is detected in the cartridge tubing after the dialyzer and before the venous blood line (blue clamp). All pumps stop when the alarm is displayed.

1. Press **MUTE** to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
Air entering the blood circuit from:	
1. Priming spike tip is not fully inserted into saline bag. (For example, the tip is not visible within the saline bag).	Push the priming spike into the saline bag using a twisting motion until tip is visible.
2. Saline bag is empty of fluid.	Replace the empty saline bag with new bag.
3. Saline "T" cap is loose.	Secure the cap on the saline "T."

After probable cause is resolved:

Press the **STOP** key to clear the alarm. Remove the air using a luer lock syringe (for a small amount of air) or reprime the cartridge, see page 5-4.

PRECAUTION

Do not reprime a Cartridge that has been used on a patient. Failure to follow the instructions for repriming a Cartridge may cause damage to the Cartridge or misloading, and may impact system performance.

To remove the air using a syringe:

1. Close the blue clamp on the post-dialyzer port.
2. Attach a 20 ml luer lock syringe to the post-dialyzer port, then open the blue clamp. Slowly pull back on the syringe to remove air. When air is removed, close the blue clamp.
3. If no air is seen, press the **ADD FLUID** key to resume.
4. Observe blood circuit lines and venous header for air. Repeat Steps 1 and 2 if air is seen.

10 - Check for Venous Air During TREATMENT (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

Air is detected in the cartridge tubing after the dialyzer and before the venous blood line (blue clamp).

All pumps stop and air must be removed before continuing. If air is present in the venous blood line, **do not** rinse back blood.

Air in the blood circuit during treatment can be dangerous. If air enters the blood stream, it can lead to an air embolism that can result in serious injury or even death. If an air embolism is suspected, follow the emergency interventions according to your center's policy. Call emergency medical personnel immediately, and then notify the doctor and center.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
Air entering the blood circuit from:	
1. Arterial connection loose or disconnected between patient and blood pump.	Secure and/or reconnect all arterial connections.
2. Arterial access dislodged.	Re-establish arterial access following your center's procedure.

Probable Cause	Actions Required
3. Air in saline line from empty saline bag.	Remove air from the saline line: • Replace the saline bag with a new bag. • Make sure the saline "T" is clamped. • If air is seen in the saline line, disconnect the saline line from the saline "T." Open the clamp on the saline line to prime the line with saline, then close the clamp the saline line and reconnect to the saline "T."
4. Air not removed during priming.	Follow the instructions below to remove air from the venous line.
5. Air not completely removed from venous header.	Follow the instructions below to remove air from the venous line.
6. Air in replacement fluid (hemofiltration therapy only).	Follow the instructions below to remove air from the venous line.

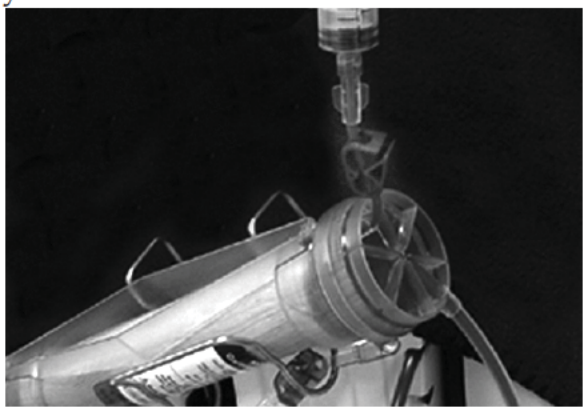
WARNING

Do not disconnect and reverse patient blood lines during treatment. This may cause an infusion of air into the patient blood lines, which may lead to an embolism.

After probable cause is resolved, remove air from the venous line:

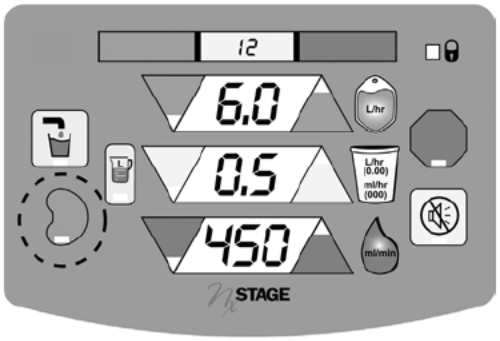
1. Press the **STOP** key.
2. Attach a 20 ml luer lock syringe to the post-dialyzer port, then open the blue clamp. Slowly pull back on the syringe to remove air.

3. Inject the blood (not the air) back through the post-dialyzer port. Close the clamp securely.



- Hold the luer lock syringe upright to prevent the return of air.
- When complete, check that the post-dialyzer port is clamped securely.

4. Press the **TREATMENT** key. The Yellow Caution window will display the number **12**.



- Watch for the Yellow Caution window to show the number 12. This means the blood pump is running slowly (50 ml/min) so that you can make sure there is no air.
- Observe for air in the venous blood line (blue clamp).

5. If air is seen, press the **STOP** key immediately. Repeat Steps 2 through 4.
   - If necessary, disconnect the blood lines and recirculate blood to remove air.
   - If unable to remove air from the venous blood line, press the **STOP** key and end the treatment. Do **not** rinse back blood.
6. If no air is seen, press the **TREATMENT** key again to continue treatment.
   - At this time, the blood flow will return to the previous rate.

7. Flush the post-dialyzer port with 3 ml of saline to clear blood, and then close the clamp on the port securely. Continue to observe the venous header for air.

10 - Check for Venous Air During RINSEBACK (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

Air is detected in the cartridge tubing after the dialyzer and before the venous blood line (blue clamp).

All pumps stop and air must be removed before continuing. If air is present in the venous blood line, **do not** rinse back blood.

Air in the blood circuit during treatment can be dangerous. If air enters the blood stream, it can lead to an air embolism that can result in serious injury or even death. If an air embolism is suspected, follow the emergency interventions according to your center's policy. Call emergency medical personnel immediately, and then notify the doctor and center.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
Air entering the blood circuit from: • Air not completely removed from venous header. • Air entering the blood circuit while making cartridge connections for rinseback.	To remove the air with a syringe: 1. Press the **STOP** key to clear the alarm.
	2. Attach a 20 ml luer lock syringe to the post-dialyzer port, then open the blue clamp. Slowly pull back on the syringe to remove air.
	3. Inject the blood (not the air) back through the post-dialyzer port, then close the blue clamp securely.
	4. Press the **ADD FLUID** key. The Yellow Caution window will display **12** Yellow Caution (air recovery underway).
	5. Observe venous blood line (blue clamp) for air and repeat steps 1 through 4 if air is seen.
	6. If no air is seen, press the **ADD FLUID** key again to resume treatment. • If unable to remove air from the venous blood line, press the **STOP** key and end the treatment. Do **not** rinse back blood.

11 - Check for Arterial Air During PRIME, Not Including Recirculation Step 23.0 (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

Air is detected in the arterial blood line (red clamp) before the dialyzer.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
Air entering the blood circuit from:	
1. Priming spike tip not visible in the saline bag.	Push the priming spike into the saline bag using a twisting motion until the tip is visible.
2. Kinked/clamped saline or arterial blood line.	Unkink or unclamp the saline or arterial blood line. NOTE Air is pulled out of solution (saline/blood) when negative pressure is increased from the kinked or clamped arterial blood line.
3. Saline bag is empty of fluid.	Replace the empty saline bag with a new bag.
4. Saline "T" cap is loose.	Secure the "T" cap.

After the probable cause is resolved

1. Press the **STOP** key to clear the alarm.
2. Press the **ADD FLUID** key to resume priming.

11 - Check for Arterial Air During TREATMENT (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

Air is detected in the cartridge tubing before the dialyzer.

All pumps stop and air must be removed before continuing.

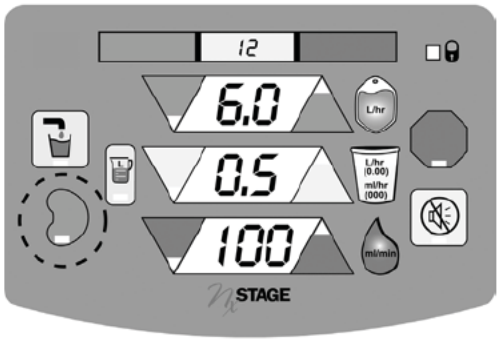
1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
1. Air is entering the blood circuit from: • Loose connection at arterial vascular access. • Arterial vascular access disconnection. • Reversing patient blood lines.	Secure connection and make sure no air is in the saline line.
2. Poor flow through arterial vascular access or clamped blood line.	Adjust the vascular access or unclamp the blood line.
3. Access pressure pod is clotted.	Perform a **manual fluid bolus,** page 5-5, to view the access pressure pod. • If the pod is clotted, end the treatment and **do not** rinse back blood. • If pod is **not** clotted, follow the instructions perform arterial air recovery, see page 5-35.

Probable Cause	Actions Required
4. Air in the saline line from empty saline bag.	Remove air from the saline line: • Replace the empty saline bag with a new bag. • Make sure the clamp on the saline "T" is closed. • If air is seen in the saline line, disconnect the saline line from the saline "T." Open the clamp on the saline line to prime the line with saline. Then close the clamp on the saline line and reconnect to the saline "T."

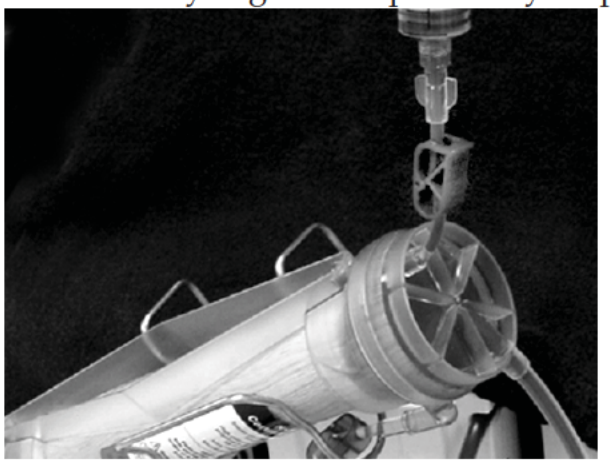
After probable cause is resolved, perform arterial air recovery:

1. Press the **STOP** key.
2. Identify and correct the source of air in the arterial blood line (red clamp).
3. Press the **TREATMENT** key.
   - The Yellow Caution window will display **12**.
   - The blood pump will now run at 100 ml/min.



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

4. Attach a 20 ml luer lock syringe to the post-dialyzer port.



5. Press the **TREATMENT** key. The blood pump will now return to the pre-alarm rate.

   If/when air is observed in the venous header of the dialyzer:

   - Open the clamp on the post-dialyzer port. Slowly pull back on the syringe to remove air.
   - Hold the syringe upright (to allow bubbles to rise) and inject the blood (but not the air) back through the post-dialyzer port. Close the clamp the on the port securely.

6. Flush post-dialyzer port with 3 ml of saline to clear the blood and then close the clamp on the port securely.

   - Continue to observe the venous header of the dialyzer for air and remove as needed.
   - If this alarm occurs again, lower the blood flow rate. The arterial vascular access may not be able to deliver the commanded blood flow.

11 - Check for Arterial Air During RINSEBACK (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

Air is detected in the arterial blood line before the dialyzer.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
1. Clamp is closed on the arterial blood line, or the arterial blood line is kinked.	Open the clamp or unkink the arterial blood line. NOTE Air is pulled out of solution (saline / blood) when negative pressure is increased from the kinked or clamped arterial blood line.
2. Insufficient fluid volume in saline bag for programmed Rinseback (Empty saline bag).	Hang a new saline bag.
3. After disconnection from arterial vascular access, the arterial blood line tip may have a small air bubble that travels past and is detected by the arterial air detector when Rinseback begins.	Remove air using the instructions below.

After probable cause is resolved, remove air:

1. Press the **STOP** key.

2. Press the **ADD FLUID** key.
   - The Yellow Caution window will display **12**.
   - The blood pump rate will now run at 100 ml/min.
   - Verify that the source of air is corrected by observing the arterial blood line (red clamp) for air (5 to 10 seconds).
3. Attach a 20 ml luer lock syringe to the post-dialyzer port.
4. Press the **ADD FLUID** key.
   - The blood pump will now return to the pre-alarm rate.
   - If air is observed in the venous header of the dialyzer:
     – Open the clamp on the post-dialyzer port. Slowly pull back on the syringe to remove air.
     – Hold the syringe upright to allow bubbles to rise. Inject the blood (but not the air) back through the post-dialyzer port. Close the clamp on the port securely.
5. Flush the post-dialyzer port with 3 ml of saline to clear the blood, and then close the clamp on the port securely. Continue to observe the venous header of the dialyzer for air and remove as needed.
6. If unable to remove air, press the **STOP** key and end Rinseback Mode.

12 - Air Recovery Underway (Yellow Caution)

Priority

- Red Alarm - High

Alarm Event

Previous Red Alarm 10 or 11 in Treatment or Rinseback Mode.

The system reduces the blood flow rate to allow time to confirm successful air removal.

Probable Cause	Actions Required
This caution will always occur after a Red Alarm 10 or 11 in Treatment or Rinseback Mode.	1. Check the following sites for air entering the system: • Arterial blood line (red clamp) (Red Alarm 11). • Venous blood line (blue clamp) (Red Alarm 10). 2. If air is observed, press the **STOP** key and repeat the air removal process. If no air is observed, press the **TREATMENT** key to resume Treatment or press the **ADD FLUID** key to resume Rinseback.

NOTES

- A Low Venous Pressure Caution or Alarm (20, 21) may occur before the **TREATMENT** key or **ADD FLUID** key is pressed due to the reduced blood flow rate.
- Do not adjust the blood flow rate at this time unless resetting the rates is desired. Prior rates will be restored once Treatment or Rinseback Mode is resumed.

13 - Check Fluid Line Inlet: Air Detected in Fluid Line Inlet (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

Air is detected in the dialysate circuit during the prime and alarms test.

Prime and alarms tests will be stopped until the situation is resolved.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
1. Insufficient priming fluid.	Verify that sufficient priming fluid is available.
2. Blocked or kinked tubing.	Unblock or unkink fluid inlet tubing.
3. Cartridge was not loaded correctly.	Prime a new cartridge. Make sure that all cartridge lines are manually pressed into air detectors.

When the probable cause is resolved, press the **STOP** key to clear the alarm, and then press the **ADD FLUID** key to resume.

14 - Check Fluid Line Inlet: Air Detected in Fluid Line Inlet (Yellow Caution)

Priority

- Yellow Caution - Medium

Alarm Event

Air is detected in the dialysate circuit.

PRECAUTION

Make sure that premixed Dialysate is at room temperature before using. If it is not at room temperature, outgassing of air may occur as the fluid is warmed, which may cause NxStage System One Cycler air alarms.

The blood pump and the ultrafiltration pump will continue to run. The dialysate pump will stop until the situation is resolved and the **TREATMENT** key is pressed.

1. Press the **MUTE** key to silence the caution.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
1. Dialysate source empty or fluid volume low.	If dialysate source is empty or low, add more dialysate: • If using a warmer, replace the dialysate bags. • If using PureFlow SL: – Check for sufficient fluid volume in the SAK. – Reposition the SAK by carefully lifting up the back end. Line inlets must be at or near the base of the tub.
2. Loose dialysate line connection(s).	Verify dialysate line connection(s) are tight.

Probable Cause	Actions Required
3. Occluded, kinked/clamped dialysate line(s).	Check dialysate line(s) and unkink/unclamp/unfold the affected lines: • On the cartridge: cartridge dialysate inlet (green clamp) • If using a warmer: Check warmer disposable (green clamps) • If using PureFlow SL, check: – Dialysate outlet (green clamp) – SAK lines within the PureFlow SL tub – Dialysate line filter. If it is plugged, discard the SAK and make another batch
4. If using a fluid warmer, the dialysate bags are not hung properly.	Verify that the dialysate bags are hung using both corner holes (two holes in each bag) and that the dialysate outlet port is located at the very bottom of the bag.

Probable Cause	Actions Required
5. If using ComfortMate Fluid Warmer: • Warmer air trap is full of air. • Warmer bag fitments not properly seated in the fluid warmer.	Remove air from the air vent on the disposable: • Unclamp the air vent line. • Loosen the protective cap to expel air. • When air is removed, tighten the cap and reclamp.  1 Air Vent Line 2 Air Trap 3 Warmer Outlet Line • Make sure bag fitments are seated properly in the ComfortMate Fluid Warmer.

Probable Cause		Actions Required
6.	If using PureFlow SL: • The **TREATMENT** key on the cycler was pressed before pressing the **GO** key on the PureFlow SL. • PureFlow SL was paused. • Air in the SAK lines.	If using PureFlow SL: • Verify that the PureFlow SL is in Batch in Use Mode. If not, press the **GO** key on the PureFlow SL twice to go to Batch in Use Mode. Then press the **TREATMENT** key on the cycler. • If PureFlow is paused, press the **GO** key to enter Config To Use Batch Mode. • If there is air is in the SAK lines, slightly open the connection between the SAK and cartridge dialysate inlet line to remove air.
When the probable cause is resolved, press the **TREATMENT** key on the cycler to resume the treatment.		
7.	Cartridge was not loaded correctly.	End the treatment and rinse back the patient's blood unless otherwise directed by the center, as long as the blood circuit is not clotted or hemolyzed and air is not seen in the blood circuit or in the patient blood lines.

20 - Check Blood Circuit: Venous Pressure Low During RINSEBACK (Yellow Caution)

Priority

- Yellow Caution - Medium

Alarm Event

Pressure is lower than expected at the venous pressure detector.

All pumps will continue to run. If, during the treatment, the venous pressure drops further, then a Red Alarm (20, 21) will occur.

Probable Cause	Actions Required
1. Arterial access flow problem.	Reposition the arterial access.
2. Venous blood line (blue clamp) leak, disconnection, or access extraction.	Secure the venous access and/or the venous blood line (blue clamp).
3. Clotting dialyzer.	If clotting is suspected, flush the dialyzer by performing a **manual fluid bolus**, page 5-5. If the dialyzer is clotted, end the treatment and **do not** rinse back blood. Failure to appropriately respond to a clotted dialyzer or blood circuit may contribute to hemolysis or thromboembolism.
When the venous pressure increases, the caution condition will clear automatically.	

20 - Check Blood Circuit: Venous Pressure Low (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

Pressure is lower than expected at the venous pressure detector.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the caution.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
1. Blood pump speed is lower than the prescribed rate. For example, too much time taken to increase blood flow rate at the start of the treatment or during air alarm recovery.	Increase blood pump speed.
2. Arterial vascular access flow problems, kinked or clamped arterial blood line (red clamp).	Reposition the arterial access and unkink or unclamp the arterial blood line (red clamp).
3. Venous blood line (blue clamp) leak, disconnection, or access extraction.	Secure the venous access and/or the venous blood line (blue clamp).
4. Manual fluid bolus caused a decrease in venous pressure.	Resume prescribed blood flow.
5. Clotted dialyzer.	If clotting is suspected, press the **STOP** key to clear the alarm, then press the **TREATMENT** key and flush the dialyzer by performing a **manual fluid bolus,** page 5-5. If the dialyzer is clotted, end the treatment and **do not** rinse back blood. Failure to appropriately respond to a clotted dialyzer or blood circuit may contribute to hemolysis or thromboembolism.
When the probable cause is resolved, press the **STOP** key to clear the alarm. Press the **TREATMENT** key to resume the treatment.	

21—Check Blood Circuit: Venous Pressure Decreasing (Yellow Caution)

Priority

- Yellow Caution- Medium

Alarm Event

Pressure is lower than expected at the venous pressure detector.

All pumps will continue to run. If, during the treatment, the venous pressure drops further, then a Red Alarm (20, 21) will occur.

Probable Cause	Actions Required
1. Arterial vascular access flow problem.	Reposition the arterial vascular access.
2. Venous blood line (blue clamp) leak, disconnection, or access extraction.	Secure the venous vascular access and/or the venous blood line (blue clamp).
3. Clotting dialyzer.	If clotting is suspected, flush the dialyzer by performing a **manual fluid bolus,** page 5-5. If the dialyzer is clotted, end the treatment and **do not** rinse back blood. Failure to appropriately respond to a clotted dialyzer or blood circuit may contribute to hemolysis or thromboembolism.
When the venous pressure increases, the caution will clear automatically.	

21 - Check Blood Circuit: Venous Pressure Decreasing (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

Pressure is lower than expected at the venous pressure detector.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
1. Arterial vascular access flow problems, kinked or clamped arterial blood line (red clamp).	To resolve arterial access flow, use either or both of the following methods: • Reposition the arterial access. • Unkink or unclamp the arterial blood line (red clamp).
2. Venous blood line (blue clamp) leak, disconnection, or access extraction.	Secure the venous access and/or the venous blood line (blue clamp).
3. Clotted dialyzer.	If clotting is suspected, press the **STOP** key to clear the alarm then press the **TREATMENT** key and flush the dialyzer by performing a **manual fluid bolus,** page 5-5. If the dialyzer is clotted, end the treatment and **do not** rinse back blood. Failure to appropriately respond to a clotted dialyzer or blood circuit may contribute to hemolysis or thromboembolism.
When the probable cause is resolved, press the **STOP** key to clear the alarm. Press the **TREATMENT** key to resume the treatment.	

22 - Check Blood Circuit: Effluent Pressure Low (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

Pressure is lower than expected at the effluent pressure circuit.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
1. Arterial access flow problem, kinked or clamped arterial blood line (red clamp).	Reposition the arterial vascular access and unkink or unclamp the arterial blood line (red clamp).
2. Effluent line clamped or disconnected from dialyzer.	Reconnect or unclamp and secure the effluent line.
3. Clotted dialyzer.	If clotting is suspected, press the **STOP** key to clear the alarm then press the **TREATMENT** key and flush the dialyzer by performing a **manual fluid bolus,** page 5-5. If the dialyzer is clotted, end the treatment and **do not** rinse back blood. Failure to appropriately respond to a clotted dialyzer or blood circuit may contribute to hemolysis or thromboembolism.
4. Flow fraction is too high.	Decrease the flow fraction by reducing the dialysate exchange or ultrafiltration rate, or by increasing the blood flow rate.
When the probable cause is resolved, press the **STOP** key to clear the alarm. Press the **TREATMENT** key to resume the treatment.	

23 - Check Blood Circuit: Effluent Pressure Decreasing (Yellow Caution)

Priority

- Yellow Caution - Medium

Alarm Event

Pressure is lower than expected in the effluent pressure circuit.

All pumps will continue to run. If the effluent pressure drops further, a Red Alarm (22 or 23) will occur.

Probable Cause	Actions Required
1. Arterial access flow problem.	Reposition the arterial access.
2. Clotting dialyzer.	If clotting is suspected, flush the dialyzer by performing a **manual fluid bolus,** page 5-5. If the dialyzer is clotted, end the treatment and **do not** rinse back blood. Failure to appropriately respond to a clotted dialyzer or blood circuit may contribute to hemolysis or thromboembolism.
3. Flow fraction is too high.	Decrease the flow fraction by reducing dialysate exchange or ultrafiltration rate, or by increasing the blood flow rate.
When the effluent pressure increases, the caution will clear automatically.	

23 - Check Blood Circuit: Effluent Pressure Decreasing (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

Pressure is lower than expected in the effluent circuit.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
1. Arterial vascular access flow problem, kinked or clamped arterial blood line (red clamp).	Reposition the arterial vascular access and unkink or unclamp the arterial blood line (red clamp).
2. Effluent line clamped or disconnected from dialyzer.	Reconnect or unclamp and secure the effluent line.
3. Clotted dialyzer.	If clotting is suspected, press the **STOP** key to clear the alarm then press the **TREATMENT** key and flush the dialyzer by performing a **manual fluid bolus,** page 5-5**.** If the dialyzer is clotted, end the treatment and **do not** rinse back blood. Failure to appropriately respond to a clotted dialyzer or blood circuit may contribute to hemolysis or thromboembolism.
4. Flow fraction is too high.	Decrease the flow fraction by reducing the dialysate exchange or ultrafiltration rate, or by increasing the blood flow rate.
When the probable cause is resolved, press the **STOP** key to clear the alarm. Press the **TREATMENT** key to resume the treatment.	

24 - Check Arterial Access: Access Pressure Decreasing to Low Limit (Yellow Caution)

Priority

- Yellow Caution - Medium

Alarm Event

Pressure is lower than expected in the arterial blood circuit.
All pumps will continue to run. If the arterial pressure decreases further, a Red Alarm 24 will occur.

- Identify and resolve the probable cause.

Probable Cause	Actions Required
Arterial access problem	Reposition the arterial access or reduce the blood flow.

When the arterial pressure increases, the caution will clear automatically.

WARNING

Do not disconnect and reverse patient blood lines during treatment. This may cause an infusion of air into the patient blood lines, which may lead to an embolism.

24 - Check Arterial Access: Access Pressure at Low Limit (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

Pressure is lower than expected in the arterial blood circuit.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
1. Arterial access flow problem, kinked or clamped arterial blood line (red clamp).	Reposition the arterial access, or reduce blood flow, or unkink or unclamp arterial blood line (red clamp).
2. Access or access pressure pod clotting.	Follow your center's procedures to assess and treat access pressure pod or vascular access clotting. Rinseback may be performed unless otherwise directed by the center, as long as the blood circuit is not clotted or hemolyzed and air is not seen in the blood circuit or in the patient blood lines.
3. May be related to the tip of the vascular access needle/catheter touching the vascular wall.	Consider repositioning vascular access catheter/needle to improve blood flow.
4. If using a catheter for vascular access, compromised blood flow may be related to patient position.	Consider repositioning patient to improve blood flow.
When the probable cause is resolved, press the **STOP** key to clear the alarm. Press the **TREATMENT** key to resume the treatment.	

WARNING

Do not disconnect and reverse patient blood lines during treatment. This may cause an infusion of air into the patient blood lines, which may lead to an embolism.

25 - Access Pressure Pod Error: Reset Access Pressure Pod (Yellow Caution)

Priority

- Yellow Caution - Medium

Alarm Event

Pressure in the arterial blood circuit is stagnant.

All pumps will continue to run. However, access pressure readings may not be available until the situation is resolved.

Probable Cause	Actions Required
1. Access pressure pod monitor line is kinked.	Unkink access pressure pod monitoring line.

Probable Cause	Actions Required
2. Access pressure pod connection error: monitor line leaking, poorly connected, or not connected.	Reset the access pressure pod. 1. Disconnect the access monitoring line from the cycler. The access pressure pod deflates. 2. Press the **STOP** key. If pod fills immediately, go directly to Step 3. If pod does **not** fill immediately: • Close the red clamp on the arterial blood line • Open the white clamps on the saline line and saline "T." The pod fills with blood. • Close the white clamps on the saline line and saline "T." • Open the red clamp on the arterial blood line. 3. Attach the access pressure pod monitoring line to the connection point located below the front handle on the right side of the cycler as instructed below: • Hold the line behind the locking collar. • Insert the tip into the connection point until it stops. • Maintain firm pressure and twist the tip ¼ turn counterclockwise to properly seal the connection. • Tighten the locking collar. 4. Press the **TREATMENT** key. 5. Check that the arterial pressures are within range.

30 - Check Blood Circuit: Venous Pressure Approaching High Alarm Limit (Yellow Caution)

Priority

- Yellow Caution - Medium

Alarm Event

Pressure is higher than expected in the venous blood circuit.

All pumps will continue to run. If the venous pressure increases further, a Red Alarm 30 will occur.

Probable Cause	Actions Required
1. Venous blood line (blue clamp) or venous access problem.	Reposition the venous access.
2. Venous access infiltration.	Correct the venous access infiltration.
3. Commanded blood flow rate is too high for the vascular access.	Decrease the blood flow rate.
4. Fluid imbalance or UF removed too quickly leading to hemoconcentrated blood.	Perform a **manual fluid bolus,** page 5-5, to check the dialyzer for clotting. If there is no clotting, adjust UF rate or goal accordingly. If clotting is present, end the treatment and **do not** rinse back blood.
• When the venous pressure decreases, the caution condition will clear automatically. • Consider weighing the patient after the treatment is restarted to evaluate UF status.	

30 - Check Blood Circuit: Venous Pressure High During PRIME, Including Recirculation Step 23.0 (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

Pressure is higher than expected in the venous blood circuit.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
1. Kinked or clamped venous blood line (blue clamp) or priming line (blue clamp).	Unkink or unclamp venous blood line (blue clamp) or priming line (blue clamp).
2. Priming spike occluded or bent.	Replace the priming line.
When the probable cause is resolved, press the **STOP** key to clear the alarm. Press the **ADD FLUID** key to resume.	

30 - Check Blood Circuit: Venous Pressure High During TREATMENT (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

Pressure is higher than expected in the venous blood circuit.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
1. Venous blood line (blue clamp) or venous access is kinked or clamped.	Unkink or unclamp venous blood line (blue clamp) or venous access.
2. Venous access infiltration.	Correct the venous access infiltration.
3. Venous blood line (blue clamp) or venous access is clotted.	If venous blood line (blue clamp) or venous access is clotted, end the treatment. **Do not** attempt to rinse back blood through the venous access.
4. Commanded blood flow rate is too high for the vascular access.	Decrease the blood flow rate.
5. Fluid imbalance or UF removed too quickly leading to hemoconcentrated blood.	End the treatment. **Do not** rinse back the patient's blood. Weigh the patient to assess UF status.
When the probable cause is resolved, press the **STOP** key to clear the alarm. Press the **TREATMENT** to resume the treatment.	

30 - Check Blood Circuit: Venous Pressure High During RINSEBACK (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

Pressure is higher than expected in the venous blood circuit.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
1. Kinked / clamped venous blood line (blue clamp).	Unkink/unclamp the venous blood line (blue clamp). • Press the **STOP** key to clear the alarm. • Press the **ADD FLUID** key to continue.
2. Venous blood line (blue clamp) is clotted.	Press the **STOP** key and end the treatment. **Do not** rinse back blood.
3. Venous vascular access is clotted.	Press the **STOP** key and end the treatment. **Do not** rinse back blood.

32 - Check Blood Circuit: Venous Pressure Increasing (Yellow Caution)

Priority

- Yellow Caution - Medium

Pressure is higher than expected in the venous blood circuit.

All pumps will continue to run. If the venous pressure increases further, a Red Alarm 30 will occur.

- Identify and resolve the probable cause.

Probable Cause	Actions Required
1. Venous blood line (blue clamp) or venous access problem.	Reposition the venous access.
2. Venous access infiltration.	Correct the venous access infiltration.
3. Commanded blood flow rate is too high for the vascular access.	Decrease the blood flow rate.
4. Fluid imbalance or UF removed too quickly leading to hemoconcentrated blood.	Perform a **manual fluid bolus**, page 5-5 to check the dialyzer for clotting. If there is no clotting, adjust UF rate or goal accordingly. If clotting is present, end the treatment and **do not** rinse back blood.

- When the venous pressure decreases, the caution condition will clear automatically.
- Consider weighing the patient after the treatment is restarted to evaluate UF status.

33, 34 - Check Dialyzer: High TMP During PRIME, Including Recirculation Step 23.0 (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

Transmembrane Pressure (TMP) is higher than expected.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
Cartridge not aligned correctly in the cycler.	Reprime the cartridge, see page 5-4.

33, 34 - Check Dialyzer: High TMP During TREATMENT (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

Transmembrane Pressure (TMP) is higher than expected.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
1. Venous blood line is kinked between the dialyzer and the cartridge venous air detector.	Unkink the venous blood line between the dialyzer and the cartridge venous air detector.
2. Pooling/clotting of blood in the venous header of the dialyzer.	If clotting is suspected, press the **STOP** key to clear the alarm then press the **TREATMENT** key and flush the dialyzer by performing a **manual fluid bolus,** page 5-5. If the dialyzer is clotted, end the treatment and **do not** rinse back blood. Failure to appropriately respond to a clotted dialyzer or blood circuit may contribute to hemolysis or thromboembolism.
• When the probable cause is resolved, press the **STOP** key to clear the alarm. Press the **TREATMENT** key to resume the treatment. • Consider weighing the patient after the treatment is restarted to evaluate UF status.	

35 - Check Waste Line: Waste Line Pressure High (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

Waste line pressure is higher than expected.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
1. Waste or drain lines or SAK dialysate line kinked, clamped, pinched, occluded, submerged, or not connected.	1. Check the waste and drain lines to clear the occlusion. Reposition, unkink/unclamp, and connect as required to ensure proper routing and free flow of waste fluid to the drain. The affected line(s) may include: • Waste line (yellow clamp) • Waste line extension (yellow clamp) 2. If using PureFlow SL: • Control Unit Adapter (yellow clamp) • Drain line - Reposition the drain line. If necessary, flush the drain line. If unsuccessful, disconnect the cartridge waste line from the PureFlow SL and connect to waste line extension. • SAK dialysate line – Check all lines and connections in the SAK for leaks or kinks and adjust any line that is kinked. – Slide line collars all the way towards the SAK. – Verify the SAK has been installed and unfolded correctly. 3. Lower dialysate rate.
2. If using a waste bag, waste bag is full.	Replace the waste bag.
3. Low effluent pressure due to poor arterial flow.	Adjust the vascular access to improve the blood flow.
When the probable cause is resolved, press the **STOP** key to clear the alarm. Press the **TREATMENT** key to resume the treatment.	

36 - Check Dialysate Source: Dialysate Inlet Pressure Exceeded (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

Dialysate inlet pressure exceeded.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
1. If using a warmer, this alarm is unlikely to occur.	End the treatment and rinse back the patient's blood unless otherwise directed by the center, as long as the blood circuit is not clotted or hemolyzed and air is not seen in the blood circuit or in the patient blood lines.

Probable Cause	Actions Required
2. If using PureFlow SL: Kinked SAK Line.	If using PureFlow SL: 1. Open the cabinet door and slide out the tub so you can see the SAK lines. 2. Check all lines and connections on the PAK and SAK for leaks or kinks. Adjust any line that is kinked. 3. Slide line collars all the way towards the SAK. 4. Verify the SAK has been installed and unfolded correctly. 5. Press the **GO** key twice on the PureFlow SL to go to Batch In Use Mode before you press the **TREATMENT** key on the cycler. 6. Press the **STOP** key on the cycler to clear the alarm and then press the **TREATMENT** key to resume the treatment. If you cannot recover from the alarm after multiple attempts, or a SAK leak is found, you must drain the SAK.

37, 38 - Check Fluid Circuit: High Balance Chamber Pressure During PRIME, Including Recirculation Step 23.0 (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

Pressure is higher than expected in the fluid balance chambers.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
1. Clamped or kinked cartridge lines.	Unclamp/unkink the cartridge lines.
2. Priming spike is occluded or the tip is bent.	Replace the priming line.
3. Priming spike tip is not fully inserted into the saline bag (the tip is not visible within the saline bag).	Push the priming spike into saline bag using a twisting motion until tip is visible.
4. Air in fluid balance system from an empty saline bag.	Hang a new saline bag.
When the probable cause is resolved, press the **STOP** key to clear the alarm and then press the **ADD FLUID** key to resume.	

NOTES

- A Yellow Caution 9 may be displayed indicating the system is recovering from a high pressure condition. **Do not** press the **STOP** key at this time. Prime will resume when the Yellow Caution 9 disappears.
- The Red Alarm 37, 38 may recur a few times after the Yellow Caution 9 disappears if the pressure remains high. Repeat steps above to resolve.

37, 38 - Check Fluid Circuit: High Balance Chamber Pressure During TREATMENT (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

Pressure is higher than expected in the fluid balancing circuit.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
1. Occluded, kinked or clamped fluid line(s).	Check fluid lines and clear occlusion. Unkink/unclamp the affected line(s) which may include: • On the cartridge: – Cartridge dialysate inlet (green clamp) – Cartridge dialysate outlet (green clamp) – Waste line (yellow clamp) (following Alarm 35) • If using a Warmer: – Warmer disposable (green clamps) – Waste line extension (yellow clamp) • If using the PureFlow SL: – Dialysate outlet (green clamp) – SAK lines (within the PureFlow SL tub) – Control unit adapter (yellow clamp) – Control unit adapter is plugged; replace the control unit adapter. – Dialysate line filter is plugged; discard the SAK and make another batch.

Probable Cause	Actions Required
2. Dialysate source low or empty.	If dialysate source is low or empty, add more dialysate: • If using a warmer, replace empty dialysate bags. • If using the ComfortMate Fluid Warmer, remove air from the air vent of the disposable: – Unclamp the air vent line. – Loosen the protective cap to expel air. – When air is removed, tighten the cap and reclamp. • If using PureFlow SL: – Check for sufficient fluid volume in the SAK. – Reposition SAK by carefully lifting up the back end. The line inlets must be at or near the base of the tub.
3. The **TREATMENT** key pressed on the cycler before the **GO** key pressed on PureFlow SL.	Verify the PureFlow SL is in Batch In Use Mode. If it is not press the **GO** key twice on the PureFlow SL to go to Batch In Use before pressing the **TREATMENT** key on the cycler.
4. Using the wrong SAK type in the PureFlow SL while running the CYC-D2E (NX1000-3) or higher at dialysate rates higher than 12 L/hr.	Lower dialysate rate to 12 L/hr or less. Load a 400 series SAK into the PureFlow SL for the next treatment to return to higher flow rates.

Probable Cause	Actions Required
5. Dialyzer clotted.	If clotting is suspected, press the **STOP** key to clear the alarm then press the **TREATMENT** key and flush the dialyzer by performing a **manual fluid bolus,** page 5-5. If the dialyzer is clotted, end the treatment and **do not** rinse back blood. Failure to appropriately respond to a clotted dialyzer or blood circuit may contribute to hemolysis or thromboembolism.
6. Air is in fluid balancing system.	Verify dialysate is flowing from the warmer or PureFlow SL to the cartridge.
When the probable cause is resolved, press the **STOP** key to clear the alarm. Press the **TREATMENT** key to resume the treatment.	

NOTES

- A Yellow Caution 9 may be displayed indicating the system is recovering from a high pressure condition. **Do not** press the **STOP** key at this time. Treatment will resume when the Yellow Caution 9 disappears.
- The Red Alarm 37, 38 may recur a few times after the Yellow Caution 9 disappears if the pressure remains high. Repeat steps above to resolve.

39 - Check Fluid Inlet: Dialysate Inlet Occlusion (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

Pressure is lower than expected at the dialysate inlet.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
1. (During Prime Mode) Priming spike is not fully inserted into saline bag.	Push and twist the saline spike to ensure it is fully inserted into the saline bag.
2. Kinked/clamped or folded dialysate fluid line(s).	Check fluid lines and unkink/ unclamp the affected line(s) which may include: • On the cartridge: cartridge dialysate inlet (green clamp) • If using a warmer: warmer disposable (green clamps) • If using the PureFlow SL: – Dialysate outlet (green clamp) – SAK lines (in the PureFlow SL tub)

Probable Cause	Actions Required
3. Dialysate source low or empty.	If dialysate source is low or empty, add more dialysate: • If using a warmer, replace the empty dialysate bags. • If using ComfortMate Fluid Warmer, remove air from the air vent on the disposable: – Unclamp the air vent line. – Loosen the protective cap to expel air. – When air is removed, tighten the cap and reclamp. • If using the PureFlow SL: – Check for sufficient fluid volume in the SAK. – Reposition SAK by carefully lifting up the back end. The line inlets must be at or near the base of the tub.
4. If using PureFlow SL: The **TREATMENT** key pressed on the cycler before the **GO** key pressed on PureFlow SL.	Verify the PureFlow SL is in Batch In Use Mode. If it is not press the **GO** key twice on the PureFlow SL to go to Batch In Use before pressing the **TREATMENT** key on the cycler.
5. If using PureFlow SL: SAK dialysate line filter is plugged.	Discard the SAK and make another batch.
6. Using the wrong SAK type in the PureFlow SL while running the CYC-D2E (NX1000-3) or higher at dialysate rates higher than 12 L/hr.	Lower dialysate rate to 12 L/hr or less. Load a 400 series SAK into the PureFlow SL for the next treatment to return to higher flow rates.
7. Air in fluid balancing system.	Verify dialysate is flowing through the warmer or PureFlow SL to the cartridge.

Probable Cause	Actions Required
When the probable cause is resolved, press the **STOP** key to clear the alarm. Press the **TREATMENT** key to resume the treatment.	

NOTES

- A Yellow Caution 9 may be displayed indicating the system is recovering from a high pressure condition. **Do not** press the **STOP** key at this time. Treatment will resume when the Yellow Caution 9 disappears.
- The Red Alarm 37, 38 may recur a few times after the Yellow Caution 9 disappears if the pressure remains high. Repeat steps above to resolve.

40 - Perform Power Recovery: Power Failure (Yellow Caution)

WARNING

The risk of blood clotting in the Cartridge and Dialyzer is higher during long treatments, when no anticoagulation is used, in certain patients who are more prone to excess clotting, or any time when the blood flow stops, including when the NxStage System One Cycler loses power or during an unrecoverable alarm. The risk of blood clotting increases the longer treatment continues and the longer blood flow is stopped. To reduce the risk of blood clotting and identify the early signs of clotting:

- Follow your center's instructions to give and monitor anticoagulant.
- During treatment, regularly check the Cartridge and Dialyzer for clotting by looking closely at the Cartridge and Dialyzer, and periodically flushing the Dialyzer with a manual fluid bolus.

Failure to respond to blood clotting in the Cartridge and Dialyzer or administering medication through the Post-dialyzer port when clotting is present in the dialyzer venous header may result in a blood clot being released into the patient's bloodstream and causing a blockage (thromboembolism). Failure to respond to clotting may also lead to sustained high pressures in the blood circuit and cause a dialyzer blood leak or hemolysis. These conditions may cause serious injury or death if not responded to promptly and appropriately. Regularly check the Dialyzer for any evidence of a leak. Do not return the blood if the blood flow is stopped for a long time. Discard the Cartridge and Dialyzer if they are clotted.

Priority

- Yellow Caution - Medium

Alarm Event

Previous loss of power to cycler.

Probable Cause	Actions Required
1. During the recirculation step of Prime Mode (**000** in Red Alarm window, **23.0** in top window): Power is restored following a power failure or cycler being turned off) during recirculation and the cartridge life has not expired.	1. Press the **TREATMENT** key. 2. Monitor the cycler screen (**20.0** to **23.0** in top window) indicating the system is rechecking the fluid balance system. 3. When **23.0** is shown, continue with air removal steps as instructed in **Removing air from the blood circuit**, page 4-19.
2. During Treatment or Rinseback Mode: Power is restored following a power failure (or cycler being turned off) for less than the preset number of minutes allowed (set by System Setting 16; see Chapter 9).	• During Treatment Mode, press the **TREATMENT** key to resume. • During Rinseback Mode, press the **ADD FLUID** key to resume.

41 - Failed Power Recovery During TREATMENT or RINSEBACK (Red Alarm)

WARNING

The risk of blood clotting in the Cartridge and Dialyzer is higher during long treatments, when no anticoagulation is used, in certain patients who are more prone to excess clotting, or any time when the blood flow stops, including when the NxStage System One Cycler loses power or during an unrecoverable alarm. The risk of blood clotting increases the longer treatment continues and the longer blood flow is stopped. To reduce the risk of blood clotting and identify the early signs of clotting:

- Follow your center's instructions to give and monitor anticoagulant.
- During treatment, regularly check the Cartridge and Dialyzer for clotting by looking closely at the Cartridge and Dialyzer, and periodically flushing the Dialyzer with a manual fluid bolus.

Failure to respond to blood clotting in the Cartridge and Dialyzer or administering medication through the Post-dialyzer port when clotting is present in the dialyzer venous header may result in a blood clot being released into the patient's bloodstream and causing a blockage (thromboembolism). Failure to respond to clotting may also lead to sustained high pressures in the blood circuit and cause a dialyzer blood leak or hemolysis. These conditions may cause serious injury or death if not responded to promptly and appropriately. Regularly check the Dialyzer for any evidence of a leak. Do not return the blood if the blood flow is stopped for a long time. Discard the Cartridge and Dialyzer if they are clotted.

Priority

- Red Alarm - High

Alarm Event

Previous loss of power to cycler.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.
3. Regardless of cause, the treatment must be ended.

Probable Cause	Actions Required
1. Power failure or cycler turned off during Treatment or Rinseback Mode for longer than the preset number of minutes allowed (set by System Setting 16; see Chapter 9) after recovering from a power failure.	If the circuit is not clotted, perform a **manual rinseback,** page 4-52, unless otherwise instructed by your center, as long as the blood circuit is not clotted or hemolyzed and air is not seen in the blood circuit or in the patient blood lines.
2. Cycler door was opened during power failure (or while the cycler power was turned off) that occurred while in Treatment or Rinseback Mode and remained open when the power returned.	If the circuit is not clotted, perform a **manual rinseback,** page 4-52, unless otherwise instructed by your center, as long as the blood circuit is not clotted or hemolyzed and air is not seen in the blood circuit or in the patient blood lines.

50 - Check Fluid Temp: Fluid Temp High (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

Fluid temperature is above fluid temperature alarm point.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
1. Heater setting too high on the fluid warmer or PureFlow SL.	Reduce the dialysate heater setting: • If using the ComfortMate Fluid Warmer: – Turn the Fluid Warmer knob counter-clockwise. • If using the Express Fluid Warmer: – Press the **DOWN ARROW** key to decrease the comfort setting. • If using PureFlow SL: – Reduce the heater setting. – Open the PureFlow SL cabinet door to help fluid cool.
2. Dialysate bags too warm prior to set up.	Cool or replace the dialysate bags.
3. Treatment environment too warm.	Cool room with air conditioning or fan.
When the probable cause is resolved, press the **STOP** key to clear the alarm. Press the **TREATMENT** key to resume the treatment.	

51 - Fluid Cooldown Underway (Yellow Caution)

Priority

- Yellow Caution - Medium

Alarm Event

Previous Red Alarm 50. The fluid temperature is cooling down.

The blood pump and ultrafiltration pump will continue to run. However, the dialysate pump will stop until the temperature of the dialysate has cooled down.

Probable Cause	Actions Required
Previous Alarm 50.	None required. Look for Yellow Caution 52.

NOTE

If Yellow Caution 52 does not occur within a reasonable amount of time, this means the dialysate temperature remains too high. Consider ending the treatment and rinsing back blood.

52 - Continue Treatment: Fluid Cooldown Complete (Yellow Caution)

Priority

- Yellow Caution - Medium

Alarm Event

Dialysate has cooled down sufficiently following a previous Red Alarm 50 and Yellow Caution 51.

The dialysate pump remains stopped.

Probable Cause	Actions Required
Fluid temperature has dropped 0.5°C or more below the fluid temperature alarm point after a Red Alarm 50 and subsequent Yellow Caution 51.	Press the **TREATMENT** key to resume the treatment.

53 - Caution: Low Fluid Temperature (Yellow Caution)

Priority

- Yellow Caution - Medium

Alarm Event

Fluid Temperature is below 33.3°C.

Blood pump and ultrafiltration pump will continue to run. This caution will occur if the fluid temperature is less than 17.1°C or remains between 17.1°C and 24.4°C for at least 20 minutes.

Probable Cause	Actions Required
1. Fluid warmer is not turned on, is set too low or is not working.	Turn on the fluid warmer or increase the dialysate heater setting: • If using the ComfortMate Fluid Warmer: – Turn the Fluid Warmer knob clockwise. • If using the Express Fluid Warmer: – Press the **UP ARROW** key. • If using PureFlow SL: – Refer to the *PureFlow SL User Guide* to change heater setting.
2. Dialysate too cold prior to set-up.	Allow warmer sufficient time to warm fluid. Press the **TREATMENT** key to continue. If patient is experiencing discomfort, end treatment.
3. Room temperature too low.	Increase room temperature.
When the probable cause is resolved, press the **TREATMENT** key to resume the treatment.	

54 - Caution: Low Temperature Monitor Disabled (Yellow Caution)

Priority

- Yellow Caution - Medium

Alarm Event

System Setting 79 has been set to **0**.

Probable Cause	Actions Required
System Setting 79 has been set to **0**.	Press **MUTE** to acknowledge the caution, or If low temperature should be enabled, see the instructions in Chapter 9, System Settings to change System Setting 79 to **1**.

60 - Check for Blood Leak: Blood Detected in Waste Line (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

The system suspects that blood may be present in the effluent.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
1. Dialyzer fiber leak.	Check the color of your waste fluid. Follow your center's instructions for testing waste fluid for the presence of blood. • If visual presence of blood (which may appear as red streaks as the fluid leaves the dialyzer) or if testing shows the presence of blood, end the treatment and perform a **manual rinseback,** page 4-52, unless otherwise instructed by your center, as long as the blood circuit is not clotted or hemolyzed and air is not seen in the blood circuit or in the patient blood lines. • If pink-tinged effluent is observed in the drain line and testing shows the presence of blood, end the treatment and perform a **manual rinseback,** page 4-52, unless otherwise instructed by the center, as long as the blood circuit is not clotted or hemolyzed and air is not seen in the blood circuit or in the patient blood lines. • If normal yellow color and if testing does not show the presence of blood, see probable cause 2.

Probable Cause	Actions Required
2. Air in effluent or flow fraction set too high.	Do one or both of the following: • Correct the source of air entering the effluent. • Lower the flow fraction. If the alarm recurs, end the treatment and perform a **manual rinseback,** page 4-52, unless otherwise instructed by the center, as long as the blood circuit is not clotted or hemolyzed and air is not seen in the blood circuit or in the patient blood lines.
3. Ultrafiltration rate at zero (**0**).	Press the **STOP** key, then press the **TREATMENT** key. Set the ultrafiltration rate to 0.1 L/hr (at least) for approximately two minutes and reset the alarm.

NOTE

Pink tinged or red effluent not associated with a blood leak (confirmed by testing) may be attributed to certain medical conditions, medications, or treatment-related hemolysis. In any case, the presence of pink effluent should be discussed with your health care provider (HCP). See the section **Observation of pink waste fluid**, page 5-12, for additional information.

61 - Check BLD: Failed Blood Leak Detector (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

The detector or detector mirror are not clean.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
One or both of the following require cleaning: • Detector • Detector mirror	Follow the instructions below: 1. Turn off the power switch to the cycler. 2. Lower the saline bag below the cycler. 3. Open the cycler door and allow the fluid to flow back into the saline bag. 4. Clean mirror and detector. See **Cleaning the blood leak detector**, page 6-5. 5. Turn on the power switch to the cycler with the door open and the handle raised. 6. When the Yellow Caution window flashes, insert the cartridge, close the door, and hang the saline bag. 7. When the **ADD FLUID** key is lit, restart Prime.

PRECAUTION

Do not reprime a Cartridge that has been used on a patient. Failure to follow the instructions for repriming a Cartridge may cause damage to the Cartridge or misloading, and may impact system performance.

62 - Check Dialyzer for Clotting (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

Arterial pressure is unstable.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
1. Arterial blood line is kinked between the cartridge and the dialyzer.	1. Unkink the arterial blood line between the cartridge and the dialyzer. 2. Press the **STOP** key to clear the alarm. 3. Press the **TREATMENT** key to resume.
2. A clot has formed in the arterial header of the dialyzer.	1. Press the **STOP** key to clear the alarm. 2. Press the **TREATMENT** key and perform a **manual fluid bolus**, page 5-5 to observe the arterial header of the dialyzer for clotting. 3. If clotting is seen, end the treatment and do not rinse back blood. Failure to appropriately respond to a clotted dialyzer or blood circuit may contribute to hemolysis. 4. If no clotting is seen, continue the treatment. If the alarm recurs, end the treatment and do not rinse back blood.

NOTE

System Setting 53 must be set to **1** and System Setting 78 must be set to **1** to enable this alarm.

70 - Change Cartridge: Cartridge Life Exceeded (Yellow Caution)

Priority

- Yellow Caution - Low

Alarm Event

The cycler has determined that the cartridge has exceeded its life expectancy.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
1. The cartridge has been used for greater than 864 L of blood processed or for longer than 72 hours of operation.	If the caution is due to exceeded cartridge life, press the **MUTE** key to clear or end the treatment and replace the cartridge.
2. The priming bag was spiked before the cycler door was closed after a new cartridge was inserted and the tubing pressed into all three air detectors.	If the caution occurred with a new cartridge as priming was initiated, clear the caution and reprime the same cartridge, see page 5-4.

71 - Schedule Preventive Maintenance: Preventive Maintenance Due (Yellow Caution)

Priority

- Yellow Caution - Medium

Alarm Event

Preventive maintenance is due on the cycler.

Probable Cause	Actions Required
Normal maintenance notification.	Complete the treatment. Schedule preventive maintenance with Technical Support.

72 - Treatment Complete (Yellow Caution)

Priority

- Yellow Caution - Low

Alarm Event

The cycler door opened at the end of Rinseback Mode.

All keys and alarms are disabled. The user may not resume Treatment or Rinseback.

Probable Cause	Actions Required
User has opened the cycler door at end of Rinseback Mode.	Turn the power switch to the cycler off. Prime a new cartridge if additional treatment is desired.

80 - Reconfigure Cartridge Line (Yellow Caution)

Priority

- Yellow Caution - Medium

Alarm Event

The venous blood line of a cartridge without pre-attached dialyzer must be reconfigured.

Probable Cause	Actions Required
Cycler has paused during the priming of a cartridge without pre-attached dialyzer and System Setting 25 (see Chapter 9) is set to **1**.	Move the venous blood line (blue clamp) of the cartridge without pre-attached dialyzer. See the cartridge without pre-attached dialyzer Instructions for Use (IFU).
Press the **ADD FLUID** key to continue.	

81 - Tap Dialyzer to Remove Air (Yellow Caution)

Priority

- Yellow Caution - Medium

Alarm Event

Priming procedure.

Probable Cause	Actions Required
System Setting 64 (see Chapter 9**)** is set to **1**. The cycler has paused during priming to give the user time to remove air from the dialyzer.	Tap the dialyzer to dislodge trapped air until the Yellow Caution disappears. For specific priming directions for the cartridge without pre-attached filter. Refer to cartridge without pre-attached filter instructions for use (IFU).

85 - Check Cartridge Loading: Waste Line Check Failure (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

During Prime, the cycler determined that the cartridge is not properly loaded.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
The cartridge is not properly loaded.	Follow the instructions below: 1. Press the **STOP** key, and then press the **ADD FLUID** key. 2. If the alarm recurs, reprime the cartridge, see page 5-4. 3. If the alarm recurs, replace the cartridge and restart Prime. 4. If the alarm recurs, record the alarm number and Prime step when the alarm occurs, then call Technical Support.

86 - Reprime (Replace) Cartridge: Failed Alarm Test (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

The system failed an alarm test during Prime.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
1. Improper priming.	For all probable causes, follow the instructions: 1. Press the **STOP** key, and then press the **ADD FLUID** key. 2. If the alarm recurs, reprime the cartridge, see page 5-4. 3. If the alarm occurs again, replace the cartridge and restart Prime. 4. If the alarm recurs a third time, record the alarm number and Prime step when the alarm occurs, then call Technical Support.
2. Faulty cartridge.	
3. Cycler malfunction.	

87 - Check Cartridge Loading: UF Occlusion Test Failure (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

The system failed an alarm test during Prime.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
1. Loose post-dialyzer port cap.	Tighten post-dialyzer port cap.
2. The cartridge is not properly loaded.	1. Press the **STOP** key, and then press the **ADD FLUID** key. 2. If the alarm recurs, reprime the cartridge, see page 5-4. 3. If the alarm recurs, replace the cartridge and restart Prime. 4. If the alarm recurs, record the alarm number and Prime step when the alarm occurs, then call Technical Support.

88 - Pressure Offset Rezeroing Needed (Yellow Caution)

Priority

- Yellow Caution - Medium

Alarm Event

Priming cannot begin until the pressure offset rezeroing procedure is done.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
1. The cycler power was turned on with the door closed.	Rezero pressure offset by doing the following: 1. Turn off the cycler power switch. 2. Lift the front door handle of the cycler up completely until it clicks. 3. Open the cycler door. 4. Turn on the cycler power switch with the door open and handle raised. Pressure offset rezeroing will be done automatically. 5. When the Yellow Caution window flashes, insert the cartridge and close the cycler door.
2. A used cartridge was installed before turning the cycler power on.	Discard the cartridge and prime a new cartridge. Pressure offset rezeroing will be done automatically.
3. A partially primed cartridge was installed before turning the cycler power on.	Reprime the cartridge, see page 5-4. Pressure offset rezeroing will be done automatically.

88 - Pressure Offset Rezeroing Needed (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

The system failed when attempting to lower the pressures during Prime.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
1. Blocked or kinked dialysate lines.	Unblock or unkink the dialysate line.
2.. Pressure offset error.	Press the **STOP** key then press the **ADD FLUID** key. • If the alarm recurs, reprime the cartridge, see page 5-4. • If the alarm recurs a second time, record the alarm number and Prime step when the alarm occurs, then call Technical Support.

89 - Pressure Offset Rezeroing Failed (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

Cycler was unable to rezero the pressure sensor offsets on startup.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
Cycler was unable to adjust a variable pressure offset on startup.	Rezero pressure offset by doing the following. 1. Turn off the cycler power switch. 2. Lift the front door handle of the cycler up completely until it clicks. 3. Disconnect the access pressure pod monitoring line (if present) from the side of the cycler. 4. Open the cycler door. 5. Turn on the cycler power switch with the door open and handle raised. (Pressure offset rezeroing will be done automatically.) 6. When the Yellow Caution window flashes, insert the cartridge and close the cycler door.

90 - Check Cartridge For Leak: Fluid Circuit Test Failure (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

The cycler detected a malfunction in the fluid balancing system.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
Malfunction of fluid balancing system.	Follow the instructions below: 1. End the treatment and perform an **automated rinseback**, see page 4-39. 2. Thoroughly check cartridge for fluid leaks, for example, at the bottom of the cartridge. If leaking, contact Technical Support.

NOTES

- For all fluid balance failure alarms, check patient weight.
- Setting the UF rate to **0** will not resolve a fluid balance system problem.

91 - Check Fluid Balance: Fluid Circuit Leak Probable (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

The cycler detected a malfunction in the fluid balancing system.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
Malfunction of fluid balancing system.	Follow the instructions below: 1. End the treatment and perform an **automated rinseback**, see page 4-39. 2. Thoroughly check cartridge for fluid leaks, for example, at the bottom of the cartridge. If leaking, contact Technical Support.

NOTES

- For all fluid balance failure alarms, check patient weight.
- Setting the UF rate to **0** will not resolve a fluid balance system problem.

92 - Check for Cartridge Leak, During PRIME or Recirculation (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

During PRIME or recirculation, the cycler detected a malfunction in the fluid balancing system.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
Cartridge integrity compromised.	Confirm the integrity of the fluid balancing system by performing all of the following steps: 1. Thoroughly check cartridge for fluid leaks, for example, at the bottom of the cartridge. Notify Technical Support of cartridge leak. Return or discard cartridge as directed. 2. If no leak is observed, press the **STOP** key and then press the **ADD FLUID** key to continue.

93 - Correct Parameters: System Settings Conflict (Yellow Caution)

Priority

- Yellow Caution - Medium

Alarm Event

The cycler detected conflicting settings.

This caution can only occur in Service or System Setting Mode — not regular start-up or Prime.

Probable Cause	Actions Required
A setting is set to a value that conflicts with the values of other settings.	Re-enter/review System Settings (see Chapter 9).

99 - Fluid Balance System Failed: Terminate Treatment (Red Alarm)*

**Not applicable in Software version 4.3*

Priority

- Red Alarm - High

Alarm Event

The system detected a malfunction of fluid balancing system.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
Malfunction of fluid balancing system.	Press the **STOP** key, then press the **TREATMENT** key, and observe **000** in the Yellow Caution window. End the treatment and perform an automated rinseback, page 4-39.

NOTE

For all fluid balance failure alarms, check patient weight.

100 - 999 System Alarm* (Red Alarm)

** Except for alarm numbers 600, 601, 602, 603, 715 and 721*

Priority

- Red Alarm - High

Alarm Event

The cycler detected a system or communications error or may be in Service Mode.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
Indicates a system error or internal communications error. Also, the cycler may be in Service Mode.	Use the following instructions: *During Prime Mode before Step 23.0* • Reprime the cartridge, see page 5-4. *During Recirculation of Prime (23.0 in top window), Treatment or Rinseback Mode:* 1. Note alarm number displayed in the Red Alarm window. • Write down the alarm number for future reference. • If **999** is shown in the Yellow Caution window, the cycler is in Service Mode. Call Technical Support immediately. Do not initiate or continue treatment.

Probable Cause	Actions Required
	2. Turn off power switch to the cycler, and then turn it on again immediately. • Watch for the number **40** in the Yellow Caution window. 3. If the cycler repeats the alarm or has a blank window after Step 2, turn off the power, wait approximately one minute, and then turn on the power again. 4. If **40** appears in the Yellow Caution window, press the **TREATMENT** key or the **ADD FLUID** key to continue. 5. If the system alarm recurs, or Red Alarm 41 appears, perform a **manual rinseback**, see page 4-52, unless otherwise instructed by your center, as long as the blood circuit is not clotted or hemolyzed and air is not seen in the blood circuit or in the patient blood lines. Contact Technical Support and provide the system alarm number.

600 - System Alarm (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

The cycler detected pump movement while cycler door was closing.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
1. After spiking the saline bag, a pump might have moved while the cycler door was being closed.	Reprime the cartridge, see page 5-4.
2. Before spiking the saline bag, a pump might have moved while the cycler door was being closed.	Follow the instructions below: 1. Turn off the power to the cycler. 2. Lift the front door handle of the cycler up completely (until it clicks) and pull toward you to open the door. 3. Remove the cartridge completely from the cycler. 4. Turn on the power to the cycler. 5. When the Yellow Caution window flashes, insert the cartridge and close the cycler door. 6. Press the **ADD FLUID** key. 7. If alarm recurs, contact Technical Support.

601, 602, 603 - System Alarm (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

The cycler detected that the pumps are not running at the proper speed.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
1. Kinked, clamped, or pinched fluid or blood lines.	*During Prime Mode before Step **23.0:*** • Check and resolve any kinked, clamped, or pinched fluid or blood lines. • Reprime the cartridge, see page 5-4. • If unable to resolve, contact Technical Support. *During Recirculation of Prime (**23.0** in top window), Treatment or Rinseback Mode:* • Check and resolve any kinked, clamped, or pinched fluid or blood lines.

Probable Cause	Actions Required
2. Pump failure.	If pump failure is suspected: 1. Turn off the cycler. 2. Wait for three seconds and then turn on the cycler. 3. When **40** appears in the Yellow Caution window, press the **TREATMENT** key to continue. 4. If alarm recurs, repeat Steps 1 through 3. Press and hold the **STOP** key**.** Perform an **automated rinseback**, see page 4-39. 5. If alarm occurs a third time, perform a **manual rinseback**, see page 4-52 unless otherwise instructed by the center, as long as the blood circuit is not clotted or hemolyzed and air is not seen in the blood circuit or in the patient blood lines. Contact Technical Support.

715 - Check Blood Leak Detector (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

The cycler detected a problem with the blood leak detector.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
1. Blood leak detector malfunction. 2. Fluid has interfered with the blood leak detector signal. 3. Improper automated calibration of blood leak detector during Prime.	Follow steps below for all probable causes: 1. Turn power off, then on again immediately. 2. If the number **40** appears, press the **TREATMENT** key to continue. 3. If the alarm recurs, or a leak is observed, end the treatment and perform a **manual rinseback**, see page 4-52, unless otherwise instructed by your center, as long as the blood circuit is not clotted or hemolyzed and air is not seen in the blood circuit or in the patient blood lines. • After rinseback is complete, check for cartridge leak. If a leak is observed, clean and dry all cycler surfaces affected by the leak. Weigh the patient to assess UF status. • Even if no leak is observed, clean and dry the blood leak detector. For the proper procedure, see **Cleaning the blood leak detector**, page 6-5. • Reinitiate Prime with a new cartridge.

721 - Door is Ajar (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

Door movement.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
Door handle was lifted any time after priming was initiated. • Indicates door locking mechanism may be damaged.	1. Clamp dialysate inlet line immediately. 2. Turn the cycler power off. 3. Perform a a **manual rinseback**, see page 4-52, unless otherwise instructed by your center, as long as the blood circuit is not clotted or hemolyzed and air is not seen in the blood circuit or in the patient blood lines. 4. Call Technical Support and report the alarm number.

999 - Service Mode Active (Yellow Caution)

Priority

- Yellow Caution - Medium

Alarm Event

The cycler is in Service Mode.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
The cycler is in Service Mode.	Do not initiate the treatment. Call Technical Support immediately.

Chapter 6 Maintenance

To reduce the risk of infection, follow the instructions in this user guide to clean and disinfect the cycler. The care and servicing of your cycler is discussed under preventive maintenance.

Cleaning and disinfection

Clean and disinfect the cycler after each treatment. Clean the blood leak detector at least once a month. The cartridge is single use. It does not need to be cleaned or disinfected.

The following steps for cleaning and disinfecting NxStage equipment were developed in accordance with the Centers for Disease Control (CDC) and the Centers for Medicare and Medicaid Services (CMS) "Conditions for Coverage for End-Stage Renal Disease Facilities."

WARNINGS

- There are no operator or customer technician serviceable parts in any NxStage equipment. Unless otherwise instructed or authorized, NxStage or its agent must perform all maintenance and repair. No changes or modifications to any NxStage equipment are allowed without NxStage's authorization. Unauthorized changes or modifications to equipment may impact performance which may lead to patient or operator injury or death.
- Always follow universal precautions when operating the NxStage System One, cleaning or disinfecting equipment, or observing patient treatment, to avoid infection.
- Clean and disinfect NxStage equipment in a well-ventilated environment in accordance with instructions included in this User Guide. Failure to follow these instructions increases the risk of exposure to infectious diseases and may also cause damage to the equipment.

PRECAUTIONS

- Keep all equipment free of dust by regularly cleaning around and under the equipment. Excessive dust on equipment can lead to poor system performance.
- Keep all equipment out of direct sunlight to prevent the device from overheating.
- Keep children and pets away from all equipment to prevent damage that may lead to poor system performance.

NOTE

If you are not familiar with a specific cleaning or disinfection procedure on your cycler, contact Technical Support.

Follow universal precautions when cleaning and disinfecting the cycler. Use the protective clothing and supplies your center advises to avoid cross-contamination when cleaning and disinfecting the cycler. The protective clothing also protects you from cleaning solutions and fumes.

Before cleaning and disinfecting your cycler, filter holder, and computer

1. Unplug the cycler from its electrical power source.
2. Remove all disposables from the cycler.
3. Close the door of the cycler. Push the handle down until it clicks to close the door.

When cleaning and disinfecting the cycler, filter holder, and computer

- Moisten a cloth with the cleaning solution or disinfectant. Do not saturate the cloth to prevent drips.
- Do not immerse any parts of the cycler into the cleaning solution or disinfectant.
- Avoid the metal connections under the computer.

Figure 6-1: Underside of the Jewel Box computer

Cleaning and disinfecting the cycler, filter holder, and computer after each treatment

To clean and disinfect the cycler after each treatment:

1. Use a soft and dry brush to remove gross debris, if needed.
2. Use a soft cloth and mild detergent to wipe the exterior of the cycler. Follow the instructions from the detergent manufacturer.

If the cycler is soiled with blood, or suspected of contamination with pathogens (bacteria, viruses, or fungi):

1. Use a bleach solution of 1:100 (1 part EPA-registered household bleach to 99 parts clean water).

   Mix 60 milliliters of bleach (2 oz/ ¼ cup) with 3.78 liters of water (128 oz/one gallon). Moisten a soft cloth with the bleach solution.

   You can also make less solution by mixing 15 milliliters (0.5 oz/ one tablespoon) of bleach in 0.95 liters (32 oz/one quart) of water.
2. Wipe the external parts of the cycler with the bleach solution.
3. Let the bleach solution remain on the equipment for 10 minutes before wiping it out.

NOTE

Use the freshly made bleach solution within 24 hours. Some blood pathogens may require a different solution and contact time for disinfection. Follow the directions from the bleach manufacturer to disinfect the suspected blood pathogen.

4. After cleaning up the blood, use a clean cloth to apply the bleach solution a second time. Let the bleach solution remain on the equipment for another ten minutes.
5. Use another clean cloth with water to rinse off the bleach solution. Air-dry.
6. Throw away the cleaning cloths and protective clothing, as appropriate.
7. Make sure the door of the cycler is closed before storage.

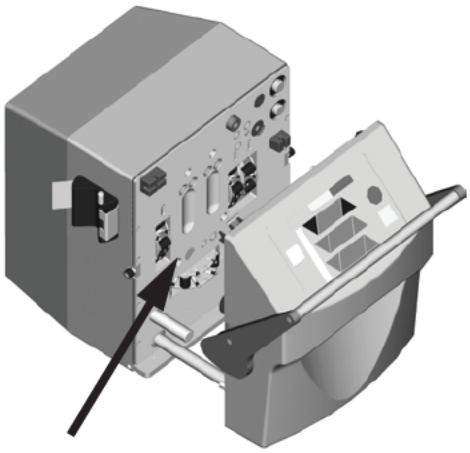
Cleaning the blood leak detector

Clean the detector at least once a month or more frequently if needed.

To clean the blood leak detector:

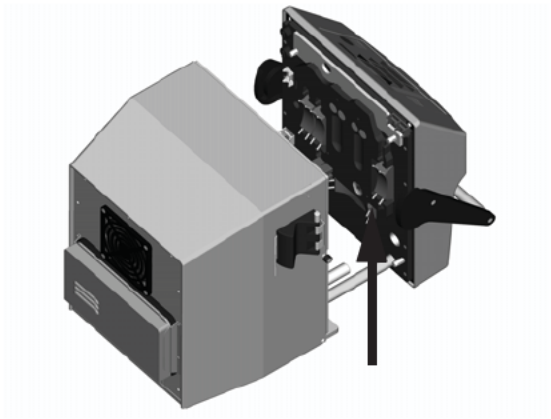
1. Open the door of the cycler. To open, lift up the handle until it clicks, and then pull it toward you. The blood leak detector is inside the cycler, on the left.

Figure 6-2: Location of blood leak detector



2. Look for the mirror directly across the blood leak detector. See Figure 6-3.

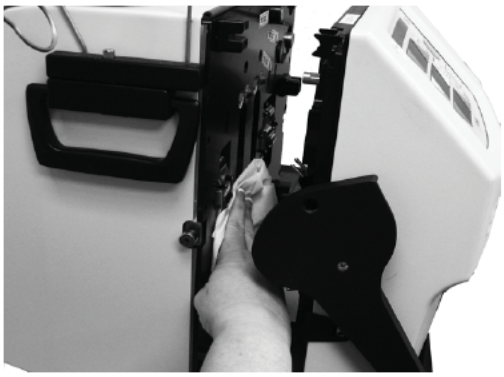
Figure 6-3: Location of the mirror



3. Moisten a soft lint-free cloth with tap water, wipe the blood leak detector and mirror to remove dust and debris.

4. Dry the blood leak detector and mirror with a clean, soft, and ultra, low-lint cloth.

Figure 6-4: Wiping the blood leak detector and mirror



- Be sure to remove all jewelry before putting your hand inside the cycler.
- Do not touch other sensors during this procedure.
- It is safest to reach inside the cycler from the side as shown in Figure 6-4.
- Camera or eyeglasses cloths can be used for cleaning the detector and mirror.

Preventive maintenance

The cycler is designed to require low preventive maintenance. There is no repair to be done by the user on the cycler.

WARNING

There are no operator or customer technician serviceable parts in any NxStage equipment. Unless otherwise instructed or authorized, NxStage or its agent must perform all maintenance and repair. No changes or modifications to any NxStage equipment are allowed without NxStage's authorization. Unauthorized changes or modifications to equipment may impact performance which may lead to patient or operator injury or death.

PRECAUTION

Preventive maintenance on NxStage equipment must be performed in accordance with this User Guide or applicable Instructions for Use. When the Cycler displays a Yellow Caution 71, it is time to contact Technical Support or an authorized distributor to schedule maintenance on the Cycler.

When you turn on the cycler, it runs a self-test to check all the systems. The cycler also checks the alarms system and the priming of the cartridge before use.

These tests are designed to detect most system problems, including:

Power-up test	Internal electronics and software, control panel, and lights
Prime and Alarm Tests	Pressure sensors. Air sensors. Blood leak detector. Door sensors. Speed, direction, and occlusion for the pumps. Clamp occlusion on venous blood line and waste line. Volumetric system. Control panel and electronics. Alarms.

When the system tests fail, the cycler generates alarms. To know how to respond to these alarms, see Chapter 5, Troubleshooting.

When it is time to do preventive maintenance on your cycler, it generates a Yellow Caution 71 alarm (Preventive maintenance due). If you receive this alarm, you need to return your cycler for maintenance. Contact Technical Support to schedule the return of your cycler and to receive a new cycler.

This page intentionally left blank.

Chapter 7 Hardware specifications

The NxStage System One was designed and built with these hardware specifications.

NxStage cycler CYC-D2E (NX1000-1 and NX1000-3)

Environmental requirements

Table 7-1: Environmental requirements for NX1000-1 and NX1000-3 cycler

Room operating temperature	15°C to 32°C (59°F to 90°F)
Room operating humidify	0% to 95% non condensing
Maximum operating altitude	Not applicable
Transport and storage temperature	0°C to 50°C (32°F to 122°F) Before using, keep cycler at room temperature for one hour
Transport and storage humidity	0% to 95% noncondensing
Protection against ingress of fluids	Drip proof IPX1 (per IEC 60529)
Chemical resistance	Resistant to 0.25% sodium hypochlorite (bleach)
Input voltage	100–120/230 VAC, auto-ranging
Frequency	50/60 Hz
Input power	600 VA: 200 VA for cycler 400 VA for AC outlet

Electrical safety

The NxStage System One Cycler models CYC-D2E (NX1000-1 and NX1000-3) meet the following standards:

- UL 60601-1:2003
- CAN/CSA-C22.2 No. 601.1-M90 inc. Supplement No. 1-94 and 2-98
- IEC 60601-1:1988 inc. Am.1:1991 and Am.2:1995
- IEC 60601-1-1:2000
- IEC 60601-1-4:2000
- IEC 60601-2-16:1999
- IEC 60529:2001 for IPX1
- EN 60601-1:1990 inc. Am. A1 and Am. A2

Table 7-2: Electrical safety for NX1000-1/NX1000-3 cycler

Classification	Portable, continuous operation, Class I, Type BF Applied Part	
Maximum Earth Leakage Current	**Standard**	**Conditions of Test**
300 micro-amps	UL 60601-1 (National Difference per 19.5 DV)	With and without the loss of protective earth with the supply conductors normal and reversed.
500 micro-amps	IEC 60601-1	With the loss of protective earth with the supply conductors normal and reversed.
1000 micro-amps	IEC 606601-1 UL 60601-1	With the loss of protective earth with the supply conductors normal and reversed and with the interruption of one supply conductor at a time.

The AC power outlet on the back of the NxStage System One cycler model CYC-D2E (NX1000-1 and NX1000-3) is for use with the NxStage ComfortMate Fluid Warmer (Model FW-200), NxStage Express Fluid Warmer (FW-300), and NxStage PureFlow SL (NX2000-1). Do not use this outlet with another device without first consulting Technical Support.

Electromagnetic compatibility (EMC)

The NxStage System One Cycler model CYC-D2E (NX1000-1 and NX1000-3) meets IEC 60601-1-2:2001, 2nd edition. The cycler is suitable for use in the specified electromagnetic environment. The user of the NxStage System One Cycler should make sure that it is used in an electromagnetic environment as described in Table 7-5, page 7-5.

NxStage cycler NX1000-4

Environmental requirements

Table 7-3: Environmental requirements for NX1000-4 cycler

Room operating temperature	15°C to 37°C (59°F to 99°F)
Room operating humidify	15% to 93% non condensing
Maximum operating altitude	0 m to 3000 m (700 hPa to 1060 hPa)
Transport and storage temperature	-25°C (13°F) without relative humidity control to 70°C 158°F) at 93% relative humidity, non condensing. Before using, keep the cycler at room temperature for one hour.
Protection against ingress of fluids	Drip proof IP22 (per IEC 60529)
Chemical resistance	Resistant to 0.25% sodium hypochlorite (bleach)
Input voltage	100–120/230 VAC, auto-ranging
Frequency	50/60 Hz
Input power	600 VA: 200 VA for cycler 400 VA for AC outlet
Fuse	5x20 mm, Time-lag, 4 amp High-breaking capacity, rated for 250 V

Electrical safety

The NxStage System One Cycler NX1000-4 meets the following standards:

- ANSI/AAMI ES60601-1:2005
- IEC 60601-1:2005
- CAN/CSA-C22.2 No. 60601-1: 2008
- IEC 60601-2-16:2008 and 2012
- IEC 60601-1-11:2010

Table 7-4: Electrical safety for the NX1000-4 cycler

Classification	Portable, continuous operation, transport operable, Class II, Type BF Applied Part

The AC power outlet on the back of the NxStage System One cycler model NX1000-4 is for use with the NxStage Express Fluid Warmer (FW-301) and NxStage PureFlow SL (NX2000-10). Do not use this outlet with another device without first consulting Technical Support.

Electromagnetic compatibility (EMC)

The NxStage System One cycler modelNX1000-4 conforms to IEC 60601-1-2:2007, 3rd Edition, and is suitable for use in the specified electromagnetic environment. The user of the NxStage System One cycler should make sure that it is used in an electromagnetic environment as described in Table 7-5, page 7-5.

Electromagnetic environment

Table 7-5: Electromagnetic environment

Test	Compliance	Environment
Emissions		
Radio Frequency Emissions	Class B	Suitable for use in all establishments, including those directly connected to a public low-voltage power supply network.
Harmonic Emissions (EN 61000-3-2)	Complies	Suitable for use in all establishments, including those directly connected to a public low-voltage power supply network.
CISPR 11 (EN 55011)	Group 1	Uses RF energy only for its internal function. Therefore, the RF emission is very low and not likely to cause any interference in nearby electronic equipment.
Voltage Fluctuations/ Flicker Emissions (EN 61000-3-3)	Complies	Suitable for use in all establishments, including those directly connected to a public low-voltage power supply network.

Test	Compliance	Environment
Immunity		
Electrostatic Discharge (ESD) (EN 61000-4-2)	+/- 6 kV Contact +/- 8 kV Air (Computer: +/- 4 kV Contact)	All floors are wood, concrete, or ceramic tile, or floors are covered with a synthetic material and the relative humidity is at least 30%.
Radiated RF (EN 61000-4-3)	10 V/m 80 MHz to 2.5 GHz	Portable and mobile RF communications equipment is used no closer to any part of the system than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter. Recommended separation distances: d = .35 √P 80 MHz to 800 MHz d = .7 √P 800 MHz to 2.5 GHz where "P" is the power rating of the transmitter in watts (W) according to the transmitter manufacturer and "d" is the recommended separation distance in meters (m). Interference may occur in the vicinity of equipment marked with the following symbol: 
Electrical Fast Transient/Burst (EN 61000-4-4)	2 kV at mains plug	Mains power quality should be that of a typical domestic, commercial, or hospital environment.
Surge (EN 61000-4-5)	1 kV differential mode 2 kV common mode	Mains power quality should be that of a typical domestic, commercial, or hospital environment.

Test	Compliance	Environment
Conducted RF (EN 61000-4-6)	3 Vrms 150 MHz to 80 MHz	Portable and mobile RF communications equipment is used no closer to any part of the system than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter. Recommended separation distance: $d = 1.17 \sqrt{P}$ where "P" is the power rating of the transmitter in watts (W) according to the transmitter manufacturer and "d" is the recommended separation distance in meters (m). Interference may occur in the vicinity of equipment marked with the following symbol: 
Power Frequency Magnetic Field (EN 61000-4-8)	50 and 60 Hz 3 A/m	Power frequency magnetic fields are at levels characteristic of a typical location in a typical (EN 61000-4-8) domestic, commercial, or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines (EN 61000-4-11)	100% Dip for 0.5 cycles 60% Dip for 5 cycles 30% Dip for 25 cycles 95% Dip for 5 seconds	Mains power quality should be that of a typical domestic, commercial, or hospital environment. The system powers off during a 5 second loss of AC mains power but is recoverable using normal operator controls once power is restored. If the user of the system requires continued operation during power mains interruptions, it is recommended that the system be powered from an uninterruptible power supply.

Recommended separation distances

The NxStage System One is suitable for use in the electromagnetic environment in which radiated disturbances are controlled. You can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment and the cycler. See Table 7-6 for the recommended separation distances at the maximum output power of the communications equipment.

Table 7-6: Recommended separation distance

Max Output Power (Watts)	Separation 150kHz to 80MHz D = (1.17)(Sqrt P)	Separation 80 to 800MHz D = (0.35)(Sqrt P)	Separation 800MHz to 2.5GHz D = (0.7)(Sqrt P)
0.01	0.12 m	0.04 m	0.07 m
0.1	0.37 m	0.11 m	0.22 m
1	1.17 m	0.35 m	0.70 m
10	3.69 m	1.11 m	2.22 m
100	11.67 m	3.50 m	7.00 m

The service computer contains components that generate RF energy. It has been tested to ensure no interference with the operation of the cycler. The device complies with Part 15 of the Federal Communications Commission (FCC) Rules. Operation is subject to the following two conditions:

1. The device may not cause harmful interference.
2. The device must accept any interference received, including interference that may cause undesired operation.

   Components generating RF energy maintain minimum spacing requirements to comply with RF exposure/Specific Absorption Rate (SAR) requirements.

Operating ranges

Table 7-7: NxStage System One Operating Ranges

Parameter	Performance	Condition
Blood Flow Rate		
Device	Peristaltic pump	
Range	50 to 600 ml/min[1] 10 to 600 ml/min[2, 3]	Set by user.
Resolution	10 ml/min	
Accuracy	± 15%	@200 ml/min; inlet pressure, -50 mmHg; outlet pressure, 50 mmHg, using water at 37°C
NOTE Blood flow and thus treatment efficacy may be reduced when pre-pump arterial pressures are extremely negative		
Protective system	Effluent and venous pressures. Hall-effect speed sensor.	Tested during Alarms Test. Monitored during treatment.
Effluent Fluid Flow (and Dialysate Exchange) Rate		
Device	Peristaltic pump	
Range	NX1000-1: 0 to 12.0 L/hr NX1000-3 or higher: 0 to 18.0 L/hr	Set by user; dialysate flow dependent on effluent flows.
Resolution	0.1 L/hr	
Accuracy	Greater of ± 10% or 10 ml/min	
Volume Accuracy	**For software versions 4.7 and below:** Greater of 300 ml/12 hr or 3% of exchange volume **Note:** Combined accuracy of ultrafiltration and dialysate exchange flows. **For software version 4.8 and higher**:	
Protective System	Effluent and waste line pressures. Hall-effect speed sensor.	Tested during Alarms Test. Monitored during treatment.

Dialysate Flow Rate (L/hr)	Specification Greater Of	
> 3	± 5% of UF* or	± 100 ml/hr*
≤ 3		± 25 ml/hr*

*Representing 95/90 tolerance interval established under controlled laboratory testing conditions.

1 For software versions below 4.6
2 For software versions 4.6 and 4.7
3 For software version 4.8 and higher

Table 7-7: NxStage System One Operating Ranges

Parameter	Performance	Condition
Ultrafiltration Only		
Device	Peristaltic pump	
Range	0 to 2.4 L/hr or 0 to 999 ml/hr	Set by user
Resolution	0.01 L/hr or 1 ml/hr	
Accuracy	**For software versions 4.7 and below:** Greater of 10% or 0.06 kg/hr **For software version 4.8 and higher:** Greater of 5% of ultrafiltration rate or 30 ml/hr* *Representing 95/90 tolerance interval established under controlled laboratory testing conditions.	
Protective system	Effluent and venous pressures. Hall-effect speed sensor.	Tested during Alarms Test. Monitored during treatment.
Fluid Bolus Flow Rate (Hemofiltration only)		
Device	Peristaltic pump	
Range	2 to 200 ml/min	System Setting
Resolution	1 ml/min	
Accuracy	Greater of ±10% of bolus volume or ±30 ml	
Protective system	Effluent and venous pressures. Hall-effect speed sensor.	Monitored during treatment bolus infusion.
Fluid Bolus Volume (Hemofiltration only)		
Range	0 to 500 ml	System Setting
Resolution	5 ml	
Dialyzer Blood Volume		
Range	10 to 220 ml	System Setting
Resolution	1 ml	
Rinseback Factor		
Range	0.1 to 5	System Setting (Rinseback Volume = (Blood-side Dialyzer Volume + Blood Cartridge Volume) **x** Rinseback Factor)
Resolution	0.01	

Alarms and monitors

During the alarms test, the cycler verifies all alarms and monitoring functions. It also normalizes the blood leak detection.

Table 7-8: NxStage System One alarms and monitors

Parameter	Performance
Venous Pressure	
Device	Electronic sensor
Range	0 to 1500 mmHg
Accuracy	Greater of ±20 mmHg or ±10%
High fixed alarm point	400 mmHg sustained, 600 mmHg sustained during ramp-up and Prime and Alarm Test. 1500 mmHg instantaneous
Low fixed alarm point	20 mmHg sustained
Low adjustable alarm point	-20 to -90 mmHg (in 10 mmHg increments) from venous pressure "lock on" (default is 60 mmHg). "Lock on" occurs when the pressure has been stable for a certain time period (based on pump flow rates) after targeted pump flow rates are achieved.
Protective system	Continuous monitoring by safety subsystem.
Arterial Pressure, Prepump	
Device	Electronic sensor
Range	-50 to -500 mmHg
Accuracy	Greater of ±20 mmHg or ±10%
Arterial Pressure, Dialyzer	
Device	Electronic sensor
Range	0 to 1500 mmHg
Accuracy	Greater of ±20 mmHg or ±10%
Effluent Pressure	
Device	Electronic sensor
Range	0 to 1500 mmHg
Accuracy	Greater of ±20 mmHg or ±10%
High fixed alarm point	1500 mmHg instantaneous
Low fixed alarm point	20 mmHg sustained

Table 7-8: NxStage System One alarms and monitors

Parameter	Performance
Low adjustable alarm point	-10 to -200 mmHg (in 10 mmHg increments) from effluent pressure “lock on” (default is 100 mmHg). “Lock on” occurs when the pressure has been stable for a certain time period (based on pump flow rates) after targeted pump flow rates are achieved.
Protective system	Continuous monitoring by safety subsystem.
Transmembrane Pressure	
Computed as the difference between venous and effluent pressures.	
High fixed alarm point	500 mmHg sustained
Waste Line Pressure	
Device	Electronic sensor
Range	0 to 1500 mmHg
Accuracy	Greater of ±20 mmHg or ±10%
High fixed alarm point	900 mmHg sustained, 1500 mmHg instantaneous
High adjustable alarm point	100 to 450 mmHg sustained
Protective system	Continuous monitoring by safety subsystem.
Balance Chamber Pressure	
Device	Electronic sensor
Range	0 to 1500 mmHg
Accuracy	Greater of ±20 mmHg or ±10%
High fixed alarm point	600 mmHg sustained, 1500 mmHg instantaneous
Air Detection	
Device	Ultrasonic detector
Sensitivity	Reduction of detector signal lasting 6 ms minimum. Approximates a 60 µl bubble at 400 mmHg venous pressure and 600 ml/min blood flow.
Protective system	Continuous monitoring by safety subsystem.

Table 7-8: NxStage System One alarms and monitors

Parameter	Performance
Dialyzer Blood Leak Detector	
Device	Optical emitter and sensor.
Sensitivity	A blood leak is indicated when the 20 second average of the detector signals drops more than 15% below the normalized detector signals. Signal reduction % based on a 0.35 ml/min leak rate of 32 Hct blood.
Protective system	Continuous monitoring by safety subsystem.
Audible Alarms	
Power fail	Continuous for at least one minute.
System fail	Continuous
Others	Continuous, may be silenced for two minutes. Immediate for Red Alarm conditions, delayed for Yellow Caution conditions. Alarm resumes if conditions remain unresolved.
Output	>65 dBA at 1 m
Fluid Temperature Sensor	
Device	Thermistor
Alarm Point (High)	42°C (108°F)[1]
Alarm Point (Low)	<33.3°C (91.9°F)[2]
1 For software versions 4.6 and higher 2 Only applies to software version 4.9 and higher	

Table 7-8: NxStage System One alarms and monitors

Parameter	Performance
Alarm Delay	33.2°C (91.8°F): 304 minutes 33.1°C (91.6°F): 274 minutes 33.0°C (91.4°F): 251 minutes 32.9°C (91.2°F): 232 minutes 32.8°C (91.0°F): 217 minutes 32.7°C (90.9°F): 204 minutes 32.4 - 32.6°C (90.3 - 90.7°F): 183 minutes 32.2 - 32.3°C (90.0 - 90.1°F): 166 minutes 31.8 - 32.1°C (89.2 - 89.8°F): 141 minutes 31.3 - 31.7°C (88.3 - 89.1°F): 123 minutes 30.6 - 31.2°C (87.1 - 88.2°F): 101 minutes 29.6 - 30.5°C (85.3 - 86.9°F): 81 minutes 27.8 - 29.5°C (82.0 - 85.1°F): 60 minutes 24.5 - 27.7°C (76.1 - 81.9°F): 40 minutes 17.1 - 24.4°C (62.8 - 75.9°F): 20 minutes <17.1°C (62.8°F): 0 minutes Delay times based on temperature estimated at the dialyzer, 35.6°C (96.1°F) pre-dialysis core temperature, 34.0°C (93.2°F) dialysis core temperature, 52 kg (115 lb) body weight, 300 ml/min dialysate rate, 350 ml/min blood flow rate, 15 - 20°C (59 - 68°F) ambient temperature, and use of a NxStage chronic cartridge in a hemodialysis configuration.
Accuracy	± 2°C (± 3.6°F)[1] $\frac{+0}{-2}$ °C $\left(\frac{+0}{-3.6}\text{°F}\right)$[2] $\frac{+2.5}{-0}$ °C $\left(\frac{+4.5}{-0}\text{°F}\right)$ at low temperature caution and dialysate rates ≥ 5 L[3].
Protective system	Continuous monitoring by safety subsystem.

1 For software versions below 4.6
2 For software versions 4.6 and higher
3 For software versions 4.9 and higher

Fluid temperature

Parameter	Performance
Input fluid temperature range	33.3 to 41.9°C
Output fluid temperature range	33.3 to 41.9°C

Energy consumption

For a typical three-hour long hemodialysis treatment, with a blood flow rate of 500 ml/min, a dialysate flow rate of 9 L/hr, and an ultrafiltration rate of 0.5 L/hr, the cycler uses approximately 0.2 kWh. Approximately 20% of the energy used is released into the environment as heat.

Contact materials

A list of generic materials that come into contact with blood and fluids is available upon request.

Chapter 8 Glossary

This section defines terms and abbreviations used throughout this user guide.

Terms

Air detectors
Sensors in the cycler that monitor the blood circuit for air. The air detectors can detect bubbles of air in the blood and fluid circuit. The air detectors start an alarm and stop the movement of fluids when there is air in the blood circuit.

Air vent
Small tube found on the ComfortMate fluid warmer to release air out of the warmer.

Ancillaries
Accessories and disposables used with the NxStage System One.

Anticoagulant
Type of medication used to prevent blood from clotting. Heparin is an anticoagulant.

Anticoagulation
Anticoagulation is the use of an anticoagulant to prevent blood from clotting.

Arterial access pressure
Pressure measured in the arterial bloodline before the blood pump. The arterial pressure measures the resistance to flow that must be overcome to pull blood from the patient access. A pressure pod placed on the arterial line measures this pressure. If there is no pressure pod on the arterial bloodline, patients cannot measure their arterial pressure.

Aseptic technique
Aseptic technique is a set of steps to follow before and during treatment to reduce the risk of germs from entering the body. Germs include bacteria, virus, and fungi. Practices include washing hands regularly and thoroughly, wearing gowns, gloves, face and shield masks, and not touching any connections on the blood and fluid lines. See also **Bacteria**.

Bacteria
Very small organisms that may be found in the air, soil, water, and inside the body and on the skin. Bacteria can cause infection, disease, and even death.

Blood-borne pathogens
Organisms too small to see with the naked eyed that may be present in human blood and transferred among humans. Blood-borne pathogens can cause disease.

Blood flow rate
Blood flow rate is the amount of blood flowing through the bloodlines and dialyzer during treatment. It is measured in milliliters per minute.

Blood leak
A blood leak is the escape of blood from the blood circuit into the dialysate. It is generally due to a small break or a tear in the dialyzer fibers or membrane.

Blood line
A general term applied to the part of a tubing set that fills with blood, also called a patient line. There are two blood lines: the arterial line between the arterial access of the patient and the dialyzer, and the venous line between the dialyzer and the venous access of the patient.

Bolus
A bolus is a single delivery of a specific amount of intravenous fluid. During treatment, a bolus of saline is generally used to treat low blood pressure.

Cartridge
A cartridge is a single use disposable used in hemodialysis. It has a blood circuit for carrying the blood to and from the patient into the dialyzer. It has a fluid circuit, isolated from the blood circuit, to deliver a flow of dialysate through the dialyzer. It drains away the waste fluid.

Catheter
A catheter is a soft tube that is inserted into a large vein in the neck, chest, or leg to access blood. See also **Vascular Access**.

Check valve
A check valve is a small valve that allows fluid to flow in one direction only.

Clamp
Any devices used to stop the flow of blood or fluid through the cartridge.

Convection
The process by which the waste products are carried across the membrane of the dialyzer by the movement of plasma, fluid, and ultrafiltrate.

Creatinine
A waste product released from the muscles of the body. Creatinine is normally removed from the blood by the kidneys. Creatinine is removed from blood of patients during hemodialysis.

Cycler
The cycler is the dialysis machine. The cycler controls the pumps; balances the fluids; and calculates the treatment time. It controls the dialysate, ultrafiltration, and blood flow rate. It controls the dialysate and ultrafiltration volume. It monitors the pressure in the arterial and venous bloodlines. It also detects bubbles of air in the blood and fluid circuit.

Dialysate
Dialysate is a solution of pure water, electrolytes, and salts used to clean the blood of patients during dialysis. See **Electrolytes**.

Dialysate line inlet
The tube opening that lets the dialysate enter the cartridge.

Dialysate line outlet
The tube opening that lets the dialysate out of the balancing system into the dialyzer.

Dialysate rate
The amount of dialysate flow measured in liters per hour.

Dialysis
Dialysis is the process of using a dialyzer to remove waste and excess fluid from the blood of patients whose kidney are no longer working well.

Dialyzer
The filter used in hemodialysis to clean the blood of accumulated waste and excess fluid. The dialyzer is a canister containing fibers with microscopic holes. During hemodialysis, the blood flows through the filter and the dialysate fills the canister around the fibers. Water and waste pass from the blood into the dialysate solution.

Diffusion
Diffusion is a process that moves waste products out of the blood through the dialyzer into the dialysate.

Disinfection
The cleaning process used to kill or prevent the growth of bacteria that could lead to infection.

Dry weight
Dry weight is the weight of the patient after removing excess fluid. Dry weight is the weight when the blood pressure is normal and there is no swelling. See also **Fluid balance.**

Effluent
Effluent is the used dialysate and excess fluid collected in a waste fluid bag or drained into a sink or toilet. This effluent contains the waste and excess fluid removed from the blood of patients.

Effluent line
The section of tubing that carries the used dialysate to the waste line.

Electrolytes
Salts dissolved in the body fluids, including sodium, potassium, magnesium, and chloride. The kidneys control the amount of electrolytes in the body. When kidneys fail, electrolytes get out of balance, causing potentially serious health problems.

Endotoxin
Endotoxins are substances found in the outer covering of some bacteria. Endotoxins can cause serious illness and infection. See also **Bacteria**.

Endotoxin filter
Endotoxin filter is a filter that removes endotoxins from water or other fluids.

Extracorporeal circuit
Extracorporeal circuit is the path of blood circulating outside the body of the patient during hemodialysis.

Female-female connector
A female-to-female connector is a plastic connector with luer fittings on both ends.

Flow fraction
The ratio of effluent to blood flow, expressed as a percentage. See also **Effluent**.

Fistula
Fistula is a direct connection of an artery to a vein. A surgeon creates the fistula to make the vein grow bigger and stronger. Once the fistula has matured, the needle can be inserted in the same fistula many times over. The National Kidney Foundation agrees that fistulas are the best type of vascular access. The fistula has a lower risk of infection and it stays functional for longer than other access types. See also **Vascular Access.**

Fluid balance
Fluid balance is the amount of fluid in the body. The kidneys maintain normal fluid balance by removing excess fluid from the body. When kidneys fail, fluid balance must be controlled during treatment to remove excess fluid from the body of patients. See also **Dry weight.**

Fluid balancing system
The fluid-balancing system is a mechanical system that controls the volume of fluid entering and leaving the cartridge on the cycler.

Fluid warmer
A fluid warmer is a device that warms the dialysate to a comfortable temperature.

Graft
A man made tubing that connects an artery to a vein under the skin. It is surgically created to access blood. A graft does not need time to enlarge and can be used soon after it is created. A graft is used when a fistula is not possible. A graft is easier to use than a catheter. It has a lower risk of infection and it stays functional for longer than a catheter. See also **Catheter**.

Grounded electrical outlet
An electrical outlet that is wired to reduce the risk of electrical shock.

Hemodialysis
Hemodialysis is a dialysis treatment option. It uses a dialyzer to clean wastes and excess fluid from the blood when the kidneys have failed. The blood is removed from the body and filtered through the dialyzer, and then returned to the body. The dialyzer has many fibers. Each fiber has a membrane that separates the blood from the dialysate. The membrane allows water and waste to pass through, but does not allow the blood cells to pass through. See also **Dialyzer**.

Hemofiltration
Hemofiltration is the process that removes waste and excess fluid from the blood through a filter using convection. See also **Convection**.

Hypotension
Hypotension means low blood pressure.

Kidney failure
Kidney failure is the loss of kidney function. Kidney failure means that the kidneys have failed to work well enough to sustain life without dialysis or kidney transplant. See also **Hemodialysis** and **Hemofiltration**.

Luer caps
Screw-on, protective caps placed on luer connectors. The caps protect the tubing ends from contamination.

Luer connector
A standard connector designed for leak tight connection. Syringes, dialyzers, and blood tubing commonly have luer connectors.

Multi-line adapter
Tubing set that allows several bags of fluids to connect and drain into a common inlet.

Nephrologist
A nephrologist is a doctor who specializes in kidney function and disorders.

Pathogen
Pathogen is any microorganisms that cause disease, for example bacteria.

Patient lines
See **Blood line**.

Power cord
Power cord is the cable that connects a device to the wall outlet. It supplies electricity to the device.

Power input
Power input is the socket for the plug that connects the power cord to the device.

Premixed dialysate
Premixed fluid containing electrolytes and specific chemicals dissolved in purified water. The dialysate removes wastes and excess fluid from the blood of patients. It also balances blood chemistry during hemodialysis. See also **Electrolytes** and **Dialysate**.

Prescription
Written instructions from the doctor directing the use of therapy based on the individual needs of patients. The dialysis prescription may include dialysate composition, volume and rate, length of treatment, frequency of treatment, blood flow rate, anticoagulants, and target dry weight.

Pressure sensor
A pressure sensor is a device inside the cycler that measures the pressure of fluid through the circuit.

Prime
Prime is a process that uses saline to remove bubbles of air from the tubing and dialyzer before treatment.

Pyrogenic
Pyrogenic means causing fever.

Pyrogens
Pyrogens are bacterial toxins that cause fever. See **Toxins**, **Endotoxin**.

Red alarm
Red alarm is an audible and visual indication of a major condition on the cycler. The cycler indicates the red alarm number in the red alarm window. A red alarm stops the pumps until the user responds to the alarm.

Replacement fluid
Replacement fluid is a solution of sterile water and electrolytes used in hemofiltration. It is used in replacement of plasma water during hemofiltration.

Rinseback
Rinseback is a process that uses sterile saline to flush the blood of patients back into the body at the end of treatment.

Saline
Saline is a sterile solution of salt in water having the same salt concentration as blood. Saline is used to remove bubbles of air in the dialyzer and bloodlines at the start of treatment. Saline is also used to deliver a bolus during treatment and to rinseback the blood at the end of treatment.

Toxins
Poisonous substances produced by living cells. In hemodialysis, toxins refer to waste that build up in the blood. Healthy kidneys normally remove toxins from blood. During hemodialysis, the dialyzer removes toxins from blood. See **Creatinine**.

Transmembrane pressure
Transmembrane pressure is the difference between venous and effluent pressure inside the dialyzer.

Ultrafiltration
Ultrafiltration is a process that removes fluid from blood. Ultrafiltration takes place in the dialyzer. Ultrafiltration removes the excess fluid from the blood of patients during treatment to reach dry weight. See also **Dry weight**.

Ultrafiltration rate
The amount of fluid removed from blood, measured in milliliters per hour or liters per hour. See also **Ultrafiltration**.

Universal Precautions
Refers to the practice, in medicine, of avoiding contact with bodily fluids of patients that may be infected with microorganisms that cause disease. See also **Aseptic technique**.

Use-by-Date
The date by which supplies must be used. Discard any supplies for which the Use-by-Date has passed.

Vascular Access
The site where the venous blood is accessed for treatment and where the filtered blood is then returned to the patient. The three basic kinds of vascular access are fistula, graft, and catheter. See also **Fistula**, **Graft**, **Catheter**.

Warmer Disposable Set
A single use disposable tubing set that fits inside the ComfortMate fluid warmer. It lets the dialysate flow from the warmer to the cartridge.

Warning
A warning alerts the user to the possibility of serious injury, other adverse reactions, or death associated with the use or misuse of the device.

Waste
Waste is any toxins removed from the blood of patients during hemodialysis, for example creatinine. See also **Effluent**.

Waste Line Extension
Waste line extension is the waste line from the cartridge to the drain.

Yellow Caution

Yellow caution is an audible and visual indication of a condition on the cycler. The cycler indicates the number in the yellow caution window. A yellow caution gives information about the condition. Some yellow cautions need a user response to the alarm; others do not.

Abbreviations

Table 8-1 lists common abbreviations used throughout this user guide.

Table 8-1: Abbreviations

Abbreviation	Descriptions
°C	degrees Centigrade
°F	degrees Fahrenheit
ACS	Arterial Connection Sensor
BFR	blood flow rate
FF	filtration fraction/flow fraction
FXR	fluid exchange rate
Ga	gauge
Hct	hematocrit
hr	hour
Hz	Hertz (frequency)
ID	inside diameter
IEC	International Electrotechnical Commission
IV	intravenous
kg	kilogram
Kuf	coefficient of ultrafiltration
L	liter
LED	light-emitting diode
m	meter
mm	millimeter
min	minute
ml	milliliter
MLA	Multi-Line Adapter
mmHg	millimeters of mercury
NA	not applicable
RF	radio frequency
RA	return authorization
TMP	transmembrane pressure
Tx	treatment
UF	ultrafiltration; ultrafiltrate

Table 8-1: Abbreviations (continued)

Abbreviation	Descriptions
UFR	ultrafiltration rate
Un	drop in main voltage
V	Volts
Vac	Volts (alternating current)
Vdc	Volts (direct current)
vol	volume

Chapter 9 System Settings

To change the System Settings on the cycler, follow the instructions in this chapter. The System Settings table lists all of System Setting parameters for the cycler.

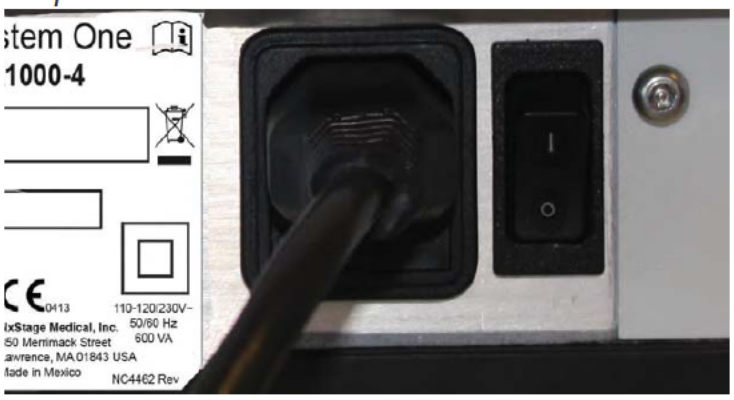
Changing system settings

The following example explains how to change the system setting to the treatment parameters that the doctor or center has prescribed for the patient. Refer to the NxStage cartridge *Instructions for Use* for suggested settings to aid priming. All System Settings are listed after the example.

In this example, System Setting 2 (Initial fluid pump (FP) rate) will be changed from 0.1 to 6.0.

1. Turn on the cycler.

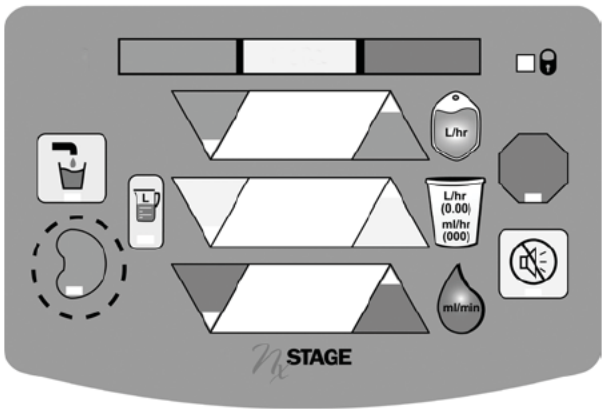
Figure 9-1: Cycler power switch



- The power switch is on the back of the cycler.
- The front panel will flash **8** multiple times in quick succession, go blank, and then flash multiple times again.

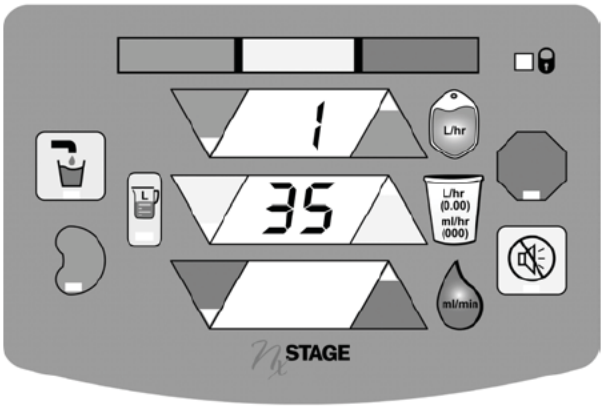
2. Listen closely for the beep and quickly press the **TREATMENT** key. You are now in the System Setting Mode.

Figure 9-2: The TREATMENT key



3. Watch for the number **0** or **1** in the top window.

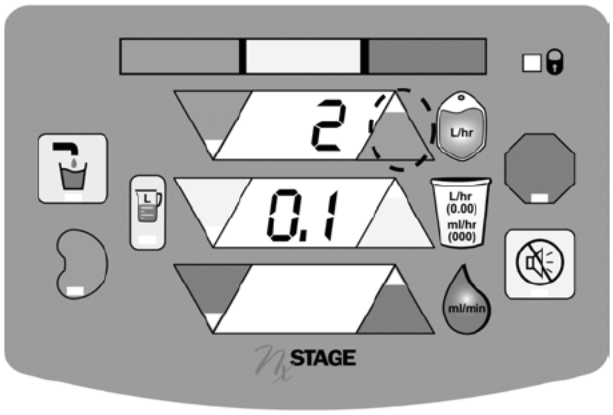
Figure 9-3: System Setting Mode



- You can now change the system settings. If the numbers do not appear, repeat Steps 1 and 2.
- The top window shows the parameter setting number. The middle window shows the current value.

4. Press the **ADJUSTMENT ARROWS** keys in the top window until you see the parameter setting you want to change.

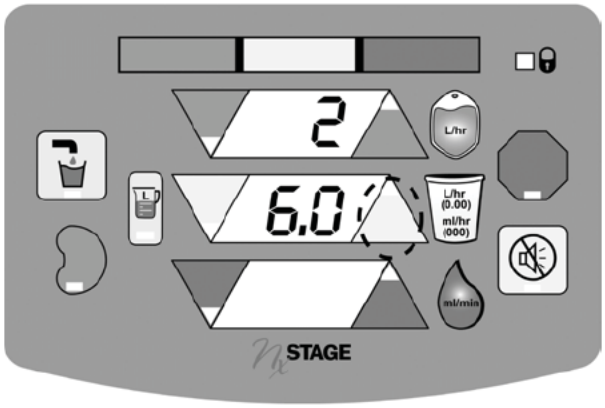
Figure 9-4: Top Adjustment Arrows keys



- See Table 9-1 for all settings options.
- For this example, System Setting 2 is selected (Initial Fluid Pump rate).

5. Press the **ADJUSTMENT ARROW** in the center window until you see the setting value that you want to use.

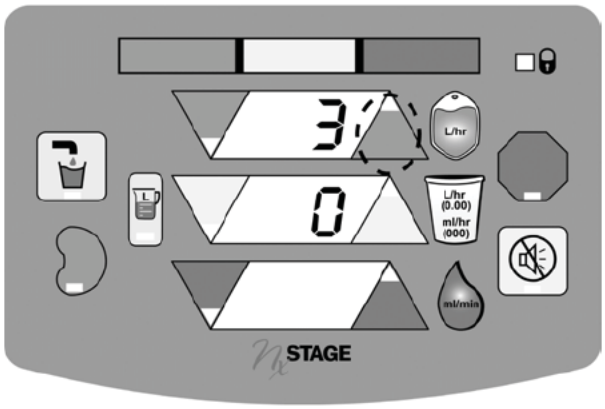
Figure 9-5: Center Adjustment Arrows keys



- In this example, **0.1** is changed to **6.0**.

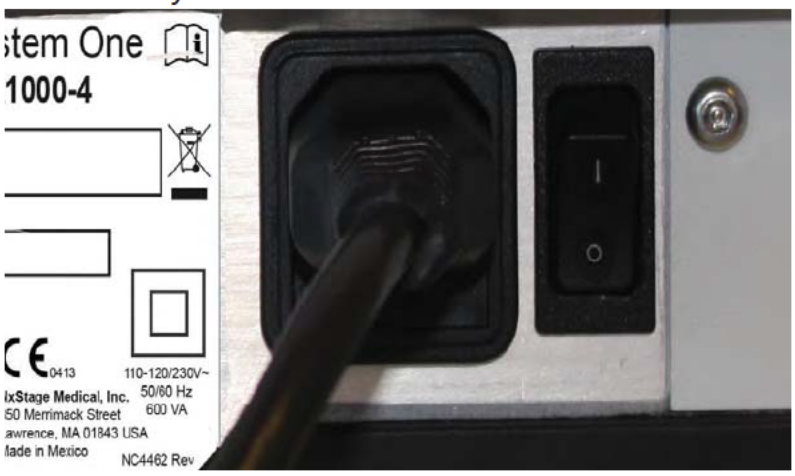
6. Repeat the steps to change other settings as needed.

Figure 9-6: Changing the System Settings



7. After changing all system settings, turn off the cycler.

Figure 9-7: Turn off the cycler



- The power switch is on the back of the cycler.
- When you turn off the cycler, the new settings are saved.

System Settings

Table 9-1: System Setting Parameters

Parameter: No.	Name	Description	Units	Resolution	Range: Low	High	Default Value
0	Cartridge Type	Cartridge type	selector	N/A[1] 1[2,5]	N/A[1] 0[2,3]	N/A[1] 11[2] 12[3] 13[4]	N/A[1] 0[2,5]
1	Maximum FF	Maximum filtration fraction/flow fraction (FF).	%	1	5	480	35%
2	Initial FP	Initial fluid pump (FP) rate.	L/hr	0.1	0	12.0 18.0[5]	0 L/hr
3	Initial UFP	Initial ultrafiltration pump (UFP) rate.	L/hr	0.01	0	2.40	0 L/hr
4	Initial BP	Initial blood pump (BP) rate.	ml/min	10	50[1] 10[2,3,5]	600	200 ml/min
5	Initial Fluid Volume	Initial fluid volume to process.	L	0.1	0	90.0	15.0 L
6	Initial Weight to Remove	Default setting for weight to remove.	L	0.1	0	99.9	0 L
7	Venous Pressure Decreasing Alarm Offset	Sets a low pressure limit below the stabilized pressure following a pump rate change. Indicates the amount pressure can drop before alarm.	mmHg	10	20	90	60 mmHg

1 For software versions below 4.6
2 For software version 4.6
3 For software versions 4.7 and 4.10
4 For software versions 4.8 and 4.9
5 For software versions 4.8 and higher

Table 9-1: System Setting Parameters

Parameter: No.	Name	Description	Units	Resolution	Range: Low	High	Default Value
8	Effluent Pressure Decreasing Alarm Offset	Sets a low pressure limit below the stabilized pressure following a pump rate change. Indicates the amount pressure can drop before alarm.	mmHg	10	10	200	100 mmHg
9	Bolus Volume	Volume of fluid to be given during automatic bolus.	ml	10^{1} $5^{2,3}$	0	500	0 ml
10	Bolus Rate	The flow rate for bolus fluid.	ml/min	10^{1} $1^{2,3}$	10^{1} $2^{2,3}$	200	100 ml/min
11	Net Positive Bolus	**0** = Bolus counted in the cycler's fluid balance. **1** = Bolus not counted in cycler's fluid balance.	selector	1	0	1	0 selector
12	Blood-side Dialyzer Volume	The blood volume of the dialyzer.	ml	1	10	220	91 ml
13	Rinseback Factor	System Setting Rinseback Volume = (Blood-side Dialyzer Volume + Blood Cartridge Volume) **x** Rinseback Factor	multiplier	0.01	0.1	$3^{1,2}$ 5^{3}	1.45 multiplier
14	Rinseback Limit	Number of full rinseback cycles permitted.	selector	1	1	5	2 selector

1 For software versions below 4.6
2 For software version 4.6
3 For software versions 4.7 and higher

Table 9-1: System Setting Parameters

Parameter: No.	Name	Description	Units	Resolution	Range: Low	High	Default Value
15	Rinseback Rate Limit	Maximum blood pump rate during rinseback is the lower of this value or the last commanded blood pump (BP) rate during treatment.	ml/min	10	50[1] 10[2]	600	200 ml/min
16	Power Failure Recovery Timeout	Time limit to recover from power failure. When setting this parameter, allow one minute for cycler initialization in addition to the desired time for operator to recover from power failure.	min	1	1	15	2 min
17	Green Window Scroll Delay	Sets the time duration during the green window scroll.	sec	1	1	10	5 sec
18	Arterial Air Override Duration	Upon start of blood pump (after Alarm 11), time before arterial air sensor activates.	sec	1	10	60	10 sec
19	Preprime FP	Fluid pump (FP) rate before Prime Step 2.1.	ml/min	1	20	200	200 ml/min
20	Preprime WBP	Target waste bag pressure (WBP) before Prime Step 2.1.	mmHg	10	200	600	450 mmHg

1 For software versions below 4.6
2 For software versions 4.6 and higher

Table 9-1: System Setting Parameters

Parameter: No.	Name	Description	Units	Resolution	Range: Low	High	Default Value
21	Flush Volume	Volume of priming solution needed to flush a wet dialyzer.	L	0.1	1	5	1.5 L
22	Dialyzer Flush FP	Fluid pump (FP) rate during dialyzer flush.	ml/min	1	0	200	100 ml/min
23	Dialyzer Flush UFP	Ultrafiltration pump (UFP) rate during dialyzer flush.	ml/min	1	0	200	40 ml/min
24	Dialyzer Flush BP	Blood pump (BP) rate during dialyzer flush.	ml/min	10	50	600	600 ml/min
25	Reconfigure Cartridge Line	**0** = Skips this step. **1** = Prompts operator to move the cartridge line.	selector	1	0	1	0 selector
26	Prime Timer	Length of time of Prime Step 3.2.	sec	1	0	600	0 sec
27	Prime FP	Fluid pump (FP) rate during Prime.	ml/min	1	40	200	200 ml/min
28	Prime UFP	Ultrafiltration pump (UFP) rate during Prime.	ml/min	1	40	200	40 ml/min
29	Prime BP	Blood pump (BP) rate during Prime.	ml/min	1	50	600	360 ml/min
30	Recirculation FP	Fluid pump (FP) rate during recirculation.	ml/min†	10†	0†	200†	40 ml/min†
31	Recirculation BP	Blood pump (BP) rate during recirculation.	ml/min	10	0	600	320 ml/min

† In recirculation, this pump does not run unless the Recirculation BP (System Setting 31) is also greater than zero.

Table 9-1: System Setting Parameters

Parameter: No.	Name	Description	Units	Resolution	Range: Low	High	Default Value
32	WBP Alarm Limit	Waste bag pressure (WBP) alarm limit.	mmHg	1	100	450	250 mmHg[1] 350 mmHg[2] 450 mmHg[3]
33	Cartridge Life Timeout	Cartridge life maximum in hours.	hrs	1	1	72	72 hrs
34	Cartridge Max. Volume	Cartridge life maximum in volume.	L	4	100	864	864 L
35	Dimming Timer	Delay before display is dimmed. (If set to **0**, dimming feature is disabled.)	min	1	0	60	0 min
36	Dimmed Caution Intensity	Sets display intensity during caution condition, if dimming feature is enabled and timer exceeded.	selector	1	0	15	15 selector
37	Dimmed Intensity	Sets display intensity during normal condition, if dimming feature is enabled and timer exceeded.	selector	1	0	15	15 selector
38	Remove Rinseback Volume	**0** = Rinseback volume not removed prior to weight to remove decrementing **1** = Rinseback volume removed prior to weight to remove decrementing.	selector	1	0	1	1 selector

1 For software versions 4.9 and lower.
2 For software versions 4.10 and higher and with dialysate flow rates less than 12 L/hr.
3 For software versions 4.10 and higher and with dialysate flow rates greater than 12 L/hr.

Table 9-1: System Setting Parameters

Parameter: No.	Name	Description	Units	Resolution	Range: Low	High	Default Value
39	Venous Pressure Decreasing/ Low Alarm Delay	Time delay for low venous pressure to alarm.	sec	0.1	0.1	8.0	5.0 sec
40	Effluent Pressure Decreasing Alarm Delay	Time delay for low effluent pressure to alarm.	sec	0.1	0.1	8.0	5.0 sec
41	TMP and VP High Alarm Delay	Time delay for high venous pressure (VP) or transmembrane pressure (TMP) to alarm.	sec	0.1	0.1	3.0	2.0 sec
42	Therapy Target Met	Notifies user that target volume has been achieved.	selector	1	0	1	1 selector
43	Volumetric Fluid Management System Check Interval	Time between VFMS checks.	min	1	15	60	30 min

NOTE

The first VFMS check of a treatment is performed at an interval defined by System Setting 63. Timing of subsequent VFMS checks is determined by this System Setting.

Table 9-1: System Setting Parameters

Parameter: No.	Name	Description	Units	Resolution	Range: Low	High	Default Value
44	Alternate UF Units	**0** = Ultrafiltration (UF) units expressed as L/hr; weight to remove expressed as 0.1 L. **1** = Ultrafiltration (UF) units expressed as ml/hr; weight to remove expressed as 0.01 L.	selector	1	0	1	0 selector
45	Effluent Pressure Decreasing Caution Offset	Sets a low pressure limit below the stabilized pressure following a pump rate change. Indicates the amount pressure can drop before an effluent pressure decreasing caution becomes active.	mmHg	10	10	200	80 mmHg
46	Effluent Pressure Decreasing Caution Delay	Time delay for the effluent pressure decreasing caution.	sec	0.1	0.1	8.0	5.0 sec
47	Access Pressure Decreasing Caution Limit	Sets the access pressure decreasing caution point.	mmHg	10	100[1] 50[2]	400	220 mmHg
48	Access Pressure Decreasing Caution Delay	Time delay for the access pressure decreasing caution.	sec	0.1	0.1	8.0	5.0 sec

1 For software versions below 4.6
2 For software versions 4.6 and higher

Table 9-1: System Setting Parameters

Parameter: No.	Name	Description	Units	Resolution	Range: Low	High	Default Value
49	Dialyzer Pressure Drop Increasing Caution Offset	Sets a pressure limit above the stabilized dialyzer pressure following a pump rate change. Indicates the amount of increase of dialyzer pressure before a caution occurs.	mmHg	10	50	500	150 mmHg
50	Dialyzer Pressure Drop Increasing Caution Delay	Time delay for the dialyzer pressure drop increasing caution.	sec	0.1	0.1	8.0	5.0 sec
51	Dialyzer Clotting Detection Pressure High Alarm Limit	Sets the dialyzer pressure high alarm point.	mmHg	10	400	900	800 mmHg[1] 600 mmHg[2]
52	Dialyzer Clotting Detection Pressure High Alarm Delay	Time delay for the dialyzer pressure high alarm.	sec	0.1	0.1	5.0	3.0 sec
53	Access Pressure in Use	**0** = Do not use access pressure sensor, even if equipped. **1** = Use access pressure sensor (must be equipped).	selector	1	0	1	1 selector

1 For software versions below 4.6
2 For software versions 4.6 and higher

Table 9-1: System Setting Parameters

Parameter: No.	Name	Description	Units	Resolution	Range: Low	High	Default Value
54	Dialyzer Pressure in Use	**0** = Do not use dialyzer pressure sensor, even if equipped. **1** = Use dialyzer pressure sensor (must be equipped).	selector	1	0	1	0 selector
55	Pump Status Indication	**0** = Do not indicate pump on/off status. **1** = After Alarms Test, right most decimal point of corresponding display is lit when pump is on.	selector	1	0	1	1 selector
56	Access Pressure Decreasing Alarm in Use	Enables access pressure alarm functionality if set to **1**.	selector	1	0	1	1 selector
57	Access Pressure Decreasing Alarm Limit	Access pressure exceeded alarm threshold. Alarm will sound if access pressure is less than -1 times this threshold.	mmHg	10	100[1] 50[2]	400	300 mmHg
58	Access Pressure Decreasing Alarm Delay	Time delay for access pressure decreasing alarm.	sec	0.1	0.1	8.0	3.0 sec

1 For software versions below 4.6
2 For software versions 4.6 and higher

Table 9-1: System Setting Parameters

Parameter: No.	Name	Description	Units	Resolution	Range: Low	High	Default Value
59	Venous Pressure Approaching High Alarm Limit Caution Offset	Venous pressure approaching high caution becomes active if the VP rises to within this offset from the venous pressure high alarm limit.	mmHg	10	0	90	0 mmHg
60	Venous Pressure Approaching High Alarm Limit Caution Delay	Time delay for the venous pressure approaching high caution.	sec	1	0.0	10.0	3.0 sec
61	Venous Pressure Decreasing Caution Offset	Sets a low pressure limit below the stabilized pressure following a pump rate change. Indicates the amount the pressure can drop before a VP decreasing caution becomes active.	mmHg	10	10	100	40 mmHg
62	Venous Pressure Decreasing Caution Delay	Time delay for the venous pressure decreasing caution.	sec	0.1	0.1	8.0	5.0 sec
63	First Volumetric Fluid Management System (VFMS) Check Interval	Time into treatment to perform the first VFMS check. Timing of subsequent VFMS Checks is determined by System Setting 43.	min	5	5	60	15 min

Table 9-1: System Setting Parameters

Parameter: No.	Name	Description	Units	Resolution	Range: Low	High	Default Value
64	Air Removal Required	**1** = Prompts user to remove air from dialyzer. **0** = No additional user prompt is displayed.	selector	1	0	1	0 selector
65	Recirculation Ultrafiltration Rate	Ultrafiltration pump (UFP) rate during recirculation.	ml/min	10†	0†	200†	40 ml/min†
66	Venous Pressure Increasing Caution Offset	Sets a high pressure limit above the stabilized pressure following a pump rate change. Indicates the amount pressure can increase before a VP increasing caution becomes active.	mmHg	10	20	380	60 mmHg
67	Venous Pressure Increasing Caution Delay	Time delay for the venous pressure increasing caution.	sec	0.1	0.1	8.0	5.0 sec
68	Prime Venous Line BP	Blood pump (BP) rate when priming the venous line (Alarms Tests only).	ml/min	10	200[1,2] 10[3]	600	360 ml/min

1 For software versions below 4.6
2 For software versions 4.6
3 For software versions 4.7 and higher
† In recirculation, this pump does not run unless the Recirculation BP (System Setting 31) is also greater than zero (**0**).

Table 9-1: System Setting Parameters

Parameter: No.	Name	Description	Units	Resolution	Range: Low	High	Default Value
69	Venous Pressure High Test BP	Blood pump (BP) rate when conducting the venous pressure test (Alarms Tests only).	ml/min	10	200	600	600 ml/min
70	Max Fluid Volume for End of Treatment	Allowable variation of dialysate to reach end of treatment.	L	0.1	0	1.5	1.0 L
71	Minimum BP for Enabling the Access Pod Caution	Minimum blood pump (BP) rate at which the access pressure pod caution will be enabled.	ml/min	10	50[1] 10[2]	200	100 ml/min
72	Blood Set Volume[2]	The blood volume of the cartridge without the dialyzer (see System Setting 12 for dialyzer volume).	ml	1[2]	40[2]	200[2]	100 ml[2]
73	TMPa Alarm[2]	Enables TMPa pressure alarm functionality if set to **1**.	selector	1[2]	0[2]	1[2]	0[2] selector
74	Blood Pump (BP) Rate for BLD Normalization[2]	Blood pump (BP) rate in Step 19 of Prime.	ml/min	10[2]	10[2]	300[2]	20 ml/min[2]

1 For software versions below 4.6
2 For software versions 4.6 and higher

Table 9-1: System Setting Parameters

Parameter: No.	Name	Description	Units	Resolution	Range: Low	High	Default Value
75	FP Rate Capability[1]	Fluid pump (FP) rate maximum.	L/hr	6.0	12.0	12.0 18.0[2]	12.0 L/hr 18.0L/hr[2]
76	Target Volume Mute Span[1]	**0**: Caution 5 is a one-time message, pressing the **MUTE** key after Caution 5 is issued will permanently mute it. **1-15**: The number of minutes of mute duration for Caution 5. When Caution 5 has been issued, if the **MUTE** key is pressed, and if after this specified number of minutes the condition is still not corrected, Caution 5 will be re-issued.	selector	N/A	0	15	0 selector

1 For software versions 4.8 and higher
2 For NX1000-3 or NX1000-4

Table 9-1: System Setting Parameters

Parameter: No.	Name	Description	Units	Resolution	Range: Low	High	Default Value
77	Volume Display Timeout[1]	Volume toggle timeout duration is specified by this in unit of seconds. Volume display replaces rate display for this duration after **VOLUME** key is pressed.	sec	10	10	180	60 sec
78	Enable BP Occlusion Alarm[1]	**0** = Suppress BP Occlusion Alarm 62. **1**= Enable BP Occlusion Alarm 62.	selector	1	0	1	1 selector
79	Enable RF Low Temperature Warning[1]	**0** = Disable RF low temperature monitoring. Will not issue Caution 53, but will issue Caution 54 (Low Temp Warning Disabled) on power up. **1** = Enable RF low temperature monitoring and issuing Caution 53 depending on RF low temperature monitoring results.	selector	1	0	1	1 selector
80	Max UFR[2]	Maximum Ultrafiltration rate (UFR)	L/hr	0.01	0	2.40	2.40 L/hr
81	Max FPR[1]	Maximum Fluid Pump (FP) rate.	L/hr	0.1	0.1	12.0 18.0[3]	12.0 L/hr 18.0L/hr[2]

1 Only for software versions 4.9 and higher
2 Only applies to software versions 4.10 and higher
3 For NX1000-3 or NX1000-4

This page intentionally left blank.

Chapter 10 Conversion Tables and Formulas

The conversion tables are tables that help you understand the conversion of one measurement to another, for example, from degree Fahrenheit (°F) to degree centigrade (°C). Endotoxin and dosing formulas are formulas that help the nurse practitioner to determine the level of exposure to endotoxins an if the dialysis dose for daily treatment is sufficient.

Volume and Rates for Water

1 milliliter (ml)	=	1 cubic centimeter (cc)
1 cubic centimeter (cc)	=	1 gram (g)
1000 milliliters (ml)	=	1 liter (L)
1000 grams (g)	=	1 kilogram (kg)
1 liter (L)	=	1 kilogram (kg)
1000 cubic centimeters/hour (cc/hr)	=	17 milliliters/minute (ml/min)
1 liter/hour (L/hr)	=	17 milliliters/minute (ml/min)
1 kilogram	=	2.2 pounds (lb)

Temperature

°F . . . . . (9/5 * °C) + 32
°C . . . . . 5/9 * (°F - 32)
Example . . . . . .37°C = 98.6° F

Weight, Molarity, and Valency

Substance	Milligrams	mmol	mEq
Na^+	23	1	1
K^+	39	1	1
Ca^{2+}	40	1	2
Mg^{2+}	24	1	2
Cl^-	35	1	1
HCO_3^- (bicarbonate)	61	1	1
$C_3H_5O_3^-$ (lactate)	89	1	1
$C_6H_5O_7^{3-}$ (citrate)	189	1	3

Endotoxin

Toxins are released by microorganisms (specifically gram-negative bacteria) when they break down or die. These toxins can cause serious illness and pyrogenic reactions upon patient exposure. Always calculate the maximum potential patient endotoxin exposure for prescribed sterile intravenous (IV) prescription fluids at the prescribed prescription fluid flow rates.

- Potential exposure/hr =
  Prescribed prescription fluid flow rate (ml/min) * endotoxin specification of prescription fluid (EU/ml) * 60 min/hr
- USP exposure threshold/hr = 5 EU * patient body weight (kg)

If potential endotoxin exposure exceeds the US Pharmacopoeia (USP) exposure threshold or is unknown, use endotoxin-reducing IV filters. Commercially available IV fluids (such as Lactated Ringers or 0.9% Saline) labeled as “nonpyrogenic” may contain endotoxins up to a USP specification level. Contact your pharmacist for additional information.

Dosing (Kt/V)

Daugirdas formula (K-DOQI recommended):

spKt/V = -Ln (R-0.008 * t) + (4-3.5*R) * UF/W

where:

R = post-BUN/pre-BUN

t = time in minutes

UF = excess fluid volume removed during the treatment

W = post dialysis weight

Chapter 11 Clinical study summary

A clinical study was done to support the daily use of hemodialysis in the home. This is the summary of the clinical study.

Introduction

From February 2004 through November 2004, a study was conducted to determine whether or not delivery of hemodialysis with the NxStage System One in the home and in-center environments is equivalent on a per treatment basis. This study was performed to support an explicit home indication for hemodialysis with or without ultrafiltration. The NxStage System One has not been clinically evaluated for isolated ultrafiltration in the home setting.

This was a prospective, multi-center, two-treatment, two-period, open-label, cross-over study conducted at 6 centers, using daily hemodialysis. For the purpose of this study, daily hemodialysis was defined by a frequency of six dialysis treatments per week lasting under 3.5 hours each. The first phase (In-Center) consisted of 48 treatments (six per week, in an eight week period) performed in the dialysis center. The second phase (Home) consisted of the same number of treatments, also performed over an eight-week period at the same frequency in the subject's home setting. Between the two phases, a two-week wash-out/run-in period (Transition Phase) occurred primarily in the home. Subjects had physical examinations at enrollment, the end of the In-Center Treatment phase and at the end of the Home phase. Subjects were evaluated on a routine basis via clinical laboratory testing and adverse event monitoring.

Thirty-two patients were enrolled and 25 patients completed the study. The reasons for study discontinuation were investigator judgment (2), patient request (4), and transplant (1). No subjects discontinued therapy due to death or adverse event. At the end of the formal clinical trial, most patients continued to use the NxStage System One at home on a simplified protocol (the "Extension Study").

Overall, the mean subject age was 51 years and ranged from 18 to 71 years. Sixty-three percent of the subjects were male. Seventy-five percent of the subjects were white, and nineteen percent were black/African-American. The primary etiology for renal disease was well distributed within the following classifications: diabetes, hypertension, glomerulonephritis, polycystic disease, and other.

During the formal clinical trial, approximately 2,200 treatments were administered, of which over 1,000 were at home. As of February 2005, after formal study completion, there had been over 4,600 dialysis treatments with patients who participated in the study, of which nearly 3,200 were done at home.

Criteria for Evaluation

The primary efficacy endpoint was the ability to deliver the clinically prescribed amount of therapy. The total effluent (spent dialysate plus net ultrafiltrate) volume produced during each treatment was electronically recorded and compared to the prescribed fluid volume, the latter of which was based on a clinically accepted urea kinetic modeling approach. Successful therapy delivery was defined by attainment of a delivered volume that was at least 90% of the prescribed volume.

The primary safety endpoint was the composite of intradialytic and interdialytic adverse event profiles.

The following secondary endpoints were also evaluated:

- Delivered single-pool urea Kt/V per treatment
- Kidney Disease Quality of Life (KDQoL) Short Form
- Successful completion of the training program by the subject and the subject's partner
- Clinical utility (defined as usability) of the NxStage System One
- Ultrafiltration: ability to achieve target net ultrafiltration volume per treatment

Results

Primary efficacy endpoint

Successful therapy delivery was 98.5% In-Center and 97.3% In-Home (p=0.0678). Neither the effect of the treatment period (center vs. home) nor study week was determined to be significant.

Primary safety endpoint

Adverse events were categorized during analysis as anticipated treatment observations (ATO), adverse events (AE), and unanticipated adverse device effects (UADE), and device issues. Event rates are summarized in the following table. (Event rate is per 100 hemodialysis treatments.)

Category	In Center (n=32)	Transition (n=27)	Home (n=27)
All anticipated treatment observations (ATO)			
Number of subjects (%) with at least one ATO	30 (93.75)	14 (51.85)	19 (70.37)
Number of reports	379	66	202
Event rate	26.45	20.89	16.93
All AEs			
Number of subjects (%) with at least one AE	24 (75)	4 (14.8)	13 (48.1)
Number of reports	76	6	25
Event rate	5.30	1.90	2.10
All unanticipated adverse device effects (UADE)			
Number of subjects (%) with at least one UADE	1 (3)	0 (0)	0 (0)
Number of reports	1	0	0
Event rate	0.07	0	0
Device issues (any problem)			
Number of subjects (%) with at least one device issue	27 (85)	12 (44)	21 (78)
Number of reports	109	24	68
Event rate	7.61	7.59	5.70

More ATOs were reported In-Center compared to in the Home. The ATO event rate in the In-Center environment was 35% higher than that in the home, although this difference was not statistically significant. The difference in event rates (In-Center minus Home, per 100 treatments) was 7.06 (95% CI: -1.32 to 15.43). The most common ATOs experienced by subjects during both the In-Center and Home treatment phases were muscle cramping and hypotension. ATOs with event rates greater than 1.0 per 100 hemodialysis treatments occurring during the In-Center treatment phase were blood under-heating, muscle cramping, hypotension, headache, dizziness, and fatigue and during the Home treatment phase were muscle cramping, hypotension, blood under-heating, and fatigue.

The AE event rate during the In-Center treatment phase (5.31) was statistically significantly higher than the AE event rate during the Home treatment phase (2.14) (p=0.0070). The most common AEs occurring in greater than 5% of subjects during In-Center treatment were dysgeusia, back pain, dizziness, sinusitis, arthralgia, night cramps, neck pain, and tremor; and the most common adverse events during In-Home treatment were arthralgia, night cramps and nausea. A statistically significantly higher rate of infections and infestations was observed for the In-Center treatment phase compared to the Home treatment phase.

One UADE, a plastic taste in mouth, was reported during the study. This was later independently adjudicated as dysgeusia and did not meet the definition of a UADE. This event was further classified as mild in severity, therapy-related, seemed to be quite transient and not associated with any serious or lasting consequences. The full analysis was provided to the FDA during the study.

The rate of device issues were not statistically different between the In-Center and Home treatment phases. The most common device issues were repeated unresolved alarms and operator error.

There were no clinically meaningful findings or patterns in clinical laboratory data, vital signs, physical examinations, or concomitant medications.

Secondary endpoints

The delivered single pool Kt/V per treatment was not different between the In-Center and Home treatment phases. The estimated mean In-Center Kt/V value was 0.5365 and the estimated mean Home Kt/V value was 0.5413 (p=0.6251).

There were no significant differences noted between the two treatment environments on the KDQoL Short Form for any of the items surveyed.

With respect to the training program, the mean number of days required to complete training for the study subjects was 14.5 (+9.21) and the mean number of days required to complete training for the subject's partners was 11.6 (+9.15). The mean number of times the examination was taken by study subjects was 1.1 (+0.38) and 1.1 (+0.27) for the partners.

Clinical utility was measured by the number and frequency of device alarms, the time taken to respond to the alarms, and the duration of treatment. The number of device alarms per treatment was 2.19 in-center vs. 2.10 in the home (difference was not significant). The time taken to respond to each alarm was not statistically different between the two environments. Treatment time, at 2.8 + 0.58 hours in center vs 2.8 + 0.61 at home, was also not significantly different between the two environments.

The planned analysis of UF volumes was not considered meaningful for multiple reasons. UF volumes were, however, included in the calculation of the primary efficacy endpoint.

Conclusions

Overall, hemodialysis with the NxStage System One in the Home and In-Center were found to be equivalent on a per treatment basis as demonstrated by the ability of the NxStage System One to deliver at least 90% of the prescribed volume. The mean single-pool urea Kt/V values were also similar across the eight weeks of study treatment in each environment. Additionally, there were no significant differences noted in the parameters surveyed on the KDQoL Short Form between the two environments.

The AE profiles were similar between hemodialysis treatment in the two environments. The nature and types of AEs reported are commonly seen with hemodialysis treatment. The incidence rate of anticipated treatment observations and device issues was also similar between the environments.

This page intentionally left blank.

Chapter 12 Warnings and Precautions

Read all the warnings and precautions before beginning your treatment with the NxStage System One. Do not use the NxStage System One without reading and understanding all warnings and precautions in the user guide.

Warnings

A warning is a statement that alerts you to the possibility of serious injury, other adverse reactions, or death associated with the use or misuse of the device.

WARNINGS

1. All NxStage equipment and disposables must be used as described in the applicable User Guides and Instructions for Use, and in accordance with a physician's prescription. Make sure that all User Guides are carefully read and understood, and are always available to the operator at the treatment location. Improper use may cause injury or death.
2. Treatment with the NxStage System One should only be done under the responsibility of a physician and performed by a trained and qualified person. A trained and qualified person must observe all treatments so that alarms and harmful conditions can be responded to promptly. Possible harmful conditions include, but are not limited to venous disconnects, inadvertent fluid administration, or excessive ultrafiltration. A patient should not dialyze alone, even if they are trained and qualified.
3. Always follow universal precautions when operating the NxStage System One, cleaning or disinfecting equipment, or observing patient treatment, to avoid infection.

4. Weigh the patient before treatment to make sure that the appropriate ultrafiltration volume is calculated. Follow the physician's prescription for maximum volume and rate of fluid to be removed. Removing too much or too little fluid, or removing fluid too quickly, may cause patient injury. In addition, prescribing physicians should be aware that certain patients, such as low weight patients and patients at or near their dry weight, may be unable to tolerate fluid balance variations in amounts less than the total fluid accuracy tolerances of the NxStage System One Cycler and other ancillary fluid delivery devices. These patients must be closely monitored for signs and symptoms of excessive ultrafiltration or fluid overload. Refer to the System One User Guide for additional information on ultrafiltration during dialysis.
5. Hemodialysis may result in significant changes in the blood concentration of electrolytes and glucose and in the patient's volume status. Appropriate monitoring of the patient's hemodynamic, fluid, electrolyte, and acid-base balance should be performed regularly, per physician orders, to ensure appropriate response to therapy. Failure to do so could result in inappropriate therapy for the patient.
6. The Dialyzer may remove medications given into the Arterial Patient Line (red clamp). Refer to the medication manufacturer's labeling for clearance characteristics of any medications given into the Arterial Patient Line (red clamp). Follow the policies and procedures of your center for infusing fluid or medications into the blood circuit. Infusing fluids or medication incorrectly may reduce the dose given to the patient or cause harm to the patient.
7. When a heart rate monitor is used during treatment, the NxStage System One Cycler's pumps may produce electrostatic discharges that may appear as artifacts on the monitor's screen. The electrostatic discharges produced by the Cycler will not harm the patient. Look at the monitor's screen when the Cycler's pumps are running and when they are stopped to confirm it is the Cycler that is producing these artifacts.
8. Observe the patient for allergic reactions, especially if the patient has a history of allergies. If the patient has an adverse reaction, stop the treatment and follow your center's instructions.
9. If you are using a Cartridge without a pre-attached Dialyzer, make sure that the Dialyzer you select has a maximum transmembrane pressure (TMP) of at least 500 mmHg or higher. Use of a Dialyzer with a lesser TMP rating increases the risk of a blood leak. NxStage defines TMP as the difference between venous pressure and effluent pressure. Follow the Dialyzer manufacturer's instructions for use for TMP rating.

10. Do not use any supplies after their expiration date or Use-by Date, or the supplies may not perform as intended.
11. Manual fluid boluses and fluid consumed during treatment are not included in the System One fluid balance calculations. Excessive fluid boluses, whether intentional or unintentional, or failure to account for consumed fluid during treatment, may cause patient injury. Include fluid boluses and the volume of fluid consumed in manual fluid balance calculations. Make sure that the administration lines used for manual bolus or rinseback are clamped after use.
12. Extreme high or low fluid temperatures may cause injury or death. The NxStage System One Cycler checks for high and low dialysate temperature during normal operation. The temperature of rinseback and manual bolus fluids is not monitored at all. At dialysate rates lower than 5 L/hr, low fluid temperatures are more likely to occur. If System Setting #79 is set to 0 or the Cycler software version is less than 4.9, low temperature monitoring is disabled at all times. In instances of low fluid temperatures, the patient may feel discomfort, which may include but is not limited to shivering. Sedated or comatose patients should be watched carefully when fluid temperature is not monitored.
13. The NxStage System One disposables are for single use only unless otherwise indicated. Do not reuse or resterilize. Materials used to make the disposables may not withstand reprocessing or reuse or both. Reuse or resterilization of the disposables may result in, but is not limited to, the following problems:
    - risk of cross contamination
    - material degradation
    - biocompatibility issues
    - endotoxin reactions
    - failure of the disposable to perform as intended.

14. The NxStage System One Cycler will automatically remove the rinseback volume when both the System Setting #38 is set to 1 and the Ultrafiltration pump rate (UFR) is greater than 0. Automatic removal of the rinseback volume is not displayed to the operator. Therefore it is important to account for the rinseback volume when calculating the ultrafiltration rate and volume for the treatment. Do not add the rinseback volume to the targeted ultrafiltration volume when the Cycler is set to automatically remove the rinseback volume or excess ultrafiltration will result. For patients that may be unable to tolerate even small fluid balance changes, such as low weight patients and patients at or near their dry weight, the excess ultrafiltration may result in hypotension or hypovolemia which may cause patient injury or death. When automatic removal of the rinseback volume is not desired, System Setting #38 should be set to 0.
15. In order to avoid electric shock, patients with a central venous catheter must not touch or be in contact with any AC powered electric devices during their treatment. Examples include but are not limited to, electric blankets or heating pads, electric lamps or lights, computers that are plugged into an electrical outlet, and electric powered chairs.
16. Physicians must ensure that central venous catheters are not placed in the right atrium. The risk of microshock to the patient resulting in fibrillation is increased when the tip of a central venous catheter placed in the right atrium touches the atrium wall during use of the NxStage System One.
17. Caution should be taken with babies and young children around the System One and PureFlow SL. The disposable lines or bags pose a strangulation hazard. The disposables also contain small parts that pose a choking hazard if swallowed.
18. The NxStage System One contains alarms that may be configured by the operator. The operator should check that the current alarm settings are correct for the patient. Incorrect settings may cause injury or death.
19. Use only physiologic fluids prescribed by a physician with the NxStage System One. Fluids must meet the requirements of local regulations, standards, or laws. Refer to fluid labeling for complete instructions. Fluids for hemofiltration, priming, bolus, and rinseback must be indicated for infusion. Dialysate fluids must be used for hemodialysis. The use of incorrect fluids may cause patient injury or death.

20. Do not use any fluid delivery devices that have a post-pump drip chamber or a maximum output pressure of less than 600 mmHg. Using these devices may cause blood loss, undesired fluid delivery, inaccurate flows, leaks, and other failure of the fluid delivery device to perform its intended function.
21. Do not connect to the accessory electrical outlet on the back of the Cycler any electrical items that are not specified as part of, or approved for use with, the NxStage System One Cycler. Unapproved or incompatible electrical items can create an electrical hazard.
22. Make sure only compatible devices are used with the NxStage equipment. Non-compatible devices may not perform as intended.
23. When using pharmacy-compounded fluids, the physician should make sure that the potential exposure to endotoxins does not exceed the USP/EP guideline levels for the prescribed therapy. If you are not sure, consult a pharmacist. If the potential exposure exceeds the guideline levels, use endotoxin-reducing IV filters with a working pressure higher than 15 psi. Using an IV filter with a working pressure lower than 15 psi may increase the risk of IV filter failure and may lead to a pyrogenic reaction. Refer to the *NxStage System One User Guid*e for tables and conversions for endotoxins.
24. Physicians should take extra care when prescribing dialysate for patients with an increased level or an impaired metabolism of lactate ions, as in severe hepatic insufficiency.
25. A trained person must install and test the NxStage System One. Improper installation and testing could lead to malfunction or damage, which may cause patient injury or death.
26. Unless specifically recommended by NxStage, non-medical electrical equipment should not be used within 1.8 meters (6 feet) of the System One. Use of such equipment may affect patient safety.
27. Do not use NxStage equipment in the presence of a Flammable Anesthetic Mixture with Air, a Flammable Anesthetic Mixture with Oxygen, or a Flammable Anesthetic Mixture with Nitrous Oxide or in an oxygen-enriched or explosive atmosphere.
28. To avoid injury, the NxStage System One Cycler must be plugged into a properly grounded outlet, except for Cyclers with the model number NX1000-4. Ask a qualified electrician to check your outlet if you are not sure that it is properly grounded. Cyclers with the model number NX1000-4 do not require a grounded outlet for their safe operation; the model number is located at the rear of the Cycler.

29. Use only routers, switches, or other data networking equipment that comply with IEC 60950 if they are used to connect the computer on the back of the NxStage System One Cycler to a wired-data network. The use of equipment that does not comply with IEC 60950 may result in electric shock to the patient or operator.
30. Do not connect printers or other equipment to the computer on the back of the NxStage System One Cycler to reduce the risk of electrical shock to the patient or operator. USB thumb drives or USB connections from the PureFlow SL are the only devices than can be connected to the computer on the back of the Cycler.
31. The NxStage System One Cycler weighs approximately 34 kilograms (75 pounds). To avoid injury, two people must lift and carry the Cycler. Close and lock the door of the Cycler before lifting and carrying it. Do not lift and carry the Cycler by the door handle. Use the grip points under the Cycler or the handles included on some models.
32. Make sure that the NxStage System One Cycler and its ancillaries are attached securely to its mobile stand or placed on a table sturdy enough to hold the weight of the Cycler, its ancillaries, and fluid bags. Check the bolts on the mobile stand regularly to make sure that they are fastened securely, especially before moving the Cycler. If the bolts are not fastened securely, the Cycler, its ancillaries, or the fluid bags may fall and cause injury.
33. Use only the power cords supplied by NxStage or its authorized distributors. Do not connect portable multiple-socket outlets or extension cords to any NxStage equipment. Non-authorized or incompatible electrical power cords and outlets can create an electrical hazard.
34. Always visually inspect the package and product before use. Do not use any disposables if the package is open, damaged, or if any of the connector's protective caps are loose, disconnected, or missing. These disposables may no longer be sterile and may cause patient infection.
35. Do not touch surfaces of any disposable covered by protective caps. This includes connectors and needleless access sites. Always use aseptic technique when handling connections. Touching these surfaces may make them non-sterile, which may cause patient infection.

36. Do not use excessively cold dialysate. Under certain conditions, including but not limited to patient weight, dialysate flow rates and treatment durations, some patients may develop hypothermia when exposed to excessively cold dialysate.
37. Do not use a knife or other sharp instrument to open any shipping carton or case containing disposables because it may cut or damage the contents. Do not use any disposables from a shipping carton or case that has been opened with a knife or other sharp instrument. Damage to disposables may cause blood or air leaks, causing patient injury or death.
38. Do not use ultrasound gel, or any gel-like substances around the air detectors. These substances may prevent the detection of air in the blood lines. If air cannot be detected it may cause an air embolism in the patient.
39. The maximum fluid volume for transporting the NxStage System One Cycler using the mobile base with the ComfortMate Fluid Warmer is 10 liters of fluid. Do not transport the Cycler with fluid using the mobile base if using the Express Fluid Warmer. The maximum fluid volume for stationary use of the Cycler with an IV pole is 29 liters of fluid when using the ComfortMate Fluid Warmer or 21 liters of fluid when using the Express Fluid Warmer. Fluid volume must not be exceeded and fluid must be evenly distributed on the IV pole to prevent accidental tipping of the Cycler.
40. Do not attach ancillary devices that can restrict blood flow, such as stopcocks, to the patient lines. Restrictions in the blood circuit can cause hemolysis.
41. Do not use a Cartridge with kinked blood lines. Always inspect the blood lines for kinks before and during use, particularly around Dialyzer connections. Kinked blood lines may cause hemolysis.

42. The risk of blood clotting in the Cartridge and Dialyzer is higher during long treatments, when no anticoagulation is used, in certain patients who are more prone to excess clotting, or any time when the blood flow stops, including when the NxStage System One Cycler loses power or during an unrecoverable alarm. The risk of blood clotting increases the longer treatment continues and the longer blood flow is stopped. To reduce the risk of blood clotting and identify the early signs of clotting:
    - Follow your center's instructions to give and monitor anticoagulant.
    - During treatment, regularly check the Cartridge and Dialyzer for clotting by looking closely at the Cartridge and Dialyzer, and periodically flushing the Dialyzer with a manual fluid bolus.

    Failure to respond to blood clotting in the Cartridge and Dialyzer or administering medication through the Post-dialyzer port when clotting is present in the dialyzer venous header may result in a blood clot being released into the patient's bloodstream and causing a blockage (thromboembolism). Failure to respond to clotting may also lead to sustained high pressures in the blood circuit and cause a dialyzer blood leak or hemolysis. These conditions may cause serious injury or death if not responded to promptly and appropriately. Regularly check the Dialyzer for any evidence of a leak. Do not return the blood if the blood flow is stopped for a long time. Discard the Cartridge and Dialyzer if they are clotted.
43. To avoid injury when closing the Cycler door, make sure to keep fingers and other body parts away from the door opening.
44. Only spike the saline bag after loading the Cartridge and closing the door of the NxStage System One Cycler. Failure to do so may cause Cartridge leaks or a misalignment of the Cartridge, resulting in compromised treatment, injury, or death.
45. Never connect the patient to the Cartridge before you see the treatment parameters in the NxStage System One Cycler's window, which indicates that the Prime and Alarms Test is completed. Some safety systems are not active during the Prime and Alarms Test. Connecting the patient at any time before completion of the Prime and Alarms Test may cause serious injury or death.
46. Do not tap the Dialyzer against a hard surface, such as the NxStage System One Cycler. This may damage the Dialyzer and may cause a blood or fluid leak, causing patient injury or death.

47. The Cartridge has multiple connection points. Failure to make the proper connections may cause compromised treatment, blood loss, injury or death. Make sure mated luer-connectors are secure but do not over-tighten, especially when connections are wet.
48. Manually prime any administration “T”s and ports, if present, even if they are not used, to prevent air from entering the patient blood lines. Secure caps and close clamps after priming, and after each use to prevent blood loss or air entering the patient blood lines.
49. Do not adjust the vascular access while the Blood Pump is running. Adjusting the vascular access while the Blood Pump is running increases the likelihood of needle dislodgement, which may result in a significant blood loss.
50. Never try to open the door of the NxStage System One Cycler when the door lock symbol is on. If the door is opened by force, all safety systems will no longer be active, which may cause patient injury or death. If the door must be opened while the patient is connected, press the STOP key, immediately clamp all fluid and blood lines, turn the power switch OFF on the Cycler, and then open the door of the Cycler.
51. When a Yellow Caution is displayed, some safety systems may not be active. Monitor the system and the patient until the Green Safe Operating condition returns. Failure to do so may cause patient injury or death.
52. Before starting treatment, check the patient blood lines for air. Check again before and during rinseback. Follow the instructions to remove air before starting treatment or rinseback. Failure to remove air from the patient blood lines may cause an infusion of air, which may lead to an embolism.
53. Do not disconnect and reverse patient blood lines during treatment. This may cause an infusion of air into the patient blood lines, which may lead to an embolism.

54. The NxStage System One Cycler may not detect slow fluid or blood leaks from loose connections, faulty components, venous access disconnection, vascular needle dislodgement, or other potential causes. Leaking fluids may cause blood loss, injury, or death. Leaking fluids on the floor may also cause a person to slip or fall.

    To reduce the risk of fluid or blood leaks, or accidental disconnections:

    - Keep vascular access sites and all Cartridge connections visible throughout the treatment. Do not cover sites or connections with a blanket, or clothing, or any objects that block the view of the site and connections.
    - Before starting treatment, make sure all manual connections are secure and fluid-tight, but not over-tight.
    - A trained and qualified observer must check the system for blood and fluid leaks during treatment and pay close attention to the blood line and access connections, especially when the patient is connected and disconnected. If any leaks are found and cannot be stopped, end the treatment and rinse back the patient's blood, unless the center gives instructions not to rinse back. Do not rinse back the patient’s blood if there are clots or air in the blood circuit or in the patient blood lines. Do not rinse back if the blood is hemolyzed.
    - Before connecting the patient, make sure that there is no blood or other lubricious fluid on the Cartridge connectors and mating connectors, such as on vascular access devices. Lubricious fluids, including but not limited to blood, silicone oil, and povidone iodine-based disinfectants on mated luer-connections may significantly increase the chance of accidental disconnections.
    - Strictly follow the center’s procedure for taping the blood lines and access device connections to the patient. Check all connections and secure taping again, if necessary, when the patient changes position, when changing the dressing of the catheter, or if there is stress on the Cartridge tubing or blood access device.
    - Use only Dialyzers, catheters or AVF needles, and other devices that have locking connectors in compliance with ISO 594 parts 1 and 2 and ISO 8638 when connected to the Cartridge. With repeated patient treatments, a temporary or permanent catheter’s connectors may change shape and no longer comply with ISO 594 parts 1 and 2 and become incompatible with the Cartridge. Using incompatible connectors with the Cartridge may cause blood loss, patient injury, or death. Contact the device manufacturer for all compliance questions.

55. Follow your center's instructions for rinsing back blood at the end of treatment. Blood that is left in the blood lines after rinseback will result in blood loss.
56. During a manual rinseback, do not apply excessive pressure or use devices that apply pressure on the saline bag (for example, blood pressure cuffs). The use of excessive pressure or a device that applies pressure to the saline bag may cause an infusion of air into the patient blood lines, which may lead to an embolism.
57. When performing manual rinseback, the NxStage System One Cycler door is open, which deactivates all safety systems. The operator must visually monitor for air in the patient blood lines, to prevent an infusion of air, which may lead to an embolism.
58. There are no operator or customer technician serviceable parts in any NxStage equipment. Unless otherwise instructed or authorized, NxStage or its agent must perform all maintenance and repair. No changes or modifications to any NxStage equipment are allowed without NxStage's authorization. Unauthorized changes or modifications to equipment may impact performance which may lead to patient or operator injury or death.
59. Clean and disinfect NxStage equipment in a well-ventilated environment in accordance with instructions included in this User Guide. Failure to follow these instructions increases the risk of exposure to infectious diseases and may also cause damage to the equipment.

Precautions

A precaution or caution is a statement that alerts you to the possibility of a problem with the device associated with its use or misuse. Such problems include device malfunction, device failure, damage to the device, or damage to other property.

⚠ PRECAUTIONS

1. Federal law (USA) restricts this device to sale by or on the order of a physician or properly licensed practitioner.
2. The maximum dialysate flow rate for the NxStage System One is 300 ml/min. Consider this when prescribing dialysis.
3. Do not use the Cartridge for more than 72 hours or 864 liters of blood processed.
4. The NxStage System One has only been studied for up to 4 hours of hemodialysis therapy in the home setting.
5. Do not alter any NxStage disposables. Performance of altered disposables cannot be guaranteed.
6. Store and transport NxStage disposables and equipment in accordance with applicable Instructions for Use or labeling. Failure to do so may affect performance.
7. Follow your center's instructions for steps to take in case of emergency. Each home patient should develop a personal disaster plan with their center to address the actions that they should take in the event of a natural or other disaster affecting their home such as a fire, flood or loss of electrical power.
8. In a low humidity environment, static electricity can build up and you will produce an Electrostatic Discharge (ESD) to any conductive surface, resulting in a small electric shock. The NxStage System One Cycler and its accessories have conductive surfaces. Static electricity can especially build up when removing the plastic outer wrap from the dialysate bags, therefore it is recommended that you grasp the IV Pole or saline hook to discharge any built up static electricity before hanging the bags.

9. Preventive maintenance on NxStage equipment must be performed in accordance with this User Guide or applicable Instructions for Use. When the Cycler displays a Yellow Caution 71, it is time to contact Technical Support or an authorized distributor to schedule maintenance on the Cycler.
10. After use, discard all disposables in accordance with local, national and federal regulations as instructed by your center. Use universal precautions when disposing of Cartridges.
11. The clamps included on disposables are intended to be used to allow flow when opened and stop flow when closed. They are not intended to be used to control the rate of flow.
12. It is the responsibility of the healthcare provider to make sure that the procedures to return the product are followed.
13. Make sure that premixed Dialysate is at room temperature before using. If it is not at room temperature, outgassing of air may occur as the fluid is warmed, which may cause NxStage System One Cycler air alarms.
14. When an IV filter is used during treatment, a check valve is required. Failure to put the check valve between the blood path and IV filter may damage the IV filter.
15. If too many devices are plugged into the same electrical circuit, the circuit may become overloaded. The NxStage System One Cycler does not require a dedicated electrical outlet, however, to avoid overloading the circuit, plug the Cycler into a circuit separate from other devices.
16. Inspect all NxStage System One Cycler components for damage before use. If product is damaged, follow the procedures to return the product included in this User Guide.
17. Do not alter the factory-set height of the IV pole. The height of the IV pole is important to maintain adequate fluid flow. Altering the height of the IV pole may negatively impact system performance and result in nuisance alarms.
18. Refer to Electromagnetic Compatibility (EMC) specifications in this User Guide to make sure that the equipment is being operated within these specifications.
19. Keep all equipment out of direct sunlight to prevent the device from overheating.
20. Keep children and pets away from all equipment to prevent damage that may lead to poor system performance.

21. Allow the Cycler to adjust to a room temperature between 15°C and 37°C (59°F and 99°F) for at least one hour before use.
22. Allow the Cartridge to adjust to a room temperature between 15°C and 37°C (59°F and 99°F) for at least one hour before use.
23. Use caution when handling any Disposable Set to avoid tearing and puncturing.
24. The default value for System Setting #9 is zero (0) for hemodialysis which disables the automatic bolus feature. In certain geographic areas outside of the US, additional labeling provides more information on using the NxStage System One to deliver an automatic fluid bolus.
25. If you do not pass the NxStage System One Cycler's Prime and Alarms Test, repeat the test. If you do not pass again or you do not pass the Display Tests, do not connect the patient to the Cartridge. Call Technical Support.
26. Remove accumulated air as instructed prior to making patient connections to minimize the chance of NxStage System One Cycler air alarms after making patient connections.
27. Do not disconnect any Cartridge pressure pod monitoring line from the NxStage System One Cycler after priming the Cartridge, unless directed to do so in the Troubleshooting section of this guide. Doing so may result in inaccurate pressure readings and may lead to false cautions and alarms or failure of appropriate cautions and alarms to occur.
28. Do not allow fluid or blood to contact the NxStage System One Cycler's pressure sensor connection points. If this happens, return the Cycler for service. This is a preventive measure to make sure that the pressure readings are accurate. It also eliminates the potential for cross contamination.
29. Do not reprime a Cartridge that has been used on a patient. Failure to follow the instructions for repriming a Cartridge may cause damage to the Cartridge or misloading, and may impact system performance.
30. Keep all equipment free of dust by regularly cleaning around and under the equipment. Excessive dust on equipment can lead to poor system performance.

This page intentionally left blank.

NxStage Customer Service Center (United States only)
Tel: 1-866-NXSTAGE (1-866-697-8243)
Fax: 1-978-687-4809
Email: customerservice@nxstage.com

Outside the United States, contact your healthcare provider or distributor.

CE 0413

EC REP

MEDISYSTEMS EUROPE, S.P.A.
Via G. Galilei, 20
Sorbara Di Bomporto (MO)
Italy 41030

NxSTAGE® Invent. Improve. Inspire.

NxStage Medical, Inc.
350 Merrimack Street
Lawrence, MA 01843 USA

Section 15 – Sterilization and Shelf Life

15.0 Sterilization and Shelf Life

(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information

[redacted]

Section 16 – Biocompatibility

16.0 Biocompatibility

We are not introducing any new materials as a result of this 510(k) submission.

The NxStage Cartridge and Filter continue to comply with FDA's Blue Book memorandum G95-1 "*Use of ISO-10993 Biological Evaluation of Medical Devices Part 1: Evaluation and Testing*" and with FDA's Guidance for the Content of Premarket Notification Submissions for Conventional and High Permeability Hemodialyzers (8/5/98).

Section 17 – Software

17.0 Software

(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information

[redacted]

Section 18 – Electromagnetic Compatibility and Electrical Safety

18.0 Electrical Safety & Electromagnetic Compatibility (EMC) Testing

(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information

[redacted]

Section 19 - Performance Testing - Bench

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

Section 20 – Performance Testing - Animal

20.0 Performance Testing – Animal

Not applicable

Section 21 – Performance Testing – Clinical

21.0 Performance Testing – Clinical

NxStage has completed IDE G070128 and the supplement to IDE G070128 investigation "Comparison of Nocturnal Hemodialysis (NHD) and Short Daily Hemodialysis (DHD) with the NxStage System One." An executive summary of the study is provided in section 10, and the Clinical Study report CR0010-1 is provided in Appendix 4.

Section 22 – Class III Summary and Certification

22.0 Class III Summary and Certification

Not applicable. The proposed device is a Class II device.

Section 23 – Financial Certification or Disclosure Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

CERTIFICATION: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS

Form Approved: OMB No. 0910-0396
Expiration Date: December 31, 2015

TO BE COMPLETED BY APPLICANT

With respect to all covered clinical studies (or specific clinical studies listed below (if appropriate)) submitted in support of this application, I certify to one of the statements below as appropriate. I understand that this certification is made in compliance with 21 CFR part 54 and that for the purposes of this statement, a clinical investigator includes the spouse and each dependent child of the investigator as defined in 21 CFR 54.2(d).

Please mark the applicable check box.

☒ (1) As the sponsor of the submitted studies, I certify that I have not entered into any financial arrangement with the listed clinical investigators (enter names of clinical investigators below or attach list of names to this form) whereby the value of compensation to the investigator could be affected by the outcome of the study as defined in 21 CFR 54.2(a). I also certify that each listed clinical investigator required to disclose to the sponsor whether the investigator had a proprietary interest in this product or a significant equity in the sponsor as defined in 21 CFR 54.2(b) did not disclose any such interests. I further certify that no listed investigator was the recipient of significant payments of other sorts as defined in 21 CFR 54.2(f).

Clinical Investigators		
	See Attached List	

☐ (2) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that based on information obtained from the sponsor or from participating clinical investigators, the listed clinical investigators (attach list of names to this form) did not participate in any financial arrangement with the sponsor of a covered study whereby the value of compensation to the investigator for conducting the study could be affected by the outcome of the study (as defined in 21 CFR 54.2(a)); had no proprietary interest in this product or significant equity interest in the sponsor of the covered study (as defined in 21 CFR 54.2(b)); and was not the recipient of significant payments of other sorts (as defined in 21 CFR 54.2(f)).

☐ (3) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that I have acted with due diligence to obtain from the listed clinical investigators (attach list of names) or from the sponsor the information required under 54.4 and it was not possible to do so. The reason why this information could not be obtained is attached.

(b)(4) Confidential and Proprietary Information

[redacted]

This section applies only to the requirements of the Paperwork Reduction Act of 1995.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Public reporting burden for this collection of information is estimated to average 1 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the necessary data, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information to the address to the right:

Do NOT send your completed form to the PRA Staff email address below.

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

FORM FDA 3454 (4/13)

PSC Publishing Services (301) 443-6740 EF

23.0 Financial Certification or Disclosure Statement

(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information

[redacted]

Section 24 – Compliance with FDA Guidance on IDEs for Devices Indicated for Nocturnal Home Hemodialysis

24.0 Compliance with FDA Guidance on Investigational Device Exemptions (IDEs) for Devices Indicated for Nocturnal Home Hemodialysis dated April 15, 2008

NxStage's initial Nocturnal Home Hemodialysis IDE study was initially approved on December 19, 2007, which was prior to the release of the above referenced guidance. However, NxStage performed a review of the guidance document to ensure compliance with all applicable recommendations. A subsequent review was also performed for the supplemental Nocturnal Home Hemodialysis IDE study which was approved July 17, 2012. A summary of the review is provided below:

Table 13
Compliance with FDA Guidance on Investigational Device Exemptions (IDEs) for Devices Indicated for Nocturnal Home Hemodialysis dated April 15, 2008

Guidance	Where Documented	Comment
Physical and/or Electronic Description	Provided in original IDE application (G070128 dated July 20, 2007) and IDE Supplement (G070128/S dated April 12, 2012) as well as in section 11 of this submission.	The NxStage System One (NSO) is a cleared device (K140526) [redacted] (b) (4) (b) (4)
System Features and Functions	Provided in original IDE application (G070128 dated July 20, 2007) and IDE Supplement (G070128/S dated April 12, 2012) as well as in section 11 of this submission.	The NxStage System One (NSO) is a cleared device (K140526).
System Features and Functions - Alarms	Provided in NSO User's Guide and home hemodialysis training document (Appendix H of the Clinical Study Report CR0010).	Results of clinical utility, including number of alarms and time to respond to alarms, are provided in the clinical report (Appendix 4).

Table 13
Compliance with FDA Guidance on Investigational Device Exemptions (IDEs) for Devices Indicated for Nocturnal Home Hemodialysis dated April 15, 2008

Guidance	Where Documented	Comment
System Features and Functions – Remote Monitoring	Remote monitoring was not required as part CP0010.	Remote monitoring was not required for this study, however NxStage does have cleared device, OneView (K040074) that has the capability to provide remote monitoring if requested by a customer.
Software	Provided in original IDE application (G070128 dated July 20, 2007) and IDE Supplement (G070128/S dated April 12, 2012) well as in section 17 of this submission.	The rev of the NSO software is 4.10.
Reports of Prior Investigations	Provided in original IDE application (G070128 dated July 20, 2007) and IDE Supplement (G070128/S dated April 12, 2012)	NxStage conducted a study (CP0008) to pursue a specific home indication (G030235). Refer section 5.3 of CR0010 for more details.
Bench Testing	Provided in original IDE application (G070128 dated July 20, 2007) and IDE Supplement (G070128/S dated April 12, 2012).	The NxStage System One (NSO) is a cleared device (K140526).
Bench Testing - Use error related hazard analysis	See System One Fault Tree Analysis, HA0001	The NxStage System One (NSO) is a cleared device (K140526). HA0001 was updated to reflect use of the device in a nocturnal application.

Table 13
Compliance with FDA Guidance on Investigational Device Exemptions (IDEs) for Devices Indicated for Nocturnal Home Hemodialysis dated April 15, 2008

Guidance	Where Documented	Comment
Biocompatibility Testing	Provided in original IDE application (G070128 dated July 20, 2007) and IDE Supplement (G070128/S dated April 12, 2012) as well as in section 16 of this submission.	The device continues to comply with FDA's Blue Book memorandum G95-1 "*Use of ISO-10993 Biological Evaluation of Medical Devices Part 1: Evaluation and Testing*"
Sterility, Disinfection and Expiration Date Testing	Provided in original IDE application (G070128 dated July 20, 2007) and IDE Supplement (G070128/S dated April 12, 2012) as well as in section 15 of this submission.	The NxStage System One (NSO) is a cleared device (K140526). There are no changes to sterilization and shelf life as a result of this submission.
Human Factors Recommendations	Provided in original IDE application (G070128 dated July 20, 2007) and IDE Supplement (G070128/S dated April 12, 2012) as well as in UE0001.	The NSO is a cleared device (K140526) with in excess of [redacted] chronic treatments performed — most in the home environment. NxStage has taken into consideration human factors issues for the design/user interface features of the device. Simulated use testing was included in the IDE applications.
Previous Clinical Data	Provided in original IDE applications (G070128 dated July 20, 2007) and IDE Supplement (G070128/S dated April 12, 2012) as well as in Clinical Study Report CR0010-1 section 5 (Appendix 4).	The original NSO study (CP0008) to support the clearance for home hemodialysis was conducted under IDE G030235, and later cleared under K050525. Details of this and other related studies were provided in the IDE applications (G070128 and G070128/S) and are summarized again in the final report.

Table 13
Compliance with FDA Guidance on Investigational Device Exemptions (IDEs) for Devices Indicated for Nocturnal Home Hemodialysis dated April 15, 2008

Guidance	Where Documented	Comment
Investigation Plan	Provided in original IDE application (G070128 dated July 20, 2007) and IDE Supplement (G070128/S dated April 12, 2012) as well as in the Clinical Study Report in Appendix 4.	Please see Appendix 4 for the Clinical Study Report.
Study Design	Provided in original IDE application (G070128 dated July 20, 2007) and IDE Supplement (G070128/S dated April 12, 2012) as well as in the Clinical Study Report in Appendix 4.	Please see Appendix 4 for the Clinical Study Report.
Subject Monitoring and Monitoring by Care Partner	Provided in NSO User's Guide and home hemodialysis training document (Appendix H of the Clinical Study Report CR0010).	The NSO User's Guide has always warned that "A patient should never dialyze alone, regardless of whether they are trained and qualified." Additionally the training for the NHD study required that the patient's partner be trained and both the patient and their partner also had to take an exam. Please see Appendix 4 for the Clinical Study Report as well as Appendix H in the Clinical Study Report for the Home HD training program.

Table 13
Compliance with FDA Guidance on Investigational Device Exemptions (IDEs) for Devices Indicated for Nocturnal Home Hemodialysis dated April 15, 2008

Guidance	Where Documented	Comment
Monitoring of Dialysate Chemistries and Water Quality	Dialysate for use with the NSO is available as pre-packaged pre-mixed sterile fluids (K033386 & K022913) or via the PureFlow SL (K140571, K111174 & K140571)	The dialysates used with the NxStage System One are already cleared devices and therefore are not the subject of this 510k.
Training	All subjects and their partners underwent training to perform NHD during the training/transition period. The training program was provided in the original IDE application (G070128 dated July 20, 2007) and IDE Supplement (G070128/S dated April 12, 2012) as well as in Appendix H of the Clinical Study Report in Appendix 4.	Training was a secondary endpoint of CP0010-1. The Home HD Training Program is provided in Appendix H of the Clinical Study Report.

Table 13
Compliance with FDA Guidance on Investigational Device Exemptions (IDEs) for Devices Indicated for Nocturnal Home Hemodialysis dated April 15, 2008

Guidance	Where Documented	Comment
Labeling	Provided in original IDE application (G070128 dated July 20, 2007) and IDE Supplement (G070128/S dated April 12, 2012) as well as in Appendix 1 of this submission.	Please see section 14 (proposed labeling) as well as Appendix 1 (predicate labeling) for the NxStage System One User's Guide. The NxStage System One Nocturnal Hemodialysis Supplement and NxStage System One User Guide were written following FDA's Guidance Document *"Write it right" - Recommendations for Developing User Instruction Manuals for Medical Devices Used in Home Health Care* and the *FDA Guidance on Medical Device Patient Labeling; Final Guidance for Industry and FDA Reviewers*. NxStage chose to follow these guidance documents when developing the Instructions for Use so that they would be understood by, and appropriate for, audiences such as lay users in the home environment.

Appendix 1 – Predicate Device Labeling

NxStage System One
User Guide

NxSTAGE®
Invent. Improve. Inspire.

NxStage® System One™
User Guide

Software Versions 4.5, 4.6, 4.7, 4.8 and 4.9

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

NC4820 Rev. 7 2014-05-21

This user guide describes the use of the NxStage System One. This guide is one part of a user-training program. This guide is applicable to NxStage System One Cycler chronic models CYC-D2E (NX1000-1), CYC-D2E (NX1000-3) and NX1000-4 for chronic renal replacement therapies.

Please note that the use of the NxStage System One, like all medical devices, involves some risks. Patients should consult with their physicians to understand the risks and responsibilities associated with home hemodialysis using the NxStage System One, including those described in this user guide.

WARNINGS

All NxStage equipment and disposables must be used as described in the applicable User Guides and Instructions for Use, and in accordance with a physician's prescription. Make sure that all User Guides are carefully read and understood, and are always available to the operator at the treatment location. Improper use may cause injury or death.

Treatment with the NxStage System One should only be done under the responsibility of a physician and performed by a trained and qualified person. A trained and qualified person must observe all treatments so that alarms and harmful conditions can be responded to promptly. Possible harmful conditions include, but are not limited to venous disconnects, inadvertent fluid administration, or excessive ultrafiltration. A patient should not dialyze alone, even if they are trained and qualified.

Customer Service and Technical Support

In the United States and Canada

Customer Service

For questions about ordering and supplies contact NxStage Customer Service:

Phone: 1-866-NXSTAGE (1-866-697-8243)

Fax: 1-978-687-4809

Email: customerservice@nxstage.com

Technical Support

For questions about equipment contact NxStage Technical Support:

Phone: 1-866-NXSTAGE (1-866-697-8243)

When calling Technical Support, have the following information available:

- Patient's name, name of person placing the call, and their relationship to the patient
- Dialysis center name, city, and state
- Serial number of cycler (4- or 5-digit number on back of cycler near the power cord)
- Cartridge lot number
- Whether cycler is in Prime or Treatment Mode
- If in Prime, which step number is shown in the green dialysate rate window?
- If calling about an alarm, which alarm number and color?

If using PureFlow SL also include:

- Serial number of PureFlow SL Control Unit (4- or 5-digit number on top of Control Panel door)
- Serial number of PureFlow SL Cabinet (6-digit number on front of PureFlow SL tub)
- Lot number of dialysate bags, or SAK and PAK

Outside the United States and Canada

Outside the United States and Canada, contact your local distributor for technical support and customer service.

Contents

NxSTAGE®
Invent. Improve. Inspire.

Chapter 1 Introduction

General information about using the NxStage System One includes:

Electromagnetic compatibility (EMC) notice

The equipment generates and uses radio frequency (RF) energy. It also radiates RF energy. For protection against electromagnetic interference (EMI), install and use the equipment according to instructions.

The equipment was tested and found to comply with the limits of acceptance specified in Standard IEC 60601-1-2 for Medical Products. These limits provide reasonable protection against EMI when using the equipment in the specified environments.

This equipment can be affected by portable and mobile RF communications equipment.

Do not stack this equipment with other equipment, except as indicated.

The equipment was tested using a NX1054 - Shielded LAN Cable, length 3.05 m (10 ft). Using other cables may result in increased emissions or decreased immunity.

See Chapter 7, Hardware specifications for additional information.

Indications for Use

The NxStage System One is indicated for the treatment of acute and chronic renal failure or fluid overload using hemofiltration, hemodialysis, and/or ultrafiltration, in an acute or chronic care facility. The system is also indicated for hemodialysis with or without ultrafiltration in the home.

All treatments must be administered under a physician's prescription, and must be observed by a trained and qualified person, considered to be competent in the use of this device by the prescribing physician.

Symbols

Table 1-1: Symbol definitions

	This symbol indicates a warning; consultation of the *User Guide* prior to equipment operation is critical to the safe operation of the device. A warning is a statement that alerts you to the possibility of serious injury, other adverse reactions, or death associated with the use or misuse of the NxStage System One.
	This symbol indicates a precaution. A precaution or caution is a statement that alerts you to the possibility of a problem with the device associated with its use or misuse. Such problems include device malfunction, device failure, damage to the device or damage to other property.
	The ON indication for the cycler.
	The OFF indication for the cycler. The "dot" indicates power is still available to the computer and devices connected to the AC outlet on the back of the cycler.
	This symbol indicates the catalog number.
	This symbol indicates the lot number.
	This symbol indicates the temperature storage limits.
	This symbol indicates the relative humidity range.
	This symbol indicates the Use-by-Date.
Rx Only	This symbol indicates Federal law (USA) restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

Table 1-1: Symbol definitions

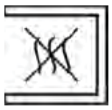
	This symbol indicates do not use if the product sterilization barrier or its packaging is compromised or if the packaging is damaged.
	This symbol indicates that the product is a sterile fluid pathway, sterilized by gamma irradiation.
	This symbol indicates that the product is a non-pyrogenic fluid pathway.
	This symbol indicates that the product is for single use only.
	This symbol indicates do not use a knife or other sharp object to open this product or its packaging.
	This symbol indicates that consultation of the instructions for use (operating instructions) is mandatory prior to use.
	This symbol indicates the product is not made with natural rubber latex.
	This symbol indicates the manufacturer.
EC REP	This symbol indicates the authorized representative in the European Community.
CE 0413	This symbol indicates compliance with the requirements for the European Union.
	This symbol indicates the date of manufacture.

Table 1-1: Symbol definitions

PHT DEHP	This symbol indicates that the product contains DEHP, which is commonly used to make PVC plastics more pliable. Animal studies indicate that repeated or prolonged DEHP exposure may result in adverse reproductive or developmental effects or both. While there is no conclusive data regarding the adverse effects in humans from DEHP exposure, certain populations such as children and pregnant or nursing women may be at the highest risk. Prior to using this product, consult with your physician for further information.
	This symbol indicates that separate waste collection is required for electrical and electronic equipment.
IPX1	This symbol indicates that the device meets the IPX1 "Drip Proof" requirements of IEC 60529.
	This symbol indicates Class II electrical equipment.
IP22	This symbol indicates the device meets the IP22 "Effective against >12.5 mm Objects," and "Drip Proof" requirements of IEC 60529.
	This symbol indicates a fuse.
	This symbol indicates Alternating Current (AC) voltage.
	This symbol indicates Type BF Applied Part. It is provided to tell the operator, patient, or both that the applied part is isolated (floating) from the rest of the device and therefore provides a higher degree of protection against electric shock and allowable leakage currents than a non-isolated applied part.
R	This symbol indicates the date of last service.

Table 1-1: Symbol definitions

	This symbol indicates Radio Frequency (RF) transmitter: Intentional RF transmissions for wireless communications.
	This symbol indicates that the NxStage System One Cycler has been tested by a Nationally Recognized Testing Laboratory (NRTL) per OSHA in the United States and by a Standards Council of Canada Testing Organization (TO) and a Certification Organization (CO) in Canada for conformance to the listed product safety standards.
	This symbol indicates the range of temperatures the equipment must be operated in.

General warnings

A warning alerts you to the possibility of serious injury, other adverse reactions, or death associated with the use or misuse of the NxStage System One. There are additional warnings throughout this guide.

WARNINGS

Treatment with the NxStage System One should only be done under the responsibility of a physician and performed by a trained and qualified person. A trained and qualified person must observe all treatments so that alarms and harmful conditions can be responded to promptly. Possible harmful conditions include, but are not limited to venous disconnects, inadvertent fluid administration, or excessive ultrafiltration. A patient should not dialyze alone, even if they are trained and qualified.

All NxStage equipment and disposables must be used as described in the applicable User Guides and Instructions for Use, and in accordance with a physician's prescription. Make sure that all User Guides are carefully read and understood, and are always available to the operator at the treatment location. Improper use may cause injury or death.

Always follow universal precautions when operating the NxStage System One, cleaning or disinfecting equipment, or observing patient treatment, to avoid infection.

Weigh the patient before treatment to make sure that the appropriate ultrafiltration volume is calculated. Follow the physician's prescription for maximum volume and rate of fluid to be removed. Removing too much or too little fluid, or removing fluid too quickly, may cause patient injury. In addition, prescribing physicians should be aware that certain patients, such as low weight patients and patients at or near their dry weight, may be unable to tolerate fluid balance variations in amounts less than the total fluid accuracy tolerances of the NxStage System One Cycler and other ancillary fluid delivery devices. These patients must be closely monitored for signs and symptoms of excessive ultrafiltration or fluid overload. Refer to the System One User Guide for additional information on ultrafiltration during dialysis.

WARNINGS

- Hemodialysis may result in significant changes in the blood concentration of electrolytes and glucose and in the patient's volume status. Appropriate monitoring of the patient's hemodynamic, fluid, electrolyte, and acid-base balance should be performed regularly, per physician orders, to ensure appropriate response to therapy. Failure to do so could result in inappropriate therapy for the patient.
- The Dialyzer may remove medications given into the Arterial Patient Line (red clamp). Refer to the medication manufacturer's labeling for clearance characteristics of any medications given into the Arterial Patient Line (red clamp). Follow the policies and procedures of your center for infusing fluid or medications into the blood circuit. Infusing fluids or medication incorrectly may reduce the dose given to the patient or cause harm to the patient.
- When a heart rate monitor is used during treatment, the NxStage System One Cycler's pumps may produce electrostatic discharges that may appear as artifacts on the monitor's screen. The electrostatic discharges produced by the Cycler will not harm the patient. Look at the monitor's screen when the Cycler's pumps are running and when they are stopped to confirm it is the Cycler that is producing these artifacts.
- Observe the patient for allergic reactions, especially if the patient has a history of allergies. If the patient has an adverse reaction, stop the treatment and follow your center's instructions.
- If you are using a Cartridge without a pre-attached Dialyzer, make sure that the Dialyzer you select has a maximum transmembrane pressure (TMP) of at least 500 mmHg or higher. Use of a Dialyzer with a lesser TMP rating increases the risk of a blood leak. NxStage defines TMP as the difference between venous pressure and effluent pressure. Follow the Dialyzer manufacturer's instructions for use for TMP rating.
- Do not use any supplies after their expiration date or Use-by Date, or the supplies may not perform as intended.

WARNINGS

Manual fluid boluses and fluid consumed during treatment are not included in the System One fluid balance calculations. Excessive fluid boluses, whether intentional or unintentional, or failure to account for consumed fluid during treatment, may cause patient injury. Include fluid boluses and the volume of fluid consumed in manual fluid balance calculations. Make sure that the administration lines used for manual bolus or rinseback are clamped after use.

Extreme high or low fluid temperatures may cause injury or death. The NxStage System One Cycler checks for high and low dialysate temperature during normal operation. The temperature of rinseback and manual bolus fluids is not monitored at all. At dialysate rates lower than 5 L/hr, low fluid temperatures are more likely to occur. If System Setting #79 is set to 0 or the Cycler software version is less than 4.9, low temperature monitoring is disabled at all times. In instances of low fluid temperatures, the patient may feel discomfort, which may include but is not limited to shivering. Sedated or comatose patients should be watched carefully when fluid temperature is not monitored.

The NxStage System One disposables are for single use only unless otherwise indicated. Do not reuse or resterilize. Materials used to make the disposables may not withstand reprocessing or reuse or both. Reuse or resterilization of the disposables may result in, but is not limited to, the following problems:

- risk of cross contamination
- material degradation
- biocompatibility issues
- endotoxin reactions
- failure of the disposable to perform as intended.

WARNINGS

- The NxStage System One Cycler will automatically remove the rinseback volume when both the System Setting #38 is set to 1 and the Ultrafiltration pump rate (UFR) is greater than 0. Automatic removal of the rinseback volume is not displayed to the operator. Therefore it is important to account for the rinseback volume when calculating the ultrafiltration rate and volume for the treatment. Do not add the rinseback volume to the targeted ultrafiltration volume when the Cycler is set to automatically remove the rinseback volume or excess ultrafiltration will result. For patients that may be unable to tolerate even small fluid balance changes, such as low weight patients and patients at or near their dry weight, the excess ultrafiltration may result in hypotension or hypovolemia which may cause patient injury or death. When automatic removal of the rinseback volume is not desired, System Setting #38 should be set to 0.
- In order to avoid electric shock, patients with a central venous catheter must not touch or be in contact with any AC powered electric devices during their treatment. Examples include but are not limited to, electric blankets or heating pads, electric lamps or lights, computers that are plugged into an electrical outlet, and electric powered chairs.
- Physicians must ensure that central venous catheters are not placed in the right atrium. The risk of microshock to the patient resulting in fibrillation is increased when the tip of a central venous catheter placed in the right atrium touches the atrium wall during use of the NxStage System One.
- Caution should be taken with babies and young children around the System One and PureFlow SL. The disposable lines or bags pose a strangulation hazard. The disposables also contain small parts that pose a choking hazard if swallowed.
- The NxStage System One contains alarms that may be configured by the operator. The operator should check that the current alarm settings are correct for the patient. Incorrect settings may cause injury or death.

General precautions

A precaution or caution is a statement that alerts you to the possibility of a problem with the device associated with its use or misuse; such problems include device malfunction, device failure, damage to the device or damage to other property. Additional precautions can be found throughout this guide.

⚠ PRECAUTIONS

⚠ Federal law (USA) restricts this device to sale by or on the order of a physician or properly licensed practitioner.

⚠ The maximum dialysate flow rate for the NxStage System One is 300 ml/min. Consider this when prescribing dialysis.

⚠ Do not use the Cartridge for more than 72 hours or 864 liters of blood processed.

⚠ The NxStage System One has only been studied for up to 4 hours of hemodialysis therapy in the home setting.

⚠ Do not alter any NxStage disposables. Performance of altered disposables cannot be guaranteed.

⚠ Store and transport NxStage disposables and equipment in accordance with applicable Instructions for Use or labeling. Failure to do so may affect performance.

⚠ Follow your center's instructions for steps to take in case of emergency. Each home patient should develop a personal disaster plan with their center to address the actions that they should take in the event of a natural or other disaster affecting their home such as a fire, flood or loss of electrical power.

⚠ PRECAUTIONS

⚠ In a low humidity environment, static electricity can build up and you will produce an Electrostatic Discharge (ESD) to any conductive surface, resulting in a small electric shock. The NxStage System One Cycler and its accessories have conductive surfaces. Static electricity can especially build up when removing the plastic outer wrap from the dialysate bags, therefore it is recommended that you grasp the IV Pole or saline hook to discharge any built up static electricity before hanging the bags.

⚠ Preventive maintenance on NxStage equipment must be performed in accordance with this User Guide or applicable Instructions for Use. When the Cycler displays a Yellow Caution 71, it is time to contact Technical Support or an authorized distributor to schedule maintenance on the Cycler.

⚠ After use, discard all disposables in accordance with local, national and federal regulations as instructed by your center. Use universal precautions when disposing of Cartridges.

⚠ The clamps included on disposables are intended to be used to allow flow when opened and stop flow when closed. They are not intended to be used to control the rate of flow.

⚠ It is the responsibility of the healthcare provider to make sure that the procedures to return the product are followed.

Aseptic technique

Treatment with the NxStage System One requires access to the patient's blood. This may expose patients, caregivers, and observers of the treatment to agents that can cause infection.

Users of the equipment must use aseptic technique to minimize infection. Examples of aseptic technique include washing hands before making connections or disconnecting parts of the equipment or disposables, not touching line connections and inside the lines with caps, keeping supplies in a clean and dry environment.

Universal precautions

Universal precautions are medical procedures to follow when caring for patients to prevent contamination from potentially infectious blood and bodily fluids. Personal protective equipment such as gloves, face shields, and gowns must be worn when opening the blood circuit or accessing the blood or waste. Patients must wear personal protective equipment to prevent contamination to hands and clothes. If you are exposed to blood or bodily fluids, always treat them as potentially infectious.

Emergency backup

Your dialysis center must have an emergency backup plan to provide your dialysis treatment if your equipment needs repair, service, or is not available for use. An emergency backup plan may tell you:

- To go to your center for treatment
- To go to another center that has an agreement with your center for emergency backup
- To receive a machine before your next treatment

Notify your center if problems with your equipment or supplies prevent you from performing your treatment.

Returning your product

PRECAUTION

It is the responsibility of the healthcare provider to make sure that the procedures to return the product are followed.

In the United States and Canada

To return a product to NxStage, you need a return authorization (RA) number. Contact Customer Service or Technical Support to receive an RA number and a returns kit with instructions for packing, labeling, and shipping the product.

Before shipping the NxStage System One, follow the cleaning instructions given in Chapter 6, Maintenance. Always notify your center when you need to return a product to NxStage.

Address for returns

NxStage Medical, Inc.
Attn: Customer Service
350 Merrimack Street Lawrence, MA 01843 USA

Email: customerservice@nxstage.com

Outside the United States and Canada

Contact your local center or distributor for product return procedures.

Disclaimer

NxStage Medical, Inc. is not responsible or liable for any NxStage System One performance failure when the failure is due (in whole or in part) to any misuse of or modification to the system or its operations. This includes, without limitation:

- The failure to have all operating procedures performed by a fully trained and qualified person.
- The failure to maintain proper electrical connections fully compliant with all codes, system specifications, and applicable international electrical standards (IEC) requirements.
- The failure to use the system at all times in accordance with this user guide.
- The failure to use only approved devices with the NxStage System One.

Conventions used in this guide

NxStage uses the following type-style conventions in this guide:

Table 1-2: Conventions

Style	Description	Example
KEYS/KNOBS	References to keys or knobs on the cycler, warmer, and PureFlow SL.	Press the **STOP** key
Modes	References to modes of operation.	The cycler is in Treatment Mode
Cross-reference	Cross-reference to a heading within this documents.	See **Ultrafiltration,** page 2-4.
Title	References to user guides for other NxStage equipment.	*NxStage PureFlow SL User Guide.*

Table 1-3: Important Keys

Key	Name	Actions
	**ADD FLUID**	• In Prime Mode - Begins Prime and Alarm Test • In Rinseback Mode - Returns blood
	**TREATMENT**	• Begins therapy • Continues therapy if it has stopped
	**STOP**	Single press • During treatment - Stops all pumps. • During alarm - Starts alarm recovery. Press and hold for two seconds • In Treatment Mode - Ends treatment • In Rinseback Mode - Ends rinseback
	**MUTE**	Silences alarms and cautions.
	**VOLUME TOGGLE**	• Press once to change the display from rate to volume. • Press again to return to the rate display or wait for the display to return automatically.
	**UP** Adjustment Arrows	• To increase
	**DOWN** Adjustment Arrows	• To decrease

Glossary

See Chapter 8, Glossary for the common terms and their meaning used in this guide.

Pictures

The pictures in this user guide are for example only. Treatment values shown in pictures are for example only. Always use the treatment values from your prescription and your cycler control panel during treatment.

Chapter 2 The NxStage System One

The NxStage System One is for short term (acute) and long term (chronic) renal replacement therapies. The System One and its components work together to deliver your treatment from beginning to end.

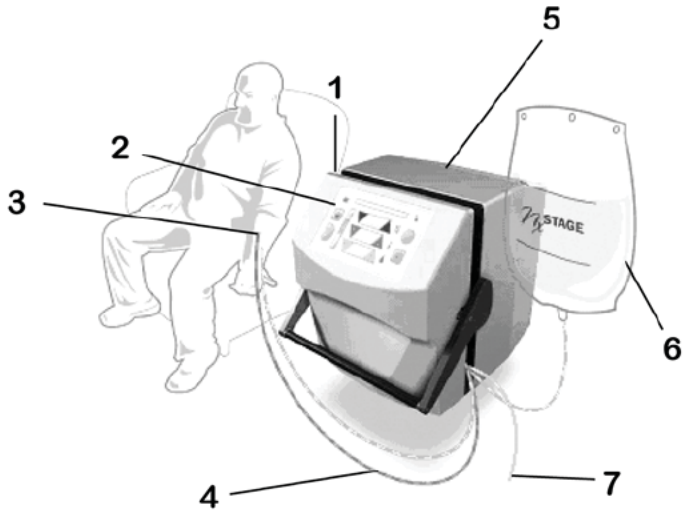
An introduction to dialysis

Dialysis is needed when the kidneys are no longer able to clean the blood of wastes or remove extra fluid. The three types of dialysis are hemodialysis, hemofiltration, and hemofiltration with or without ultrafiltration.

Kidneys have several functions in the body. The most well known function is to make urine. When the kidneys can no longer filter the blood and make urine, there is a buildup of waste products and excess fluid in the blood. Dialysis removes waste and excess fluid from the blood of patients.

A dialyzer filters the blood of waste products and removes excess fluid from the blood. A mix of water and electrolytes, called the dialysate, is pumped through the dialyzer to remove waste products like urea and creatinine from the blood. It does not remove the blood cells, proteins, and important substances the body needs.

Figure 2-1: The therapy system



1	Dialyzer (not shown)	5	Machine
2	Control panel	6	Dialysate
3	Vascular access	7	To drain
4	Blood tubing set		

The vascular access

The vascular access is the site on the patient's body where blood is removed and returned during dialysis. The three types of vascular access for dialysis are the fistula, graft, and catheter. From the vascular access, the blood is pumped through a blood circuit outside the body. The blood goes through the dialyzer where the waste products and excess fluid are removed. The filtered blood is returned to the body through the vascular access.

The dialysis machine

The dialysis machine controls the flow of the dialysate. It also controls the flow of blood while it is outside the body. The dialysis machine has a control panel to enter the treatment settings prescribed by a doctor. The machine also monitors the treatment, which helps keep the patient safe.

Alarms alert patients and caregivers to potential dangers that need prompt attention. To protect the patient, NxStage labeling requires that a trained and qualified person must observe all treatments so that alarms and dangers are recognized and treated promptly. Patients should not dialyze alone. A disconnected blood line, errors in fluid administration, or ultrafiltration errors are examples of potential dangers during treatment.

The dialyzer

The dialyzer is a filter. It has many tiny tubes through which the blood flows. The tubes are made of a very thin membrane with very small holes. The small holes keep blood cells, proteins, and other important substances from passing through the membrane into the dialysate. Smaller waste products in the blood like urea, creatinine, potassium, and extra fluids pass through the membrane.

During dialysis, the dialysate fluid flows along the outside of the tubes. The waste products flow into the dialysate. After the dialysate passes through the dialyzer, it is sent to a drain.

The prescription

The doctor writes a prescription for each patient. A common prescription includes the type of dialyzer to use and the chemical composition of the dialysate. It also includes the frequency and duration of treatment, the rate of blood flow, and the rate and volume of dialysate to use.

Risks of dialysis therapy

Use of the NxStage System One, like all medical devices, involves some risks. Risks may be mild or severe. Common risks during treatment include anxiety, back pain, bleeding, blood clotting, chest pains, cramps, depression, dizziness that could result in fainting, electrolyte imbalance, fluid overload, fatigue, fever, headache, high blood pressure, infection, itching, low blood pressure, low red blood cell count, nausea, shakes and chills, and vomiting.

Less common risks include allergic reaction including severe hives, blockage of a blood vessel by an air bubble, damage to the vascular access, decrease in platelet count, fluid build-up in the lungs, heart rhythm disturbances, heart attack, seizure, shock, stroke, and even death.

To help control the risks of dialysis, check the blood pressure, vital signs, and general well-being of the patient at regular intervals during treatment. Identified early in the treatment, risks can be treated promptly.

Before treatment, review potential risks with your doctor. Review the potential risks given in this user guide.

Ultrafiltration

When the kidneys work well, they remove excess water from the body to maintain body weight without excess fluid. For patients on dialysis, it is necessary to remove this excess water to get the patient back to dry weight. Dry weight is the body weight without excess fluid.

Ultrafiltration is the process of removing excess fluid during dialysis to get the patient back to dry weight. The doctor or center determines the dry weight of each patient. Patients check their weight at the start of each treatment to determine how much fluid to remove during the treatment and to confirm that their dry weight is met at the end of treatment.

At the start of treatment, patients enter into their dialysis machine how much excess fluid to remove. This is called the ultrafiltration volume goal. They also enter how quickly to remove the excess fluid. This is called the ultrafiltration rate. It is important for patients and caregivers to enter the correct volume and rate given by their doctor or center to avoid potential risks and side effects.

Removing too much fluid or removing fluid too fast can affect the body in harmful ways, some life threatening. During and after treatment, it can cause low blood pressure, nausea, vomiting, dizziness, and muscle cramps.

If not enough fluid is removed during treatment, other side effects can occur. Between treatments, excess fluid can cause swelling of ankles, calves, face, or hands, difficulty breathing, coughing, and high blood pressure.

To prevent the risks and complications of ultrafiltration, during each treatment, do the following:

- Enter the ultrafiltration volume goal and rate in the dialysis machine as given by your doctor or center. See Chapter 9, System Settings.
- Remember to add the rinseback volume to the ultrafiltration volume goal if System Setting 38 is set to **0**.
- Do not remove excess fluid faster than the rate set by your doctor or center. Do not remove more fluid than the volume set by your doctor or center. Better yet, distribute the volume to be removed over the duration of the treatment. Be familiar with the symptoms of removing too much fluid or too little fluid.
- Use the correct dry weight. Measure the dry weight in kilograms, not pounds, to calculate the ultrafiltration volume goal. Use a digital medical scale that reads kilograms.
  - Weight yourself three times and average the three numbers. Each weight should be within 0.1 kg of each other. Disregard any weight above this number and average the remaining weights.
  - Do not eat or drink after measuring your pre-dialysis weight or during dialysis. You will gain weight if food or fluid is consumed during dialysis. If you drink after measuring your pre-dialysis weight or during treatment, add the amount you drank to the ultrafiltration volume goal.
- You should not drink for at least 30 minutes before or during the treatment, unless you have symptoms that suggest you need fluid. If you have symptoms (for example, you feel weak, very thirsty or dizzy) ask your center for guidance.

NOTE

At the end of treatment, determine the weight removed from the patient by comparing the patient's weight before and after dialysis. This value may be different from the ultrafiltration volume goal. Weight calculation or scale errors, food and drink taken during treatment can explain this difference. Sweating and breathing can also result in a small weight loss. The dialysis machine tolerances may also explain the difference in weight.

For more information, go to the National Kidney Foundation www.kidney.org and to the American Association of Kidney Patients www.aakp.org.

The NxStage System One

The NxStage System One is a complete system designed to provide many types of renal replacement therapies.

The system includes:

- A cycler to control your treatment
- A cartridge to route your blood and the dialysate
- A dialyzer attached to the cartridge to filter the blood
- Dialysate to clean the blood of waste products. Dialysate may be pre-mixed or made by the PureFlow SL.
  - Pre-mixed dialysate is commonly available in 5-liter bags
  - The PureFlow SL is an option to make your own dialysate instead of using pre-mixed solutions
- A warmer to warm the dialysate to a comfortable temperature

Some additional supplies that are needed to complete your treatment are listed on page 2-23.

The cycler is available with two maximum dialysate flow rates, see Table 2-1.

Table 2-1: Cycler Models

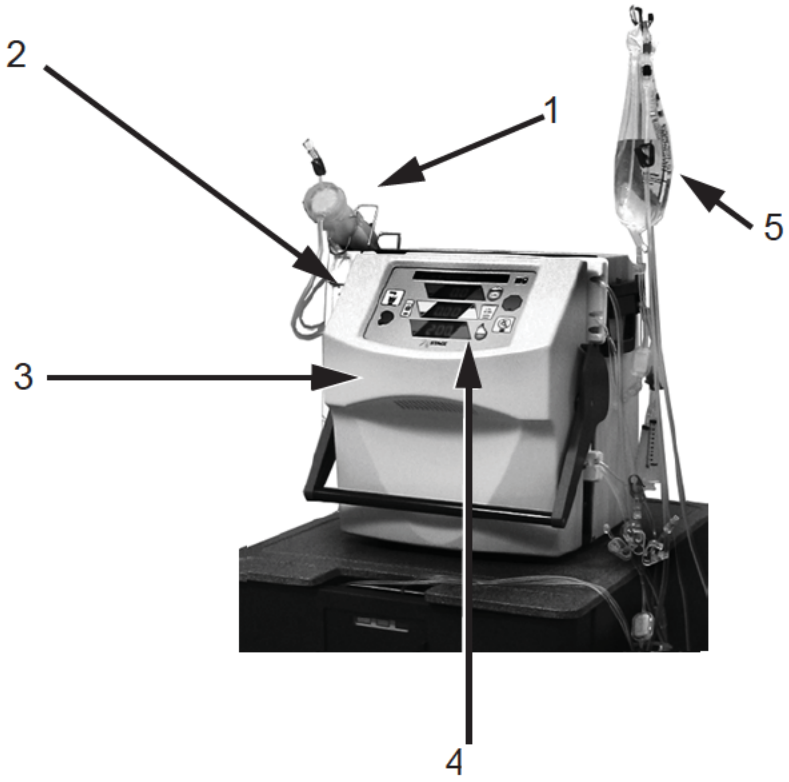
Brand Name	Part Number	Model Number	Max Dialysate Flow Rate
NxStage System One	CYC-D2E	NX1000-1	12 L/hour
NxStage System One S	CYC-D2E	NX1000-3	18 L/hour
NxStage System One S		NX1000-4	18 L/hour

The System One CYC-D2E (NX1000-1) cycler delivers up to 12 liters of dialysate per hour. The System One S CYC-D2E (NX1000-3) and the NX1000-4 deliver up to 18 liters of dialysate per hour.

To deliver higher flow rates with the CYC-D2E (NX1000-3) cycler or the NX1000-4 cycler, you must set up the system for high flow rate. See **High flow configuration**, page 3-9. When using a warmer, the dialysate rate must never exceed 12 liters per hour.

If your treatment calls for dialysate flow rates above 12 liters per hour, you cannot use a pre-mixed dialysate. In its place, you must use a dialysate prepared with the PureFlow SL. Contact your center to receive a PureFlow SL if your treatment calls for flow rates above 12 liters per hour.

Figure 2-2: The NxStage System One



1	Dialyzer (shown pre-attached)	Filters waste fluid, toxins, and electrolytes without removing blood cells or significant blood protein.
2	Cartridge (shown inside the cycler)	A single-use disposable containing all fluid pathways.
3	Cycler	Contains all pumps, sensors, and control to administer therapy.
4	Control panel	Allows operator to control and monitor therapy.
5	Fluids	*Priming/Bolus/Rinseback*: Sterile saline solution to prepare circuit for use and to administer intravenously to patient. *Therapy (dialysate or replacement):* Used to deliver prescribed therapy.

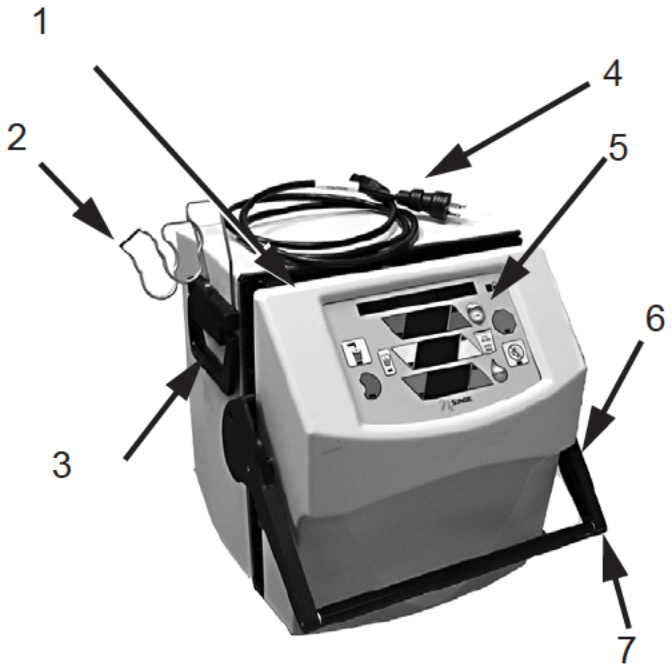
Cycler

The cycler controls the blood pump, the treatment, and monitors the safety systems.

NOTES

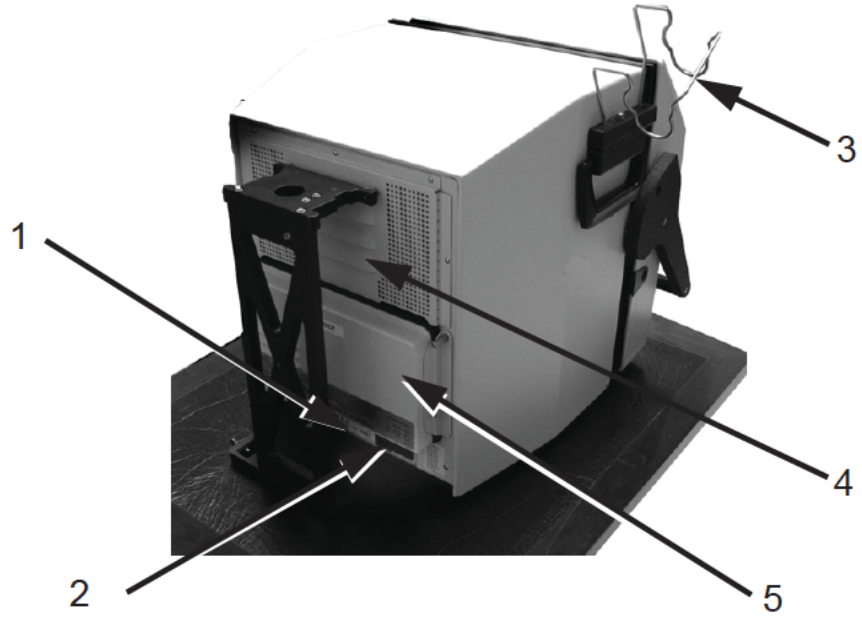
- The CYC-D2E (NX1000-1 and NX1000-3) cyclers have a power cord with a three-prong plug, with ground.
- The NX1000-4 cycler has a power cord with two prongs, no ground.

Figure 2-3: Front View (shown with AC power cord)



1	Serial Number Label	5	Control Panel
2	Filter Holder	6	Access Pressure Connection Point
3	Lift/Carry Handle: One on each side	7	Cycler Door Handle: Lift to Open, Push Down to Close
4	AC Power Cord		

Figure 2-4: Back View (Shown with table top stand)



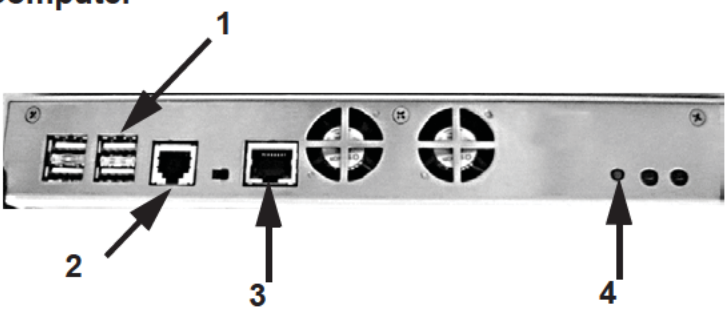
1	Serial Number Label	4	Cooling Fan
2	Power Input and Power Switch	5	Jewel Box or ConNxBox Computer (Jewel Box shown)
3	Filter Holder		

Figure 2-5: Power Indicator

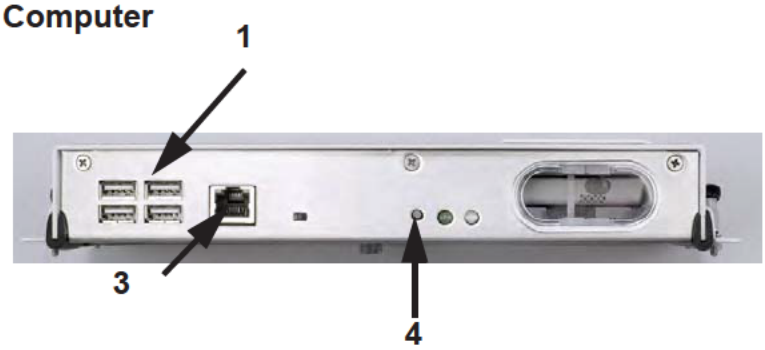
On	
Off	

Figure 2-6: Underside of computer

Jewel Box Computer



ConNxBox Computer

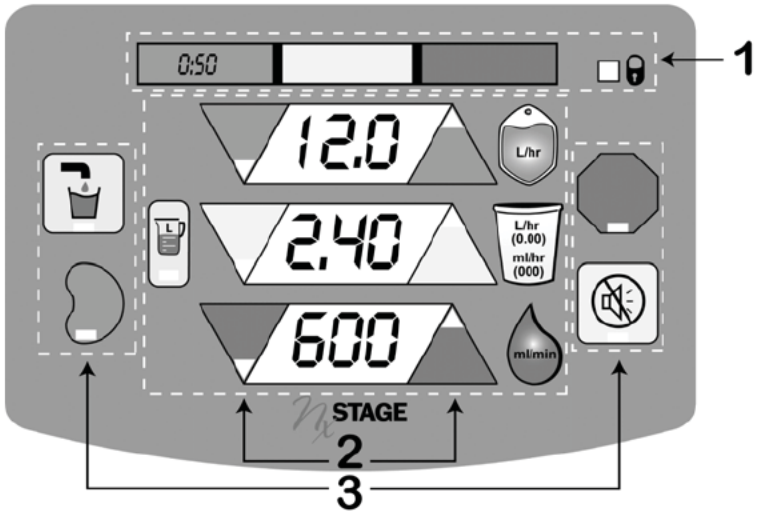


1	USB Ports	3	Network Connection
2	Telephone Connection (Jewel Box only)	4	Reset Button

Control panel

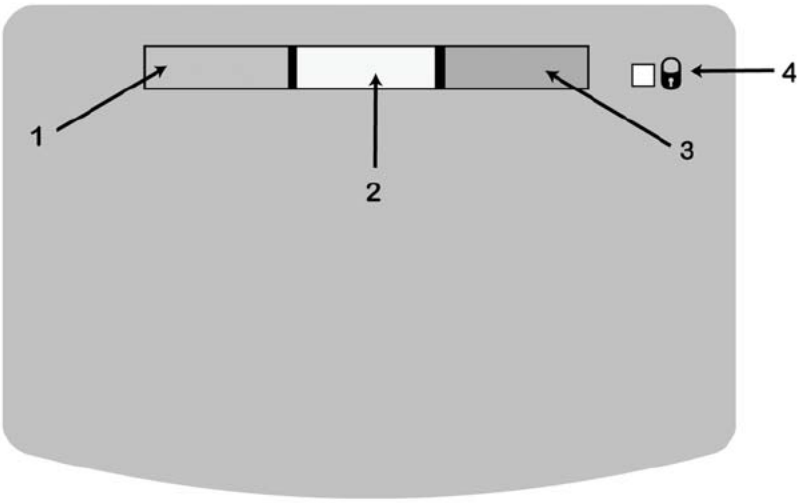
The control panel allows you to set and adjust your treatment parameters, and monitor the treatment.

Figure 2-7: The control panel



1	Status Window
2	Rate/Volume Controls
3	Treatment Keys

Figure 2-8: Status window

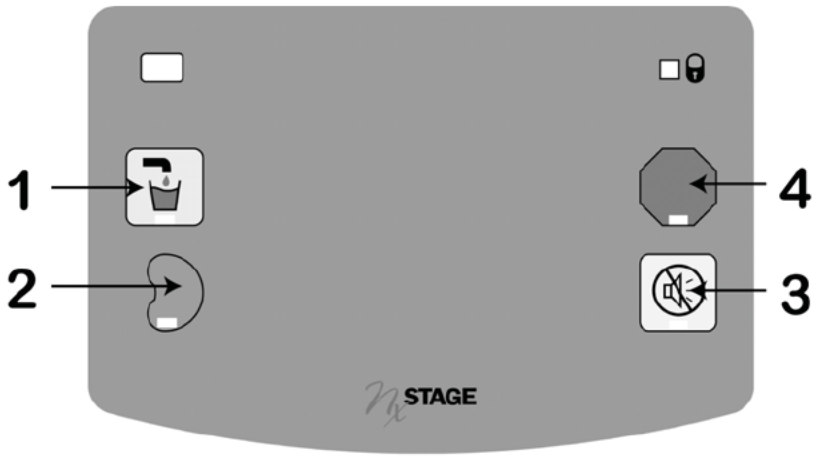


1	Green Operating	• Safe operating condition • No action required Also displays: – Time left in Prime – Time left in Treatment – Venous pressure – Effluent pressure – Flow fraction – Access pressure (optional)
2	Yellow Caution	• Caution event • Action may be required, see Chapter 5, Troubleshooting
3	Red Alarm	• Alarm event • Action will be required, see Chapter 5, Troubleshooting
4	Door Lock	When lit, door is locked

Treatment keys

The treatment keys allow you to adjust your treatment. Treatment keys light up when they are available for use. When the pumps are running, the **STOP** key is available for use.

Figure 2-9: Treatment keys and functions

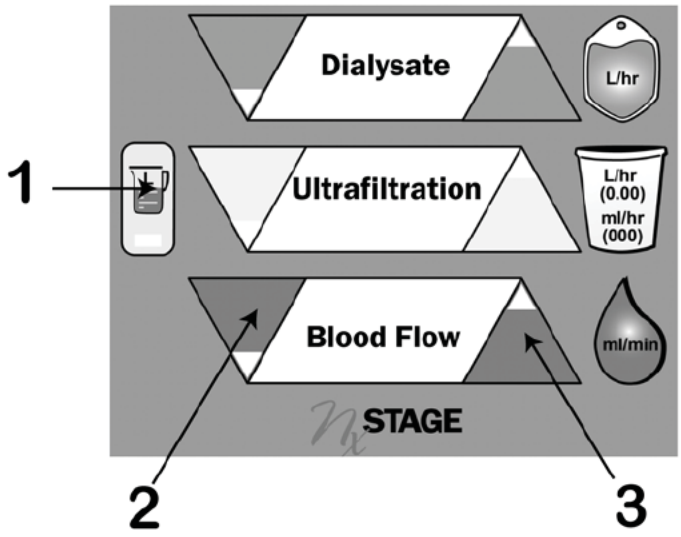


1	**ADD FLUID**	• Prime – Begins Prime and Alarm Test • Rinseback – Returns blood
2	**TREATMENT**	• Begins therapy or continues therapy if it has stopped
3	**MUTE**	• Silences alarms and cautions
4	**STOP**	• Single press – Stops all pumps (during treatment) or initiates alarm recovery (during alarm) • Press and hold (for two seconds) – Enters end of Treatment or end of Rinseback

Rate and volume keys

The rate and volume keys allow you to adjust the rate and volume for the dialysate, ultrafiltration, and blood flow. The rate and volume keys light up when they are available for use. The rate and volume keys are toggle-keys.

Figure 2-10: Rate/Volume controls and functions



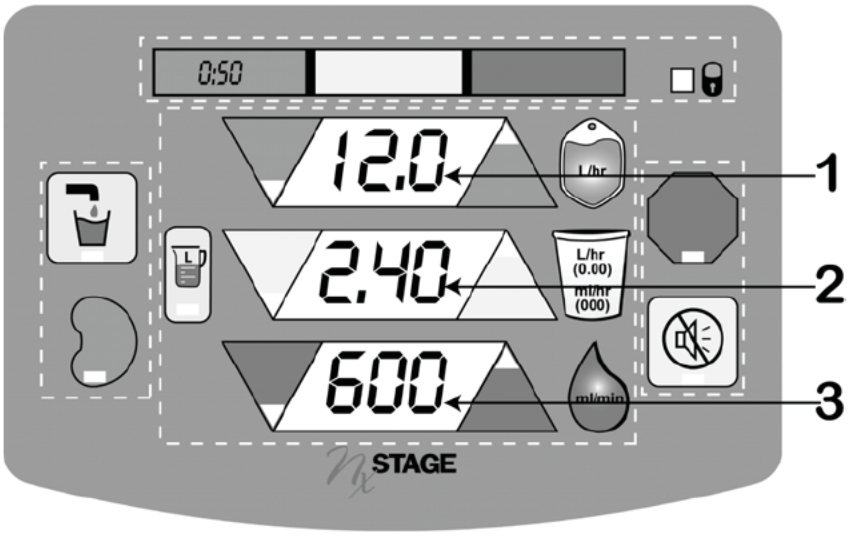
1	VOLUME TOGGLE	Changes window from rate to volume when the key is pressed.
2	DOWN ADJUSTMENT ARROWS	To decrease rate or volume
3	UP ADJUSTMENT ARROWS	To increase rate or volume

NOTE

Press the **VOLUME TOGGLE** key to change the windows from **rate** to **volume**. The volume windows returns automatically to the rate windows after a period of time, based on the cycler software version and your System Settings. See Chapter 9, System Settings.

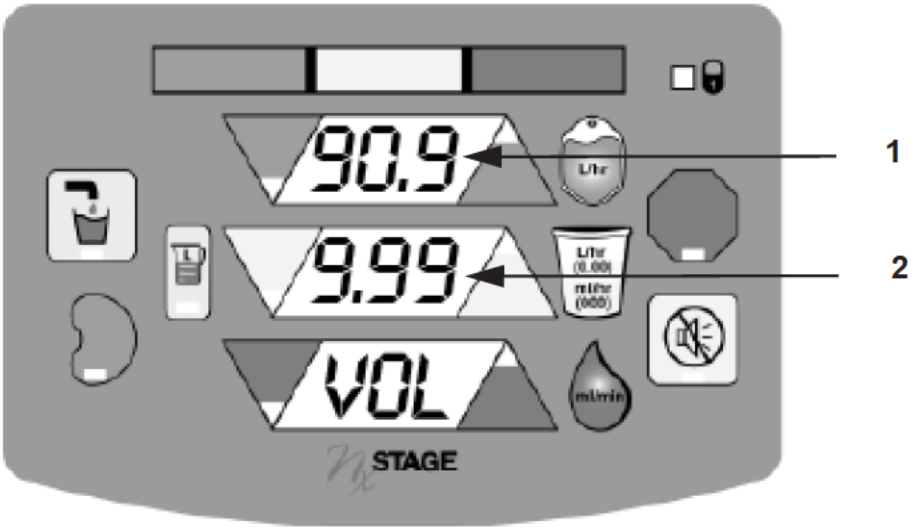
Rate and volume windows will show different information when the **VOLUME TOGGLE** key is pressed.

Figure 2-11: The rate window



1	Dialysate	Shows the flow of dialysate in liters per hour (L/hr).
2	Ultrafiltration	Shows how fast excess fluids are removed from the patient, in liters per hour (L/hr). See Chapter 9 for details.
3	Blood flow	Shows how fast the blood flows through the cartridge, in milliliters per minute (ml/min).

Figure 2-12: The volume window



1	Dialysate	Shows the volume of prescribed dialysate left to exchange, in liters.
2	Ultrafiltration	Shows the excess fluid left to remove, in liters. See Chapter 9.

Pump ON indicator

The pump ON indicator is a red dot in the lower right corner of each rate and volume window. It indicates which pumps are running during treatment or automatic rinseback. See Chapter 9 for details.

NOTE

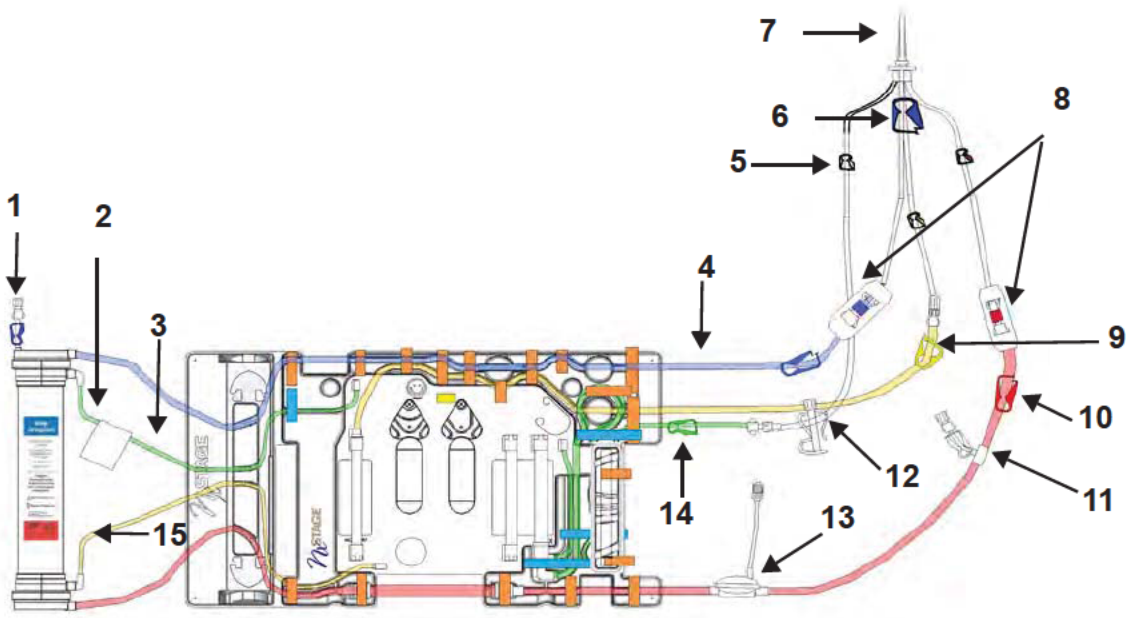
You can turn off the pump ON indicator. See System Setting 55.

Figure 2-13: Pump ON indicator location

Cartridge

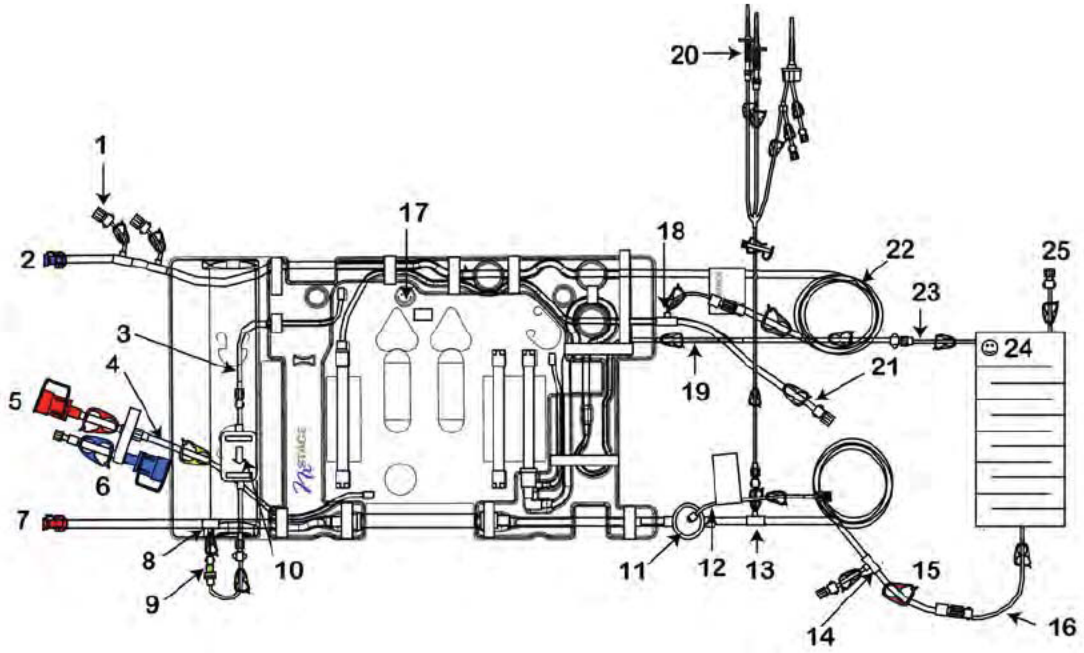
The cartridge is a single-use disposable. It includes a blood circuit and a fluid circuit. NxStage cartridges are available with or without a pre-attached dialyzer. The pictures in this chapter are examples of both kinds of NxStage cartridges. For other cartridges, check their instructions for use. This guide uses the NxStage cartridges with a pre-attached dialyzer for all examples.

Figure 2-14: Cartridge with a pre-attached dialyzer (priming configuration)



1	Post-dialyzer port (blue clamp)	9	Waste line (yellow clamp)
2	Cartridge information label	10	Arterial blood line (red clamp)
3	Dialysate outlet line	11	Saline "T" (white clamp)
4	Venous blood line (blue clamp)	12	Female-female connector
5	Saline line (white clamp)	13	Access pressure pod
6	Waste & Venous Line (Dual Line) clamp (blue clamp)	14	Dialysate inlet line (green clamp)
7	Priming spike	15	Effluent line
8	Connector tabs		

Figure 2-15: Cartridge without a pre-attached dialyzer (priming configuration)



1	Post-filter "T"	14	Pre-pump arterial "T"
2	Venous filter line (blue cap)	15	Arterial blood line (red clamp)
3	Therapy fluid line	16	Warmer inlet
4	Effluent line	17	Smiling face
5	Red Hansen connector	18	Waste "T"
6	Blue Hansen connector	19	Therapy fluid inlet
7	Arterial filter line (red cap)	20	Priming line (white clamps)
8	Pre-filter "T"	21	Waste line
9	Check valve	22	Venous blood line (blue clamp)
10	Air filter	23	Warmer outlet
11	Access pressure pod	24	Air trap
12	Access pressure pod monitoring line	25	Air vent
13	Saline "T"		

NxStage cartridges have two flow circuits: one for the blood and one for the dialysate.

Figure 2-16: Blood circuit (Cartridge loaded)

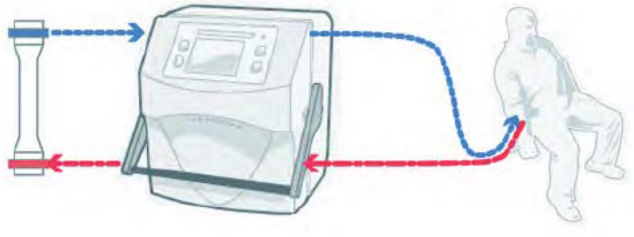
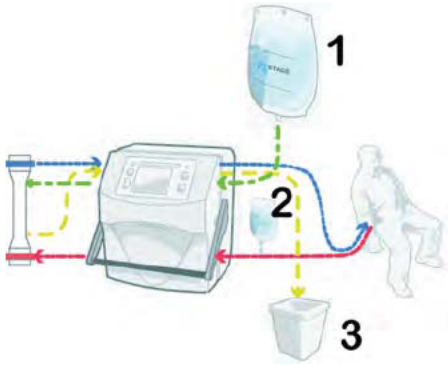


Figure 2-17: Fluid circuit (Cartridge loaded)

1	Dialysate
2	Saline
3	Waste

Figure 2-18: Blood and fluid circuits (Cartridge loaded)



1	Dialysate
2	Saline
3	Effluent

Supplies

Supplies for your treatment must be compatible with the NxStage System One. To use these supplies, check the instructions for use from the manufacturer.

The basic treatment supplies include:

- A dialyzer, if your cartridge does not have a pre-attached dialyzer
- Bags of pre-mixed dialysate
- Bags of sterile saline
- A digital scale
- A set of luer-lock syringes
- An anticoagulant prescribed by your doctor
- A female-to-female adapter (Molded Product Part MPC-150) or equivalent

WARNINGS

Use only physiologic fluids prescribed by a physician with the NxStage System One. Fluids must meet the requirements of local regulations, standards, or laws. Refer to fluid labeling for complete instructions. Fluids for hemofiltration, priming, bolus, and rinseback must be indicated for infusion. Dialysate fluids must be used for hemodialysis. The use of incorrect fluids may cause patient injury or death.

Do not use any fluid delivery devices that have a post-pump drip chamber or a maximum output pressure of less than 600 mmHg. Using these devices may cause blood loss, undesired fluid delivery, inaccurate flows, leaks, and other failure of the fluid delivery device to perform its intended function.

Do not connect to the accessory electrical outlet on the back of the Cycler any electrical items that are not specified as part of, or approved for use with, the NxStage System One Cycler. Unapproved or incompatible electrical items can create an electrical hazard.

Make sure only compatible devices are used with the NxStage equipment. Non-compatible devices may not perform as intended.

Sterile saline

Use the sterile normal saline:

- to prime and flush the cartridge and the dialyzer before treatment.
- to rinse back the blood.
- to give a bolus during treatment. Your doctor prescribes the amount of bolus needed for your treatment.
- to re-circulate the cartridge circuits after returning the blood. See **temporary disconnection,** page 4-50.

Digital scale

Use a digital scale to weight the patient before and after treatment. A medical-grade digital scale is preferred. Calibrate and set the scale to display the weight in kilograms (kg). Measuring the weight in kilograms prevent errors from converting pounds into kilograms.

Dialysate

WARNINGS

When using pharmacy-compounded fluids, the physician should make sure that the potential exposure to endotoxins does not exceed the USP/EP guideline levels for the prescribed therapy. If you are not sure, consult a pharmacist. If the potential exposure exceeds the guideline levels, use endotoxin-reducing IV filters with a working pressure higher than 15 psi. Using an IV filter with a working pressure lower than 15 psi may increase IV filter failure and may lead to a pyrogenic reaction. Refer to the *NxStage System One User Guide* for tables and conversions for endotoxins.

Physicians should take extra care when prescribing dialysate for patients with an increased level or an impaired metabolism of lactate ions, as in severe hepatic insufficiency.

PRECAUTION

Make sure that premixed dialysate is at room temperature before using. If it is not at room temperature, outgassing of air may occur as the fluid is warmed, which may cause NxStage System One Cycler air alarms.

The dialysate cleans waste products from the blood. It also helps keep electrolytes at normal levels in the blood. Dialysate comes in pre-mixed bags. The dialysate can also be prepared with the NxStage PureFlow SL by mixing water and concentrates. The prescription written by your doctor includes the type and volume of dialysate to use, the number of dialysate bags, and the administration rate.

Figure 2-19: NxStage PureFlow Solution

NOTES

- Store pre-mixed dialysate bags with lactate at room temperature between 15°C–30°C, as labeled. The International Conference on Harmonization (ICH) has verified by tests that dialysate stored at slightly higher or lower temperatures is safe to use. The ICH guidelines also allow that frozen bags of dialysate that have been thawed can be used safely for treatment. However, do not freeze dialysate bags. When frozen, the bag material becomes brittle and may leak.
- Dialysate bags kept at up to 40°C for a few days are safe to use after bringing them back to the recommended room temperature. The bag material may be discolored but it does not affect the quality of the dialysate.

Dialyzer

If using a cartridge without a pre-attached dialyzer, check the instructions from the dialyzer manufacturer for the maximum transmembrane pressure. Check the cartridge instructions for how to use the cartridge with the dialyzer.

WARNING

If you are using a Cartridge without a pre-attached Dialyzer, make sure that the Dialyzer you select has a maximum transmembrane pressure (TMP) of at least 500 mmHg or higher. Use of a Dialyzer with a lesser TMP rating increases the risk of a blood leak. NxStage defines TMP as the difference between venous pressure and effluent pressure. Follow the Dialyzer manufacturer's instructions for use for TMP rating.

Other supplies

Other supplies include:

- 20 ml luer-lock syringes
- Anticoagulant (prescribed by your doctor)
- Female-to female connector (Molded Product Part MPC-150), or equivalent
- IV air removal filter (Churchill Medical Part AMS 423-1) or equivalent (for hemofiltration)

WARNING

When an IV filter is used during treatment, a check valve is required. Failure to put the check valve between the blood path and IV filter may damage the IV filter.

This page intentionally left blank.

Chapter 3 Preparing for Use

Before starting your treatment, you need to set up the NxStage System One and prepare for treatment.

WARNINGS

A trained person must install and test the NxStage System One. Improper installation and testing could lead to malfunction or damage, which may cause patient injury or death.

Unless specifically recommended by NxStage, non-medical electrical equipment should not be used within 1.8 meters (6 feet) of the System One. Use of such equipment may affect patient safety.

Do not use NxStage equipment in the presence of a Flammable Anesthetic Mixture with Air, a Flammable Anesthetic Mixture with Oxygen, or a Flammable Anesthetic Mixture with Nitrous Oxide or in an oxygen-enriched or explosive atmosphere.

To avoid injury, the NxStage System One Cycler must be plugged into a properly grounded outlet, except for Cyclers with the model number NX1000-4. Ask a qualified electrician to check your outlet if you are not sure that it is properly grounded. Cyclers with the model number NX1000-4 do not require a grounded outlet for their safe operation; the model number is located at the rear of the Cycler.

Use only routers, switches, or other data networking equipment that comply with IEC 60950 if they are used to connect the computer on the back of the NxStage System One Cycler to a wired-data network. The use of equipment that does not comply with IEC 60950 may result in electric shock to the patient or operator.

Do not connect printers or other equipment to the computer on the back of the NxStage System One Cycler to reduce the risk of electrical shock to the patient or operator. USB thumb drives or USB connections from the PureFlow SL are the only devices than can be connected to the computer on the back of the Cycler.

WARNINGS

The NxStage System One Cycler weighs approximately 34 kilograms (75 pounds). To avoid injury, two people must lift and carry the Cycler. Close and lock the door of the Cycler before lifting and carrying it. Do not lift and carry the Cycler by the door handle. Use the grip points under the Cycler or the handles included on some models.

The maximum fluid volume for transporting the NxStage System One Cycler using the mobile base with the ComfortMate Fluid Warmer is 10 liters of fluid. Do not transport the Cycler with fluid using the mobile base if using the Express Fluid Warmer. The maximum fluid volume for stationary use of the Cycler with an IV pole is 29 liters of fluid when using the ComfortMate Fluid Warmer or 21 liters of fluid when using the Express Fluid Warmer. Fluid volume must not be exceeded and fluid must be evenly distributed on the IV pole to prevent accidental tipping of the Cycler.

Make sure that the NxStage System One Cycler and its ancillaries are attached securely to its mobile stand or placed on a table sturdy enough to hold the weight of the Cycler, its ancillaries, and fluid bags. Check the bolts on the mobile stand regularly to make sure that they are fastened securely, especially before moving the Cycler. If the bolts are not fastened securely, the Cycler, its ancillaries, or the fluid bags may fall and cause injury.

Use only the power cords supplied by NxStage or its authorized distributors. Do not connect portable multiple-socket outlets or extension cords to any NxStage equipment. Non-authorized or incompatible electrical power cords and outlets can create an electrical hazard.

Do not connect to the accessory electrical outlet on the back of the Cycler any electrical items that are not specified as part of, or approved for use with, the NxStage System One Cycler. Unapproved or incompatible electrical items can create an electrical hazard.

⚠ PRECAUTIONS

⚠ If too many devices are plugged into the same electrical circuit, the circuit may become overloaded. The NxStage System One Cycler does not require a dedicated electrical outlet, however, to avoid overloading the circuit, plug the Cycler into a circuit separate from other devices.

⚠ Inspect all NxStage System One Cycler components for damage before use. If product is damaged, follow the procedures to return the product included in this User Guide.

⚠ Do not alter the factory-set height of the IV pole. The height of the IV pole is important to maintain adequate fluid flow. Altering the height of the IV pole may negatively impact system performance and result in nuisance alarms.

⚠ Refer to Electromagnetic Compatibility (EMC) specifications in this User Guide to make sure that the equipment is being operated within these specifications.

⚠ Keep all equipment out of direct sunlight to prevent the device from overheating.

⚠ Keep children and pets away from all equipment to prevent damage that may lead to poor system performance.

Treatment environment

WARNINGS

In order to avoid electric shock, patients with a central venous catheter must not touch or be in contact with any AC powered electric devices during their treatment. Examples include but are not limited to, electric blankets or heating pads, electric lamps or lights, computers that are plugged into an electrical outlet, and electric powered chairs.

Physicians must ensure that central venous catheters are not placed in the right atrium. The risk of microshock to the patient resulting in fibrillation is increased when the tip of a central venous catheter placed in the right atrium touches the atrium wall during use of the NxStage System One.

The NxStage System One must be used in a treatment area that is safe, secure, and well organized. The treatment area is an area of 1.8 m (6 feet) around the equipment and patient. A safe treatment area includes keeping household pets away from the area to reduce the risk of injury or infection. Be careful if non-trained people, children, other family members or friends enter the treatment area.

The minimum requirements for a safe treatment area are:

- A clean, well-lit room with a temperature between 15°C and 37°C (59°F and 99°F)
- A properly grounded 100–120/230 VAC, 50/60 Hz electrical outlet
- A table or cart on which to place the system and that can hold at least 68 kg (150 lbs), is at least 45 cm wide and 60 cm deep (18 inches wide x 24 inches deep), and is non-tipping
- A clean and dry space for storing supplies
- A digital scale, preferably medical grade, as required by your center
- A hand washing sink close to the treatment area
- A telephone
- Other supplies to measure vital signs, as required by your center
- Access to an emergency kit, as required by your center
- At least 1.8 meters (6 feet) of distance from any electronic device, for example, a television set. Do not touch the NxStage System One and another electronic device (such as a television set) at the same time. In addition, no other person should touch any electronic devices and the patient at the same time.

Unpacking and initial test

PRECAUTION

Allow the Cycler to adjust to a room temperature between 15°C and 37°C (59°F and 99°F) for at least one hour before use.

NOTE

Save the box and packing material for future use.

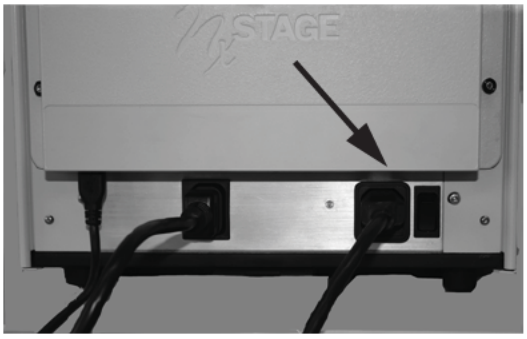
Figure 3-1: The cycler and the filter holder

To unpack your cycler and prepare for the initial tests:

1. Carefully remove the cycler from the box. If the box or cycler is damaged, call Customer Service.
2. Set up the cycler on a firm, stable surface. Set up other devices (fluid warmer and PureFlow SL) as instructed in their user guides. Leave at least 15 cm (6 inches) of space around the back of the cycler for air to cool the cycler.

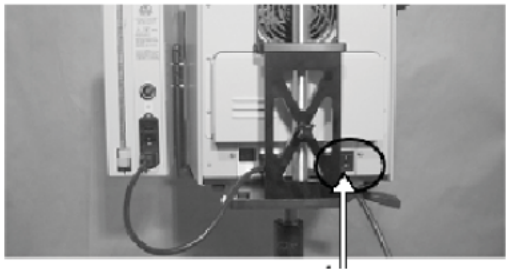
3. Plug the power cord into the power input on the back of the cycler. Align the pins on the power cord with the holes on the power input.

Figure 3-2: Power input for the cycler



4. Turn off the cycler power switch.

Figure 3-3: Power switch for the cycler



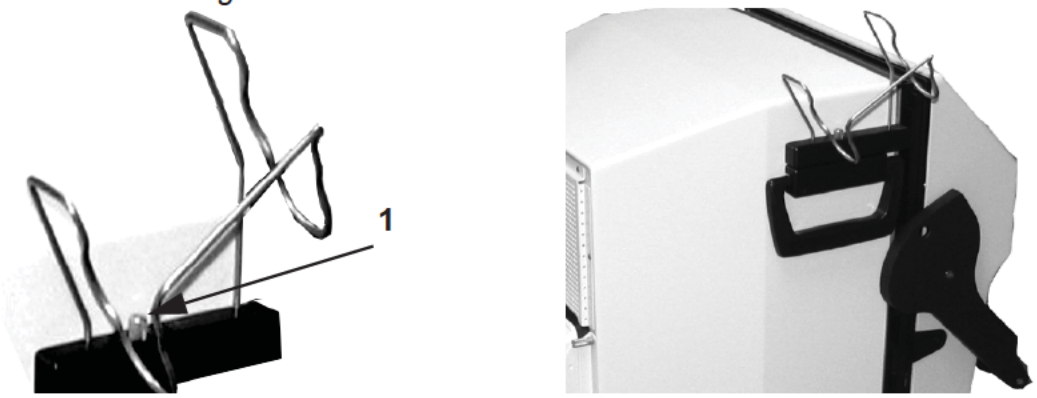
5. Plug the cycler power cord into an electrical wall outlet. Cycler models CYC-D2E (NX1000-1) and CYC-D2E (NX1000-3) must be plugged into a wall outlet with a ground.

NOTE

If you need to disconnect the cycler from power, unplug the power cord from the back of the cycler or unplug the power cord from the electrical wall outlet.

6. Facing the control panel, attach the filter holder to the handle on the left side of the cycler. Line up the thumbscrew with the hole in the handle and tighten the screws.

Figure 3-4: Attaching the filter holder



1	Thumbscrew

7. Turn the cycler on to test the power connection. Make sure the control panel lights up and flashes. The software version appears in the rate/volume window. After 25 seconds, the cycler is ready to use.
8. Turn off the cycler.
9. Enter the system settings as given by your center. See **Changing system settings**, page 9-2. Confirm the settings.

NOTES

- If using the CYC-D2E (NX1000-3) cycler for dialysate flows rates higher than 12 liter per hour, be sure to set the System Setting 0 (CAR Type) to 13, and the System Setting 1 to your prescribed flow fraction.
- You must turn off the cycler before going to the next step.

10. Open the door of the cycler. To open, lift up the front handle until it clicks and pull the door toward you.
11. Turn on the cycler. The switch is at the back of the cycler. The control panel lights up and performs a system check. If the system passes the self-test, load the cartridge. See **Loading the cartridge**, page 4-8.

    If there is an alarm that cannot be resolved, contact Technical Support.

High flow configuration

If your treatment calls for a dialysate flow rate higher than 12 liters per hour:

- Check the part number on your cycler. It must be part number CYC-D2E (NX1000-3) or higher.
- Set the System Setting 0 to 13.
- Set the System Setting 1 to the exact flow fraction determined by your center.
- Make sure the software version of your PureFlow SL is version 1.15 or higher.
- Make sure your SAKs are the 400 series
- Select the correct SAK type on your PureFlow SL control unit. From the user maintenance menu on the control unit, select the settings menu to enter the SAK type.

If your setup does not meet these requirements, contact Customer Service. You cannot run dialysate flow rates higher than 12 liters per hour if your setup does not meet these requirements, alarms will occur. See Chapter 5, Troubleshooting. Refer also to the troubleshooting section of the *PureFlow SL User Guide*.

Network or telephone line connection

All cyclers come with a Jewel Box or a ConNxBox computer attached to the back of the cycler to communicate with your center or NxStage.

- ConNxBox communicates with your center over cellular air waves. If cell coverage is poor and your home has a wired network, connect the ConNxBox to the network using the cable specified by NxStage.
- Jewel Box communicates with the NxStage server. You can connect the computer to:
  - a wired network in the home with CAT5 cable.
  - a telephone line with a telephone cable (US only).

Figure 3-5: Network connection on the computer

Connecting to the network (Jewel Box or ConNxBox)

To connect the computer to a network:

1. Connect one end of the network cable to the 10/100 LAN connection on the computer.
2. Connect the other end of the network cable to your network router.

NOTES

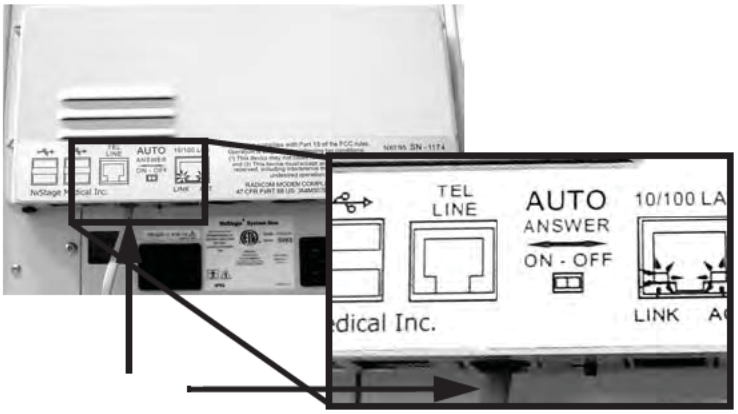
- For the connection to work, plug the cycler into the electrical wall outlet. It is not necessary to turn on the cycler for the connection to work.
- The transfer of data starts as soon as your treatment ends.

Connecting to the telephone line (Jewel Box in the US only)

To connect the computer to the telephone line:

1. Connect one end of the telephone cable to the telephone line (TEL LINE) connection on the computer.

Figure 3-6: Telephone line connection

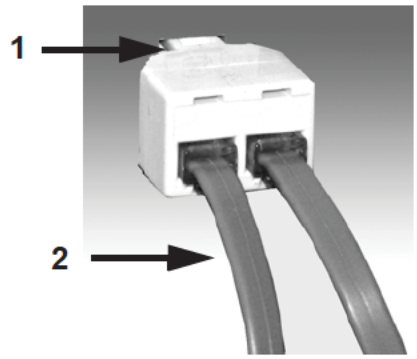


NOTE

Set the auto-answer to off unless Technical Support asks you to turn it on.

2. Connect the other end of the telephone cable to a telephone jack. A line splitter lets you connect your cycler and your telephone to the same jack.

Figure 3-7: Line splitter



1	Wall jack
2	One line to your telephone and the other to your cycler

NOTES

- Your line splitter may look different from the one shown in the illustration. The connection and function are the same.
- For the connection to work, plug the cycler into the electrical wall outlet. It is not necessary to turn on the cycler for the connection to work.
- The transfer of data starts at 2:00 am eastern standard time (EST).

Transport and storage

Before traveling with your cycler, contact Customer Service for packing instructions and information for having supplies shipped to your destination.

Your cycler and its components must be transported and stored at temperatures between 0°C and 50°C (32°F and 90°F).

PRECAUTION

Allow the Cycler to adjust to a room temperature between 15°C and 37°C (59°F and 99°F) for at least one hour before use.

NxSTAGE®
Invent. Improve. Inspire.

Chapter 4 Hemodialysis

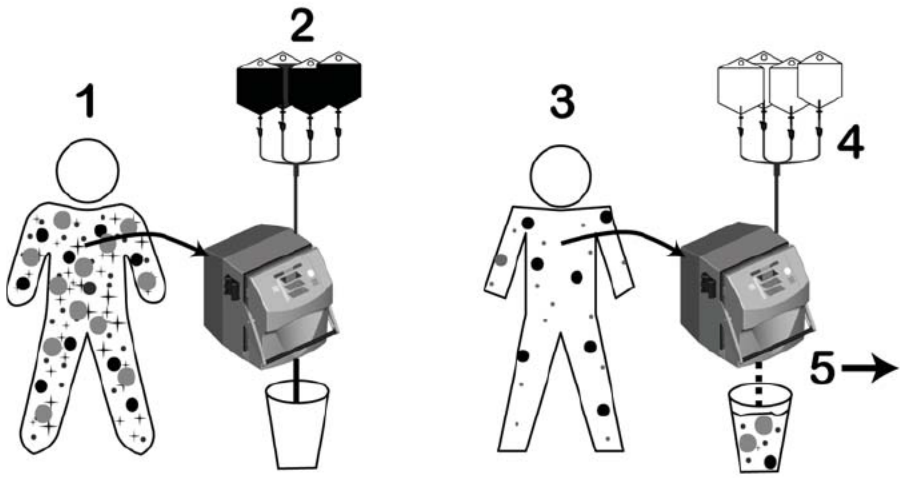
The NxStage System One uses a cartridge with a pre-attached dialyzer set up for hemodialysis. Other cartridges are available. Check with your doctor.

Overview

Using the same cartridge and cycler, the NxStage System One performs hemodialysis with or without ultrafiltration.

During hemodialysis, the blood flows on one side of the dialyzer fibers or small tubes. The dialysate flows on the other side of the dialyzer fibers or small tubes. Waste products and excess fluid pass from the blood and into the dialysate. Needed electrolytes pass from the dialysate into the blood. This process is called diffusion.

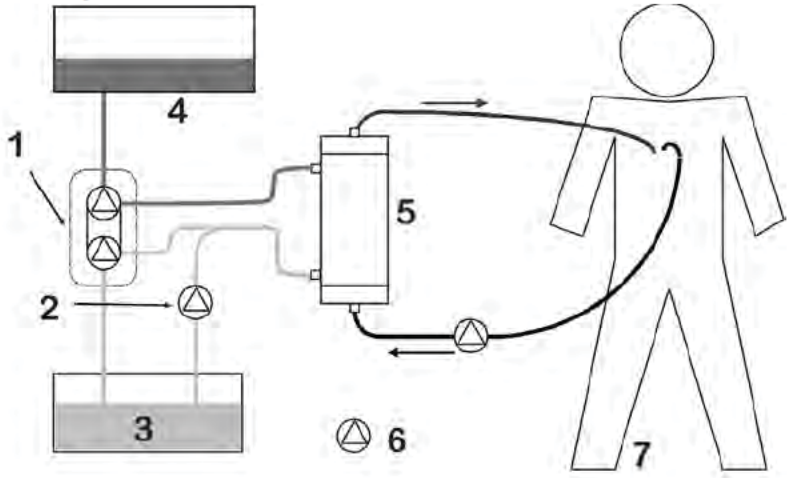
Figure 4-1: Hemodialysis and ultrafiltration therapies



1	Before treatment	3	After treatment
2	Dialysate going in	4	Bags empty of dialysate
		5	Waste and excess fluid going out

With ultrafiltration, excess fluid is removed from the blood through the dialyzer. Ultrafiltration can be done during dialysis or separately. When ultrafiltration is done separately to remove extra fluid from the body, it typically does not use dialysate.

Figure 4-2: Hemodialysis and ultrafiltration connections



1	Exchange balancing	5	Dialyzer
2	Ultrafiltration (removal of excess fluid)	6	Pump symbol
3	Waste	7	Patient
4	Dialysate		

Preparing for treatment

To prepare for treatment:

- Get all the supplies. See page 4-7.
- Load the cartridge. See page 4-8.
- Perform the prime and alarms tests. See page 4-12.
- Make the cartridge connections. See page 4-22

WARNINGS

Always visually inspect the package and product before use. Do not use any disposables if the package is open, damaged, or if any of the connector's protective caps are loose, disconnected, or missing. These disposables may no longer be sterile and may cause patient infection.

Do not touch surfaces of any disposable covered by protective caps. This includes connectors and needleless access sites. Always use aseptic technique when handling connections. Touching these surfaces may make them non-sterile, which may cause patient infection.

Do not use excessively cold dialysate. Under certain conditions, including but not limited to patient weight, dialysate flow rates and treatment durations, some patients may develop hypothermia when exposed to excessively cold dialysate.

Do not use a knife or other sharp instrument to open any shipping carton or case containing disposables because it may cut or damage the contents. Do not use any disposables from a shipping carton or case that has been opened with a knife or other sharp instrument. Damage to disposables may cause blood or air leaks, causing patient injury or death.

Do not use any fluid delivery devices that have a post-pump drip chamber or a maximum output pressure of less than 600 mmHg. Using these devices may cause blood loss, undesired fluid delivery, inaccurate flows, leaks, and other failure of the fluid delivery device to perform its intended function.

WARNINGS

Do not use ultrasound gel, or any gel-like substances around the air detectors. These substances may prevent the detection of air in the blood lines. If air cannot be detected it may cause an air embolism in the patient.

The maximum fluid volume for transporting the NxStage System One Cycler using the mobile base with the ComfortMate Fluid Warmer is 10 liters of fluid. Do not transport the Cycler with fluid using the mobile base if using the Express Fluid Warmer. The maximum fluid volume for stationary use of the Cycler with an IV pole is 29 liters of fluid when using the ComfortMate Fluid Warmer or 21 liters of fluid when using the Express Fluid Warmer. Fluid volume must not be exceeded and fluid must be evenly distributed on the IV pole to prevent accidental tipping of the Cycler.

Do not attach ancillary devices that can restrict blood flow, such as stopcocks, to the patient lines. Restrictions in the blood circuit can cause hemolysis.

Do not use a Cartridge with kinked blood lines. Always inspect the blood lines for kinks before and during use, particularly around Dialyzer connections. Kinked blood lines may cause hemolysis.

The risk of blood clotting in the Cartridge and Dialyzer is higher during long treatments, when no anticoagulation is used, in certain patients who are more prone to excess clotting, or any time when the blood flow stops, including when the NxStage System One Cycler loses power or during an unrecoverable alarm. The risk of blood clotting increases the longer treatment continues and the longer blood flow is stopped. To reduce the risk of blood clotting and identify the early signs of clotting:

- Follow your center's instructions to give and monitor anticoagulant.
- During treatment, regularly check the Cartridge and Dialyzer for clotting by looking closely at the Cartridge and Dialyzer, and periodically flushing the Dialyzer with a manual fluid bolus.

Failure to respond to blood clotting in the Cartridge and Dialyzer may result in a blood clot being released into the patient's bloodstream and causing a blockage (thromboembolism). Failure to respond to clotting may also lead to sustained high pressures in the blood circuit and cause a dialyzer blood leak or hemolysis. These conditions may cause serious injury or death if not responded to promptly and appropriately. Regularly check the Dialyzer for any evidence of a leak. Do not return the blood if the blood flow is stopped for a long time. Discard the Cartridge and Dialyzer if they are clotted.

PRECAUTIONS

- Allow the Cycler to adjust to a room temperature between 15°C and 37°C (59°F and 99°F) for at least one hour before use.
- Allow the Cartridge to adjust to a room temperature between 15°C and 37°C (59°F and 99°F) for at least one hour before use.
- Make sure that premixed Dialysate is at room temperature before using. If it is not at room temperature, outgassing of air may occur as the fluid is warmed, which may cause NxStage System One Cycler air alarms.
- Use caution when handling any Disposable Set to avoid tearing and puncturing.
- The default value for System Setting #9 is zero (0) for hemodialysis which disables the automatic bolus feature. In certain geographic areas outside of the US, additional labeling provides more information on using the NxStage System One to deliver an automatic fluid bolus.
- Do not alter any NxStage disposables. Performance of altered disposables cannot be guaranteed.

Getting the supplies

As you prepare for treatment, make sure you have the following supplies:

- Dialysate bags and disposables
- A hemodialysis cartridge set
- Saline bags
- Personal protection supplies for universal precautions. Check with your center to know which protection supplies you need.
- Other supplies for use during treatment. Check with your center to know which other supplies you need.

Before starting your treatment:

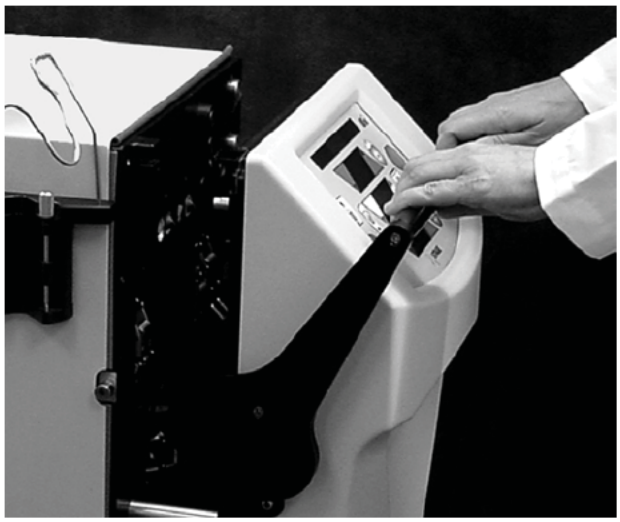
- Make sure your center gives you a list of all the non-NxStage supplies you need.
- Check all supplies for damage or missing parts.
- Read the instructions for use given with the supplies.
- Check that all your supplies match your prescription. If they do not match your prescription, call your center.
- Make sure the cycler's power supply is attached to the back of the cycler and plugged into an electrical outlet.
- Check your prescription and cartridge IFU for the System Settings information.

Loading the cartridge

To open the cycler:

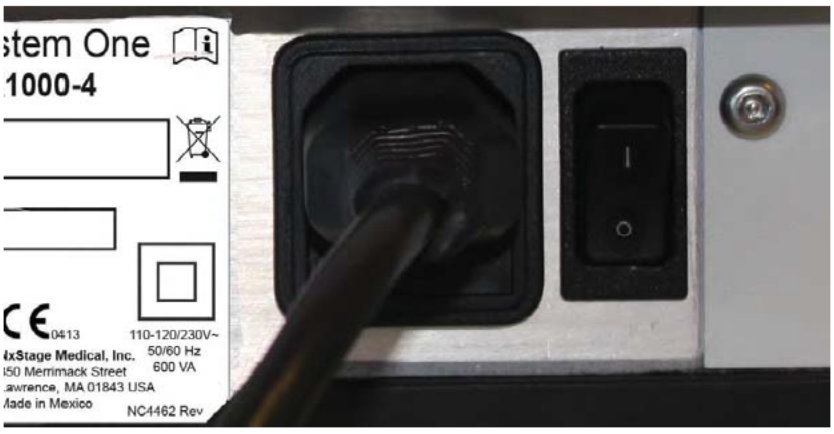
1. Open the door of the cycler. To open, lift up the front handle until it clicks and pull the door toward you.

Figure 4-3: Open the cycler door



2. Turn on the cycler. The switch is at the back of the cycler. The control panel lights up and performs a brief system check.

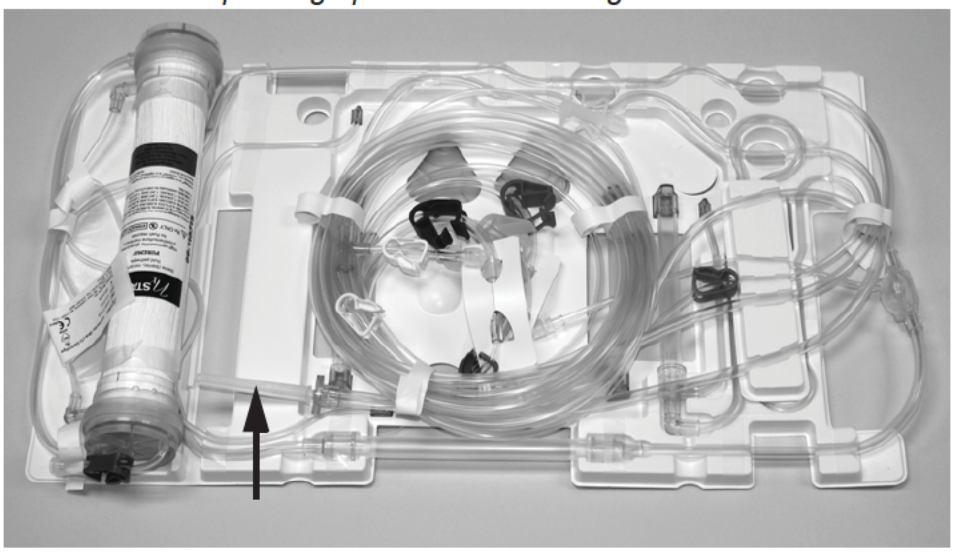
Figure 4-4: The cycler power switch



To unpack the cartridge:

1. Remove the cartridge from its package carefully. Look for the blood line connections with red and blue luer connections on the priming spike and tighten them. Tighten all caps and luer connections on the lines, saline "T" and post-dialyzer port.
2. Lift the priming spike carefully out of the cartridge.

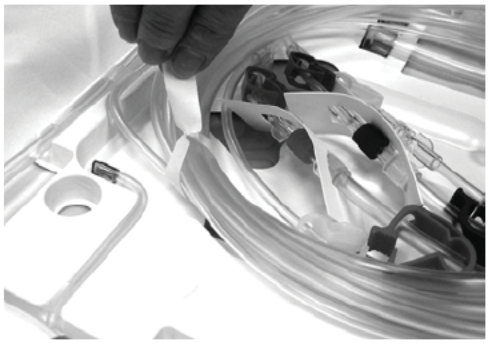
Figure 4-5: Locate the priming spike on the cartridge



3. Remove the connector tabs and paper tape.

Figure 4-6: Remove the connector tabs

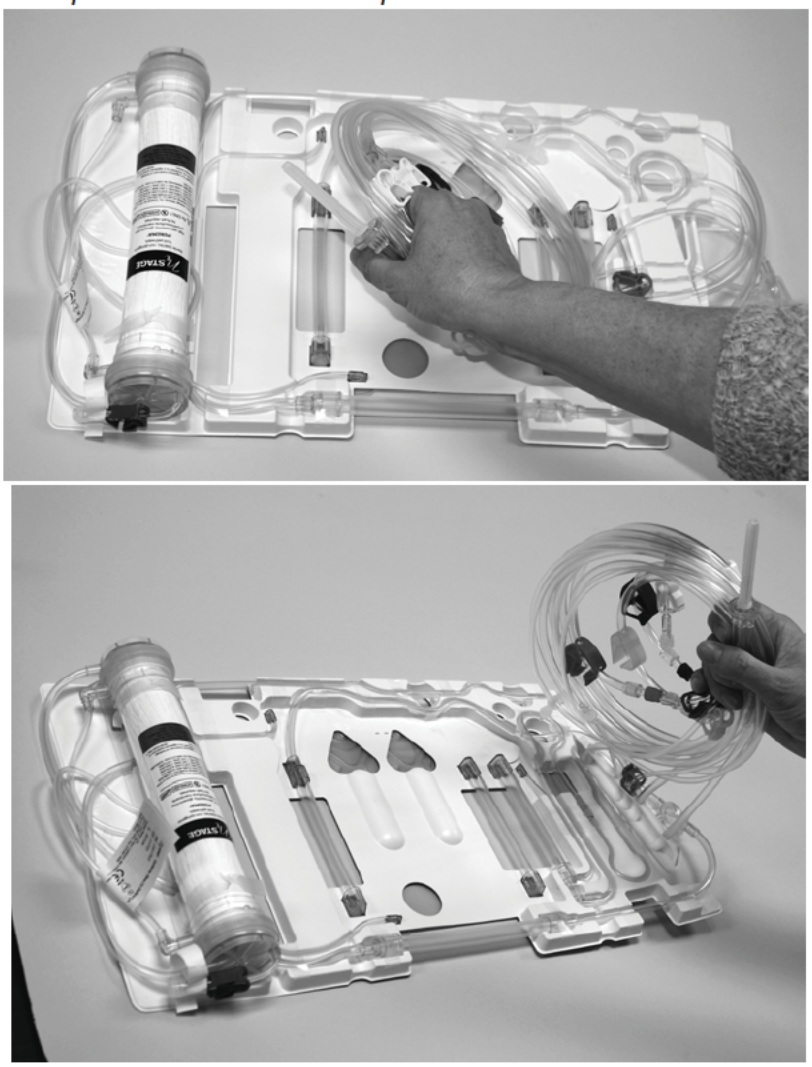
Pinch



Tear

4. Hold the coiled lines in one hand and pull the lines out of the line organizer.

Figure 4-7: .Grasp the coiled lines and pull



5. Remove the line organizer from the cartridge and throw it away.

Figure 4-8: Remove the line organizer

6. Check the lines for any kinks or dents. Do not use any blood tubing that is dented or flattened by more than one-third.

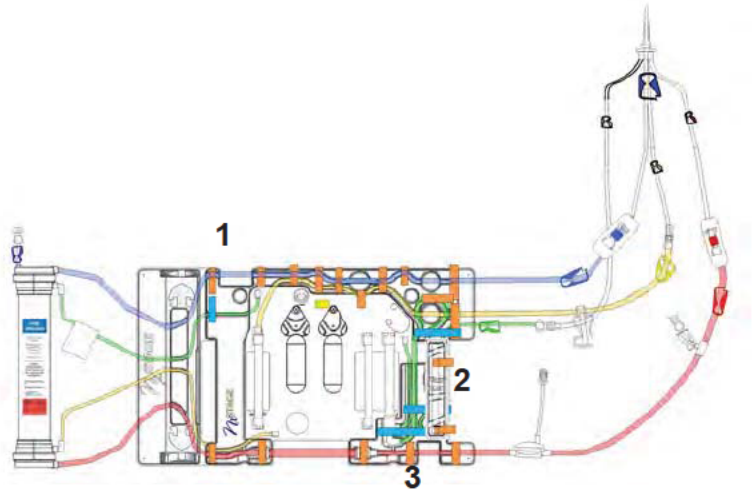
NOTE

You can also keep the tabs in place until you connect the arterial and venous blood lines to the vascular access.

To load the cartridge:

1. Place the cartridge into the cycler. Press the lines into the three air detectors:
   - the venous blood line in the top left corner
   - the dialysate line in the middle right corner
   - the arterial blood line at the bottom right corner.

Figure 4-9: Location of cartridge air detectors



1	Venous Air Detector
2	Dialysate Air Detector
3	Arterial Air Detector

2. Make sure that all lines, clamps, and caps are away from the door handle, including the luggage tag on the cartridge.

3. Close the door of the cycler. Push down the door handle until it clicks to lock it.

Figure 4-10: Close the cycler door

WARNING

To avoid injury when closing the Cycler door, make sure to keep fingers and other body parts away from the door opening.

Prime and alarms test

Before treatment is possible, the cartridge lines and dialyzer must be flushed with saline to eliminate all air. This is called priming the cartridge. The cycler and cartridge must also test the safety systems.

WARNINGS

Only spike the saline bag after loading the Cartridge and closing the door of the NxStage System One Cycler. Failure to do so may cause Cartridge leaks or a misalignment of the Cartridge, resulting in compromised treatment, injury, or death.

Never connect the patient to the Cartridge before you see the treatment parameters in the NxStage System One Cycler's window, which indicates that the Prime and Alarms Test is completed. Some safety systems are not active during the Prime and Alarms Test. Connecting the patient at any time before completion of the Prime and Alarms Test may cause serious injury or death.

⚠ PRECAUTIONS

⚠ After use, discard all disposables in accordance with local, national and federal regulations as instructed by your center. Use universal precautions when disposing of Cartridges.

⚠ If you do not pass the NxStage System One Cycler's Prime and Alarms Test, repeat the test. If you do not pass again or you do not pass the Display Tests, do not connect the patient to the Cartridge. Call Technical Support.

⚠ Remove accumulated air as instructed prior to making patient connections to minimize the chance of NxStage System One Cycler air alarms after making patient connections.

Priming the cartridge:

1. Put on gloves. Remove the protective cap from the priming spike.
2. Insert the priming spike into a 1-liter bag of saline using a twisting motion. Insert the spike as far as you can until the saline outlet is flush with the disk on the priming spike.

Figure 4-11: Fully insert the priming spike into the saline bag

- When the tip is fully inserted into the bag when you can see the tip inside the bag. If the tip is not fully inserted, air may enter the cartridge.
- Make sure that the cartridge is loaded and the door is locked before inserting the spike into the saline bag. If not, the cartridge may not load or be damaged. It may impair the performance of the system.

- The size of the administration port on the saline bags may be different from one manufacturer to another. As a result, you may have to use more or less force to insert the spike into the saline bag.

Connecting the access pressure pod monitoring line:

If your cartridge has an access pressure pod monitoring line, connect it now.

1. Hold the line behind the locking collar.
2. Insert the tip of the line into the connector on the right side of the cycler, next to the front handle.

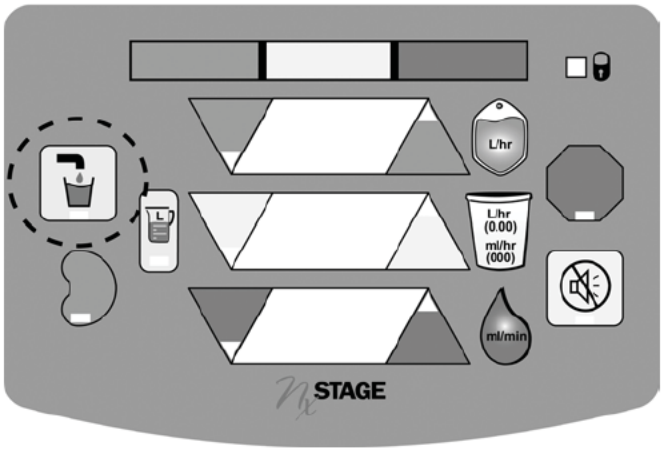
Figure 4-12: Connect the access pressure pod monitoring line

3. Press the monitoring line into the connector. Twist the tip a quarter turn to the left to seal the connection.
4. Tighten the locking collar.

To prime the system:

1. Press the **ADD FLUID** key to prime the system.

Figure 4-13: Location of the ADD FLUID key



During prime:

- The cycler pumps the saline into the cartridge to remove air.
- The Green Operating window shows the time left to prime the system. It takes about 15 minutes to prime the system.
- The top window shows the priming step. The bottom window shows the alarm tests.

NOTE

If the cycler fails to prime or if an operator error occurs, see **Re-priming a cartridge**, page 4-44.

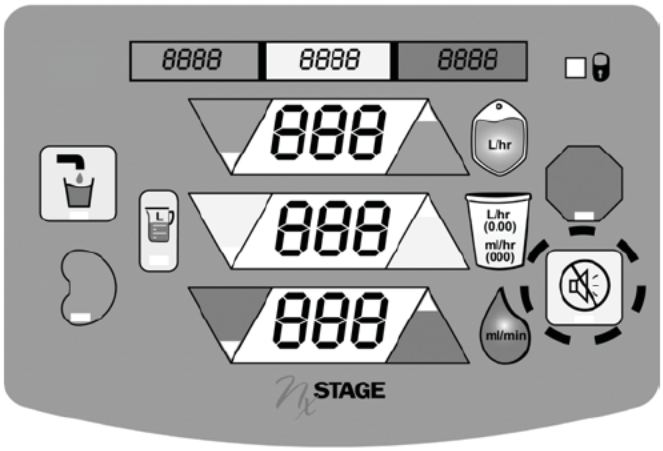
2. Prepare the dialysate source.
   - If using a ComfortMate Fluid Warmer or Express Fluid Warmer, follow the instructions to set-up the pre-mixed dialysate.
   - If using a PureFlow SL, follow the instructions to prepare the SAK dialysate.

End of the prime and alarms test

When the prime and alarms test ends, note the first display test:

1. Check that the control panel displays the number eight in all the windows.
2. Listen for the audible alarm sound.
3. Check that all light segments are turned on.
4. Press the **MUTE** key. All lights segments are turned off.

Figure 4-14: First display test and MUTE key



5. When the first display test is successful, note the second display test. Make sure the windows on your control panel are exactly as shown here. Press the **MUTE** key to continue.

Figure 4-15: Second display test and MUTE key

6. The numbers and letters displayed must be exactly as shown in this example:

   The top status window of the control panel shows:

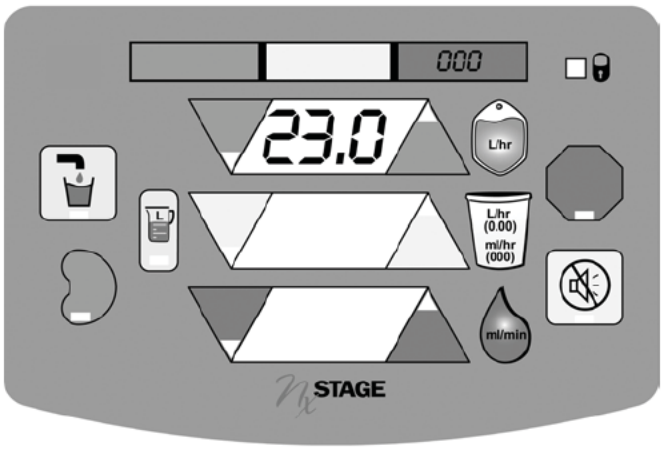
   - 1234 and a-h from left to right:

   The three rate and volume windows show:

   - 9-1 from top to bottom:

7. Check for the number **23.0** in the top window. This number tells you that the system is in Recirculation Mode. During recirculation, the blood and fluid pumps are running. The pumps circulate fluid through the cartridge and saline bag.

Figure 4-16: Top window during recirculation



Do **not** press the **STOP** key. Do **not** close the clamps. Do not disconnect the lines. Instead, do one of the following:

- If you are not moving your cycler to another location, go to **Removing air from the blood circuit**, page 4-19.
- If you are moving your cycler, you can turn off the cycler during the priming step 23.0. Move the cycler to the new location.
- Turn on the cycler power. When you turn on the cycler within the time specified in your System Setting 33, the number **40** appears in the Yellow Caution window and the **TREATMENT** key lights up. System Setting 33 is the cartridge life timeout.
- Press the **TREATMENT** key. The number **20.0** appears in the top window and changes to **23.0** meaning that the balancing system was checked a second time.
- Do **not** press the **STOP** key. Do **not** close the clamps. Do **not** disconnect the lines.
- When the number **23.0** appears in the top window, the cycler is back in recirculation. Go to **Removing air from the blood circuit**, page 4-19.

Removing air from the blood circuit

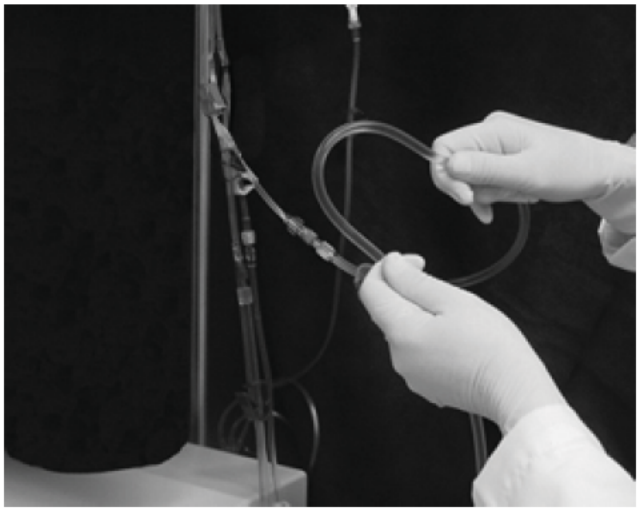
PRECAUTION

Remove accumulated air as instructed prior to making patient connections to minimize the chance of NxStage System One Cycler air alarms after making patient connections.

To remove air from the blood circuit:

1. Start at the red port on the priming spike. Snap and tap the arterial blood line (red clamp). Observe the air moving to the cycler.

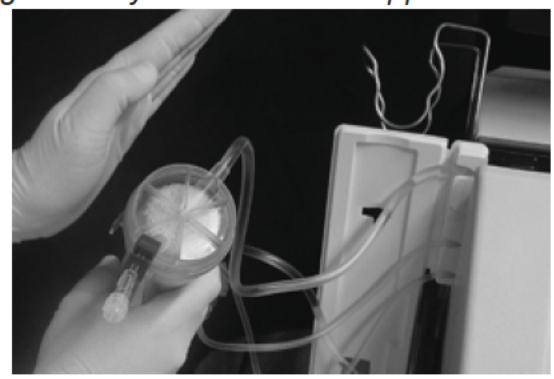
Figure 4-17: Removing air from the blood circuit



2. Pull out the dialyzer from the left side of the cartridge. Turn the dialyzer upside down so that the venous blood line is up. This lets air out of the dialyzer. Be careful not to twist the lines.

3. Tap the dialyzer a few times against the palm of your hand to remove trapped air. You can also tap the dialyzer on a padded surface.

Figure 4-18: Tapping the dialyzer to remove trapped air



WARNING

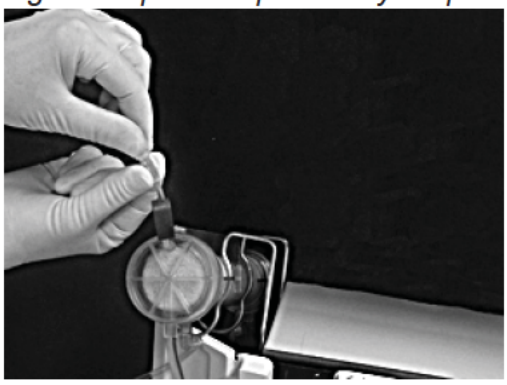
Do not tap the Dialyzer against a hard surface, such as the NxStage System One Cycler. This may damage the Dialyzer and may cause a blood or fluid leak, causing patient injury or death.

4. Place the dialyzer into the filter holder so that the post-dialyzer port is up.

To prime the post-dialyzer port

1. Loosen the cap on the post-dialyzer port to remove air.
2. Tighten the post-dialyzer port cap and close the clamp securely.

Figure 4-19: Loosening the cap of the post-dialyzer port



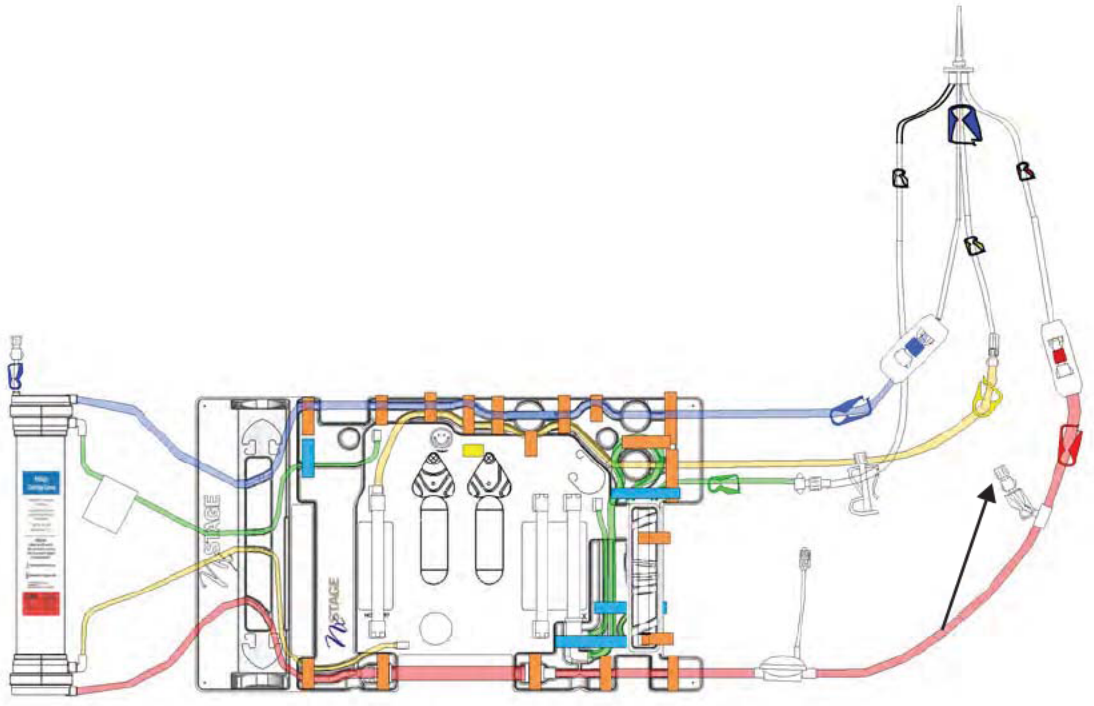
- You can attach a 20 milliliter syringe with a luer lock to the port.
- Make sure there are no kinks in the blood line when placing the dialyzer in the filter holder.

NOTE

Do not administer fluid or medication through the post-dialyzer port.

3. Follow the blood circuit to the right side of the cycler. Snap and tap the venous blood line (blue clamp). Observe the air moving to the saline bag.
   - Repeat the steps to remove air from the blood circuit, to make sure there is no air left in the blood circuit.
   - Check the blood lines carefully a second time to make sure there is no air in the lines. If there is air or if the cycler is left in recirculation, repeat the steps to remove air from the blood circuit. If the cycler is left in recirculation, you will need to repeat steps for air removal again.
4. Press the **STOP** key.
5. Check that the default treatment rates for the patient appear in the windows.
6. Prime the saline "T" (white clamp). Loosen the cap on the saline "T" to remove air. Tighten the cap. Close the white clamp on the saline "T."

Figure 4-20: Location of the saline "T"



Making the cartridge connections

After the prime and alarms and display tests, make the non-patient connections to the cartridge.

WARNINGS

- The Cartridge has multiple connection points. Failure to make the proper connections may cause compromised treatment, blood loss, injury or death. Make sure mated luer-connectors are secure but do not over-tighten, especially when connections are wet.

- Manually prime any administration “T”s and ports, if present, even if they are not used, to prevent air from entering the patient blood lines. Secure caps and close clamps after priming, and after each use to prevent blood loss or air entering the patient blood lines.

- Do not touch surfaces of any disposable covered by protective caps. This includes connectors and needleless access sites. Always use aseptic technique when handling connections. Touching these surfaces may make them non-sterile, which may cause patient infection.

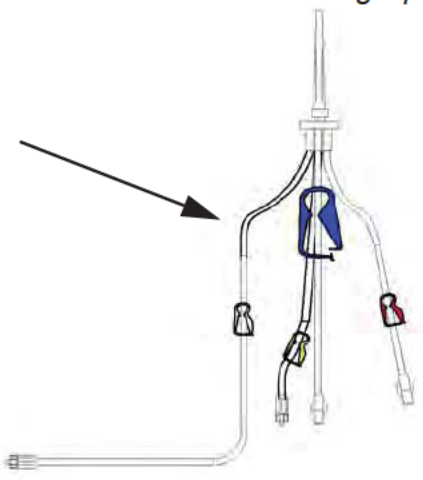
PRECAUTION

- Remove accumulated air as instructed prior to making patient connections to minimize the chance of NxStage System One Cycler air alarms after making patient connections.

To make the cartridge connections:

1. At the priming spike, look for the start of the saline line. The saline line is the only line with no clamp near the spike. Follow the saline line to the white and green clamps.

Figure 4-21: Location of Saline Line on the Priming Spike



2. Close the green clamp on the dialysate inlet line.
3. Close the white clamp on the saline line.
4. Disconnect both the dialysate and saline lines. Keep the connections sterile.
5. Remove the cap from the saline "T." Connect the saline line to the saline "T." **Do not open the white clamps.**
6. Remove the cap from the dialysate source line. Connect the dialysate inlet line to the dialysate source line. Both lines have green clamps. Open both green clamps.
7. Close the yellow clamp on the priming spike. Close the yellow clamp on the cartridge waste line. Disconnect both lines.
8. Make the cartridge waste line connections.
   - If you are using bagged dialysate, connect the cartridge waste line to the waste line extension. Place the other end of the waste line extension into an appropriate plumbing drain, such as a tub or sink. Open the yellow clamps on the cartridge waste line and the waste line extension.
   - If you are using the NxStage PureFlow SL, connect the cartridge waste line to the PureFlow Control Unit Waste Line Adapter. Make sure the yellow clamps on the cartridge waste line and the waste line adapter are open.

Performing treatment

WARNING

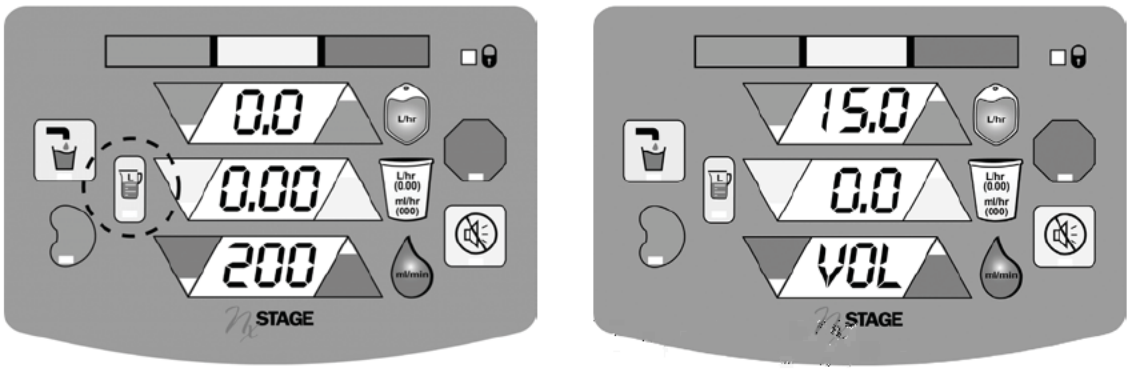
The NxStage System One Cycler will automatically remove the rinseback volume when both the System Setting #38 is set to 1 and the Ultrafiltration pump rate (UFR) is greater than 0. Automatic removal of the rinseback volume is not displayed to the operator. Therefore it is important to account for the rinseback volume when calculating the ultrafiltration rate and volume for the treatment. Do not add the rinseback volume to the targeted ultrafiltration volume when the Cycler is set to automatically remove the rinseback volume or excess ultrafiltration will result. For patients that may be unable to tolerate even small fluid balance changes, such as low weight patients and patients at or near their dry weight, the excess ultrafiltration may result in hypotension or hypovolemia which may cause patient injury or death. When automatic removal of the rinseback volume is not desired, System Setting #38 should be set to 0.

Entering the treatment settings

To enter the treatment settings:

1. Press the **VOLUME TOGGLE** key. VOL appears in the bottom window.

Figure 4-22: Volume toggle changes between rate and volume windows

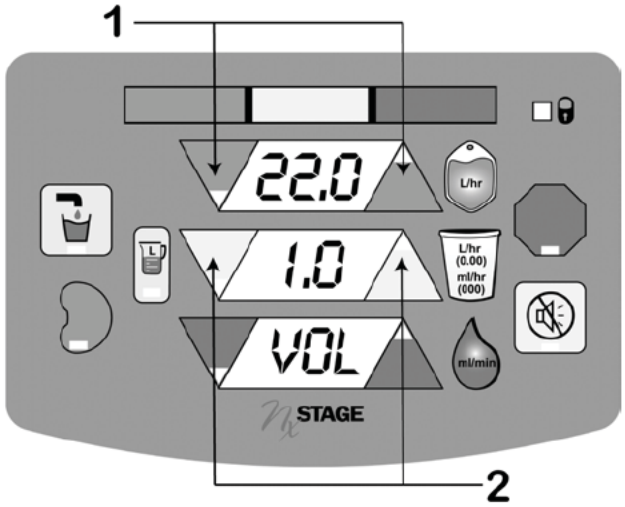


Rate Window **Volume Window**

2. Press the **ADJUSTMENT ARROWS** keys to enter the dialysate volume goal.

3. Press the **ADJUSTMENT ARROWS** keys to enter the ultrafiltration volume goal.

Figure 4-23: Location of dialysate and ultrafiltration adjustment arrows



1	Dialysate volume • Top window, green arrows
2	Ultrafiltration volume (weight to remove) • Middle window, yellow arrows

NOTE

Make sure you have the correct patient weight before entering the ultrafiltration volume. See **Ultrafiltration**, page 2-4.

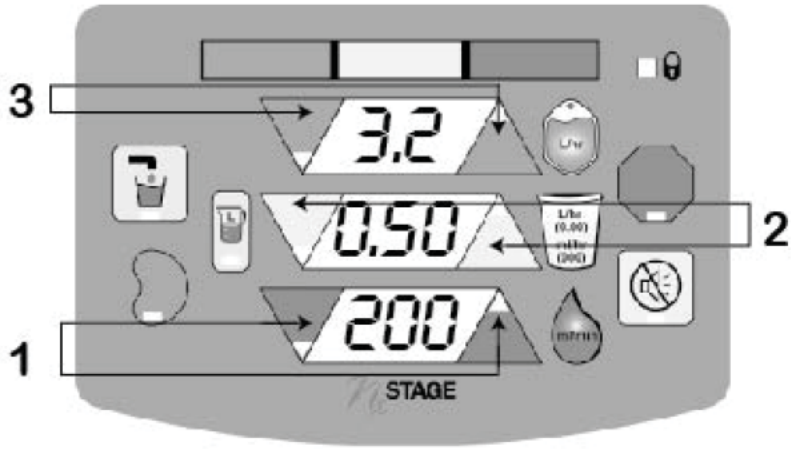
4. Press the **VOLUME TOGGLE** key to return to the rate window.

NOTE

The volume window returns automatically to the rate window after a period of time that is determined by the software version of your cycler and your system settings. See Chapter 9, System Settings.

5. Note the blood flow rate. Adjust the ultrafiltration rate and the dialysate rate. Press the **ADJUSMENT ARROWS** keys to enter rate changes.

Figure 4-24: Location of adjustment arrows



1	Blood flow rate • Bottom window, red arrows
2	Ultrafiltration rate • Middle window, yellow arrows
3	Dialysate rate • Top window, green arrows

NOTES

- If your cycler is model CYC-D2E (NX1000-1), the maximum dialysate rate you can enter is 12 liters per hour. If your cycler is model CYC-D2E (NX1000-3) or NX1000-4, the maximum dialysate rate you can enter is 18 liters per hour.
- To avoid an unexpected large or sudden decrease in blood pressure from removing fluid too fast, remove the ultrafiltration fluid gradually over the length of your treatment. See **Ultrafiltration**, page 2-4.

Starting and monitoring the treatment

After priming the cartridge and entering your treatment settings, make the patient connections. Always use universal precautions and aseptic technique as taught by your center when connecting the vascular access and blood lines and when making patient connections.

Treatment starts when you press the **TREATMENT** key. During treatment, you can monitor the treatment and change treatment settings on the cycler control panel, as needed.

WARNINGS

Do not adjust the vascular access while the Blood Pump is running. Adjusting the vascular access while the Blood Pump is running increases the likelihood of needle dislodgement, which may result in a significant blood loss.

The risk of blood clotting in the Cartridge and Dialyzer is higher during long treatments, when no anticoagulation is used, in certain patients who are more prone to excess clotting, or any time when the blood flow stops, including when the NxStage System One Cycler loses power or during an unrecoverable alarm. The risk of blood clotting increases the longer treatment continues and the longer blood flow is stopped. To reduce the risk of blood clotting and identify the early signs of clotting:

- Follow your center's instructions to give and monitor anticoagulant.
- During treatment, regularly check the Cartridge and Dialyzer for clotting by looking closely at the Cartridge and Dialyzer, and periodically flushing the Dialyzer with a manual fluid bolus.

Failure to respond to blood clotting in the Cartridge and Dialyzer may result in a blood clot being released into the patient's bloodstream and causing a blockage (thromboembolism). Failure to respond to clotting may also lead to sustained high pressures in the blood circuit and cause a dialyzer blood leak or hemolysis. These conditions may cause serious injury or death if not responded to promptly and appropriately. Regularly check the Dialyzer for any evidence of a leak. Do not return the blood if the blood flow is stopped for a long time. Discard the Cartridge and Dialyzer if they are clotted.

WARNINGS

Never try to open the door of the NxStage System One Cycler when the door lock symbol is on. If the door is opened by force, all safety systems will no longer be active, which may cause patient injury or death. If the door must be opened while the patient is connected, press the STOP key, immediately clamp all fluid and blood lines, turn the power switch OFF on the Cycler, and then open the door of the Cycler.

When a Yellow Caution is displayed, some safety systems may not be active. Monitor the system and the patient until the Green Safe Operating condition returns. Failure to do so may cause patient injury or death.

Manual fluid boluses and fluid consumed during treatment are not included in the System One fluid balance calculations. Excessive fluid boluses, whether intentional or unintentional, or failure to account for consumed fluid during treatment, may cause patient injury. Include fluid boluses and the volume of fluid consumed in manual fluid balance calculations. Make sure that the administration lines used for manual bolus or rinseback are clamped after use.

Weigh the patient before treatment to make sure that the appropriate ultrafiltration volume is calculated. Follow the physician's prescription for maximum volume and rate of fluid to be removed. Removing too much or too little fluid, or removing fluid too quickly, may cause patient injury. In addition, prescribing physicians should be aware that certain patients, such as low weight patients and patients at or near their dry weight, may be unable to tolerate fluid balance variations in amounts less than the total fluid accuracy tolerances of the NxStage System One Cycler and other ancillary fluid delivery devices. These patients must be closely monitored for signs and symptoms of excessive ultrafiltration or fluid overload. Refer to the System One User Guide for additional information on ultrafiltration during dialysis.

Before starting treatment, check the patient blood lines for air. Check again before and during rinseback. Follow the instructions to remove air before starting treatment or rinseback. Failure to remove air from the patient blood lines may cause an infusion of air, which may lead to an embolism.

Do not disconnect and reverse patient blood lines during treatment. This may cause an infusion of air into the patient blood lines, which may lead to an embolism.

WARNING

The NxStage System One Cycler may not detect slow fluid or blood leaks from loose connections, faulty components, venous access disconnection, vascular needle dislodgement, or other potential causes. Leaking fluids may cause blood loss, injury, or death. Leaking fluids on the floor may also cause a person to slip or fall.

To reduce the risk of fluid or blood leaks, or accidental disconnections:

- Keep vascular access sites and all Cartridge connections visible throughout the treatment. Do not cover sites or connections with a blanket, or clothing, or any objects that block the view of the site and connections.
- Before starting treatment, make sure all manual connections are secure and fluid-tight, but not over-tight.
- A trained and qualified observer must check the system for blood and fluid leaks during treatment and pay close attention to the blood line and access connections, especially when the patient is connected and disconnected. If any leaks are found and cannot be stopped, end the treatment and rinse back the patient's blood, unless the center gives instructions not to rinse back. Do not rinse back the patient’s blood if there are clots or air in the blood circuit or in the patient blood lines. Do not rinse back if the blood is hemolyzed.
- Before connecting the patient, make sure that there is no blood or other lubricious fluid on the Cartridge connectors and mating connectors, such as on vascular access devices. Lubricious fluids, including but not limited to blood, silicone oil, and povidone iodine-based disinfectants on mated luer-connections may significantly increase the chance of accidental disconnections.
- Strictly follow the center’s procedure for taping the blood lines and access device connections to the patient. Check all connections and secure taping again, if necessary, when the patient changes position, when changing the dressing of the catheter, or if there is stress on the Cartridge tubing or blood access device.
- Use only Dialyzers, catheters or AVF needles, and other devices that have locking connectors in compliance with ISO 594 parts 1 and 2 and ISO 8638 when connected to the Cartridge. With repeated patient treatments, a temporary or permanent catheter’s connectors may change shape and no longer comply with ISO 594 parts 1 and 2 and become incompatible with the Cartridge. Using incompatible connectors with the Cartridge may cause blood loss, patient injury, or death. Contact the device manufacturer for all compliance questions.

WARNING

Manually prime any administration “T”s and ports, if present, even if they are not used, to prevent air from entering the patient blood lines. Secure caps and close clamps after priming, and after each use to prevent blood loss or air entering the patient blood lines.

PRECAUTIONS

Do not disconnect any Cartridge pressure pod monitoring line from the NxStage System One Cycler after priming the Cartridge, unless directed to do so in the Troubleshooting section of this guide. Doing so may result in inaccurate pressure readings and may lead to false cautions and alarms or failure of appropriate cautions and alarms to occur.

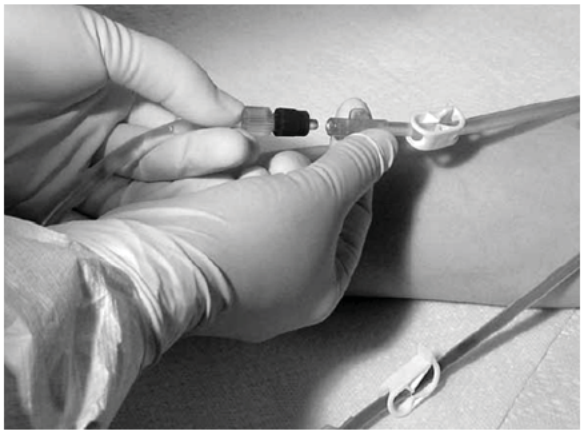
Do not allow fluid or blood to contact the NxStage System One Cycler's pressure sensor connection points. If this happens, return the Cycler for service. This is a preventive measure to make sure that the pressure readings are accurate. It also eliminates the potential for cross contamination.

To connect the patient:

1. Close the red and blue clamps on the priming spike, arterial blood line and venous blood line.
2. Using aseptic technique, disconnect the arterial blood line and the venous blood line from the priming spike.

3. Connect the arterial blood line and venous blood line to the vascular access.

Figure 4-25: Connect the blood lines to the patient's vascular access



4. Open the red and blue clamps on the blood lines and the clamps on the vascular access lines.
5. Connect a luer-lock syringe to the red and blue ports on the priming spike to keep them sterile.

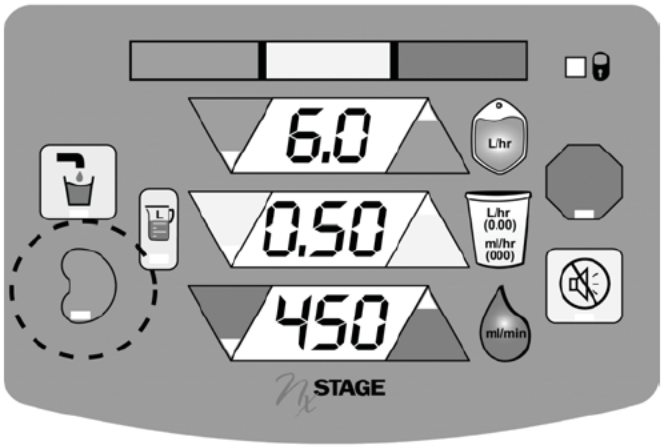
Before starting the treatment, check the following:

- The dialyzer is in the filter holder with the post-dialyzer port upright.
- The waste line on the cartridge is connected to the drain line. Both lines have yellow clamps. The clamps should be open.
- The blood lines are visible, free of kinks and connected to the vascular access and all clamps are opened.
- The white clamps on the saline line and saline "T" are closed.
- The dialysate source is connected and ready to use.
- The clamps from the dialysate source are open.

To start the treatment:

1. Press the **TREATMENT** key.

Figure 4-26: Location of the TREATMENT key



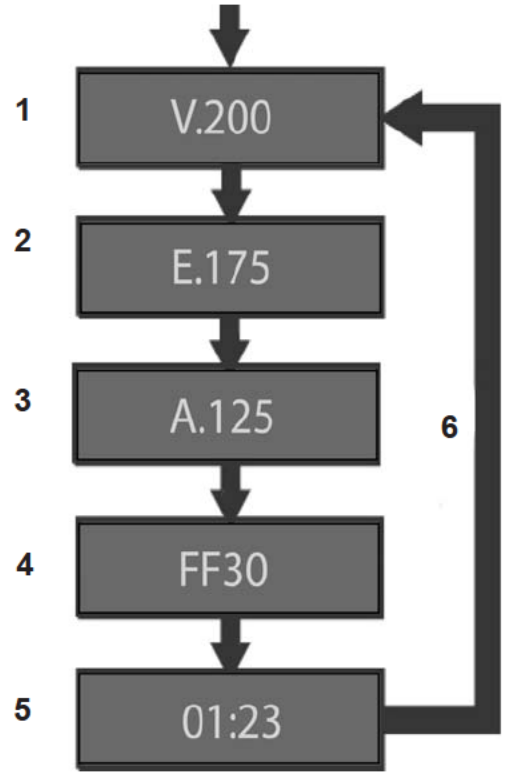
- Monitor the arterial and venous pressures while increasing the blood flow rate to the prescribed rate. Increase the dialysate flow rate until it stops.
- Check for air in the venous blood line (blue clamp).
- Check for air in the arterial blood line (red clamp). Small air bubbles in the arterial blood line may appear if the blood flow rate is set too high.
- Monitor the arterial and venous pressures. Watch for pressures outside normal ranges. A normal arterial pressure is between -50 and -200 mmHg. A normal venous pressure is between 20 and 300 mmHg. If pressures are outside the range, it may be necessary to adjust the blood flow rate to obtain a good access flow. Check the recommendations given by your center to re-adjust the blood flow rate.
- If the access flow is poor, check for kinks and clots in the blood lines. Check to make sure all clamps are open.
- Monitor the control panel until the Green Safe Operating condition occurs.

NOTE

The cycler displays the arterial access pressure without the negative sign. Therefore, when the arterial pressure decreases (more negative), the arterial pressure displayed on the cycler shows a higher number indicating a more restricted flow.

2. Monitor the treatment values as they scroll through the Green Operating window.

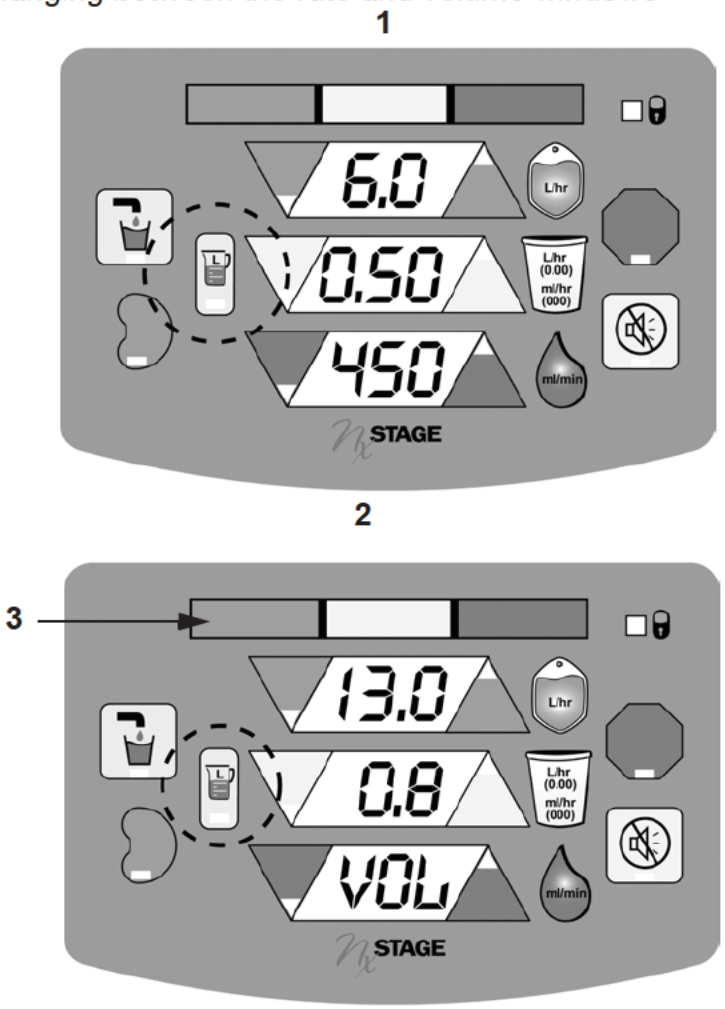
Figure 4-27: Treatment values



1	Venous Pressure
2	Effluent Pressure
3	Access Pressure (Optional)
4	Flow Fraction
5	Time Remaining
6	Repeat Cycle

3. Press the **VOLUME TOGGLE** key to determine how much of the treatment is left.

Figure 4-28: Changing between the rate and volume windows

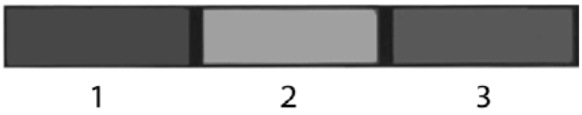


1	Rate window: Shows current rates
2	Volume window: Shows volumes of remaining dialysate to exchange and ultrafiltration to remove
3	Elapsed treatment time shown in Green Operating window

4. Press the **VOLUME TOGGLE** key a second time to show the rate window. You can also wait for the rate window to appear automatically, after a short delay. The delay is determined by the software version of your cycler and your system settings. See Chapter 9, System Settings.

5. Note alarms and cautions in the status windows. Correct all alarm and caution conditions as necessary.

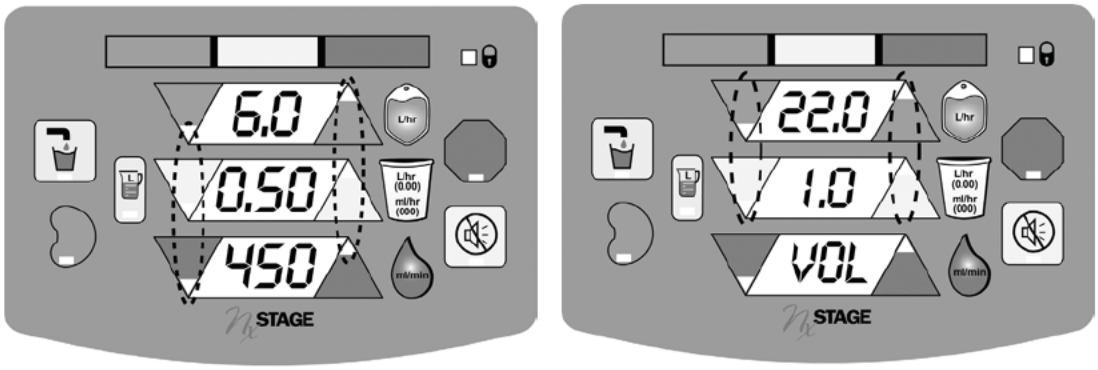
Figure 4-29: The status windows



1	Green Operating Window
2	Yellow Caution Window
3	Red Alarm Window

- If a red alarm or yellow caution appears, see the **List of alarms and cautions**, page 5-19 for alarms procedures.
- All red alarms require immediate attention.
- It is normal for some yellow cautions to appear during treatment.

6. Press the **ADJUSTMENT ARROWS** to change the fluid rate and volume targets if needed.



Rate Window **Volume Window**

7. Monitor your treatment:
   - Respond immediately to all alarms and cautions.
   - Make sure the blood lines are visible and secured to the vascular access.
   - Monitor the vital signs to determine response to treatment.
   - Monitor the arterial and venous pressures. Watch for any values outside normal ranges. The normal arterial pressure is between -50 and -200 mmHg; the normal venous pressure is between 20 and 300 mmHg. If pressures are outside the ranges, it may be necessary to adjust the blood flow rate to obtain a good access flow. If the access flow is good, check for kinks, clotting, or other obstruction.

NOTE

The cycler displays the arterial access pressure without the negative sign. Therefore, when the arterial pressure decreases (more negative), the arterial pressure displayed on the cycler shows a higher number indicating a more restricted flow.

WARNING

Do not disconnect and reverse patient blood lines during treatment. This may cause an infusion of air into the patient blood lines, which may lead to an embolism.

- If the cartridge has an access pressure pod, check that the pod is pulsing. If the pod does not pulse, reset it (see page 4-46) and check that the access pressures are within the expected range.
- If using a warmer, confirm that the dialysate bags drain evenly.
- Check that the saline line is primed with both white clamps closed to prevent the infusion of fluid or air by accident.
- Check for air in the venous header on the dialyzer. If there is air, remove the air from the post-dialyzer port with a 20 ml luer lock syringe. Flush the port with 3 ml of saline to clear the blood and then close the clamp.
- Check for clots in the blood circuit. You can check for clots by giving a manual bolus of fluid while closing the red clamp on the arterial blood line. See the instructions on page 4-49.

End of treatment

At the end of the treatment, you rinse back your blood from the cartridge.

WARNINGS

- Never try to open the door of the NxStage System One Cycler when the door lock symbol is on. If the door is opened by force, all safety systems will no longer be active, which may cause patient injury or death. If the door must be opened while the patient is connected, press the STOP key, immediately clamp all fluid and blood lines, turn the power switch OFF on the Cycler, and then open the door of the Cycler.
- Follow your center's instructions for rinsing back blood at the end of treatment. Blood that is left in the blood lines after rinseback will result in blood loss.
- Before starting treatment, check the patient blood lines for air. Check again before and during rinseback. Follow the instructions to remove air before starting treatment or rinseback. Failure to remove air from the patient blood lines may cause an infusion of air, which may lead to an embolism.

The treatment ends automatically when:

- The prescribed volume of dialysate has been delivered to the patient.
- The prescribed ultrafiltration volume has been removed from the patient.
- All alarm conditions have been cleared.

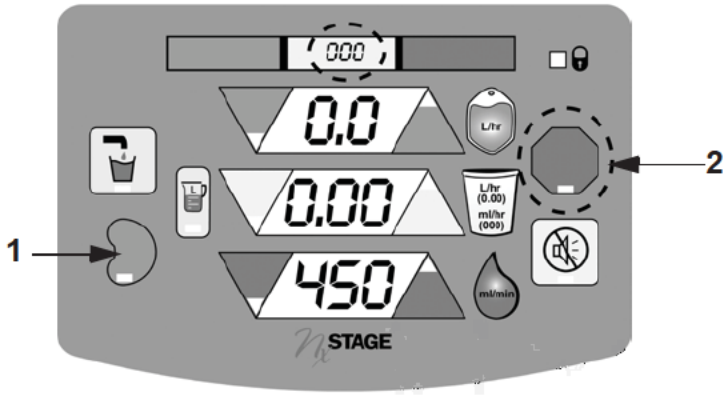
You can also end the treatment before reaching the volume goals.

1. To end the treatment, press the **STOP** key for two seconds.

NOTE

If you need to resume treatment at previous rates, press the **TREATMENT** key.

Figure 4-30: Location of STOP and TREATMENT buttons



1	**TREATMENT** key
2	**STOP** key

At the end of the treatment:

- Three zeros (**000**) appear in the Yellow Caution window
- The dialysate and ultrafiltrate rates go to zero (**0**)
- The blood pump continues to run

Do not press the **STOP** key until you are ready to rinse back the blood.

NOTE

All alarm conditions must be cleared before **000** End of Treatment can occur. If an alarm cannot be cleared or if the power fails, refer to **manual rinseback** on page 4-52.

Do not try to rinse back the blood manually:

- if the blood circuit is clotted or hemolyzed,
- if you see air in the blood circuit or blood lines, or
- if your center tells you differently.

Automated rinseback

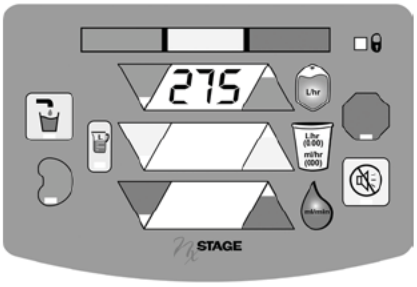
Before rinsing back the blood:

1. Make sure there is enough saline to rinse back the blood.

Figure 4-31: Checking saline level in bag

- The bag should have between 300 and 500 ml of saline left in the bag. If not, hang a fresh bag of saline.
- To prevent air entering the blood circuit, make sure that the saline line is primed.

2. Press the **STOP** key to stop the blood pump.
3. Check that the rinseback volume is shown in the top window of the control panel. For example, **275**.



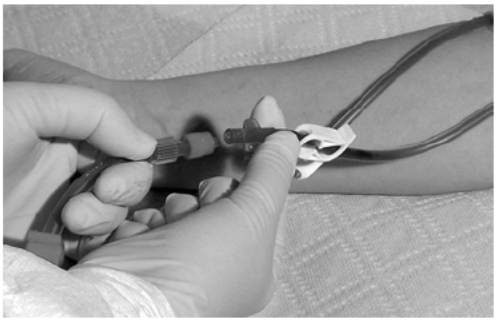
NOTE

The volume number shown in the picture is for example only. Your cycler may show a different number based on your System Settings 12 and 13.

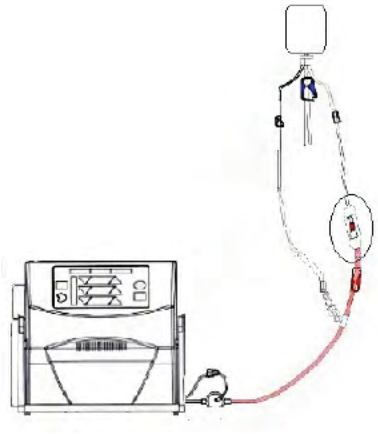
4. Close the red clamp on the arterial blood line and the clamp on the vascular access, using aseptic technique.

5. Disconnect the arterial blood line.
6. Connect the arterial blood line to the priming spike (red clamp).

Figure 4-32: Disconnect the arterial blood line and reconnect to the priming spike



Disconnecting



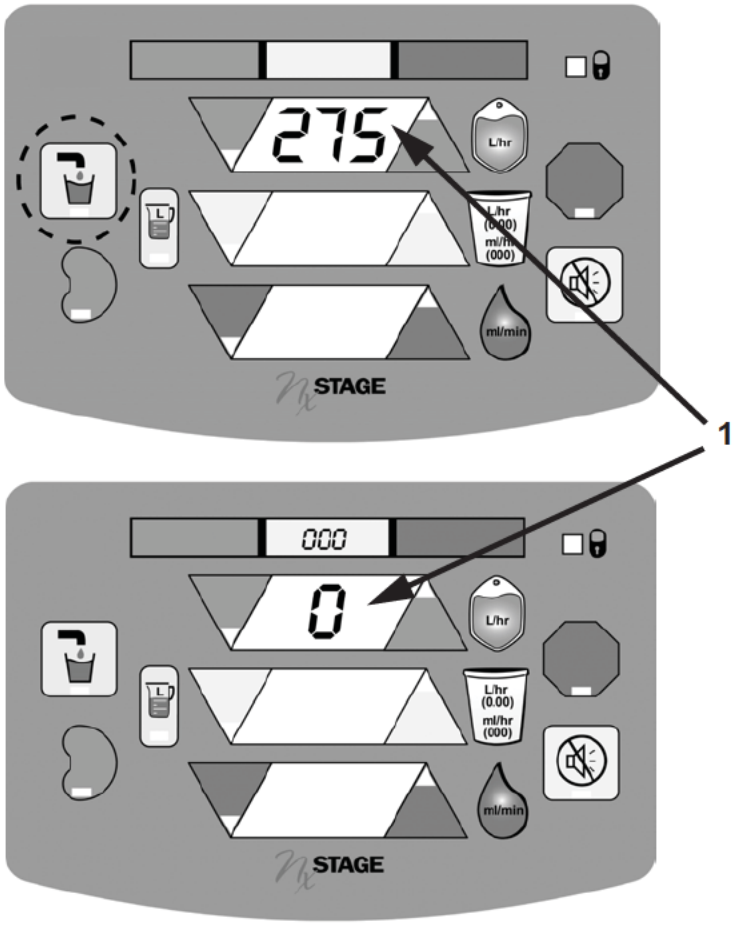
Reconnecting

7. Open the red clamps on the arterial blood line and priming spike.

To rinseback the blood:

1. Press the **ADD FLUID** key. The rinseback volume number (**275**) drops to zero (**0**).
2. Monitor the venous blood line (blue clamp) for air.

Figure 4-33: Top window counting down for Rinseback



1	Top window counts down as saline is used to rinse back. Rinseback is complete when top window reads **0** and Yellow Caution window reads **000**.

3. If needed, press the **ADD FLUID** key again until all blood lines are clear.

   If you administer extra fluid during rinseback, the ultrafiltration volume shown in the middle window increases as this extra fluid is given back to the patient.

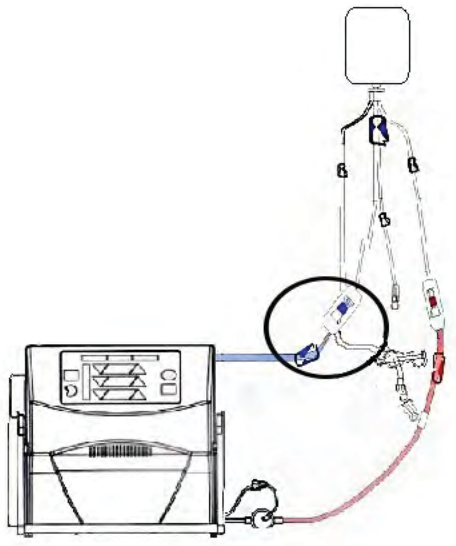
NOTE

A low venous pressure alarm (Yellow Caution 20, 21) may occur during rinseback due to a change in the fluid thickness. Press the **MUTE** key to clear the alarm.

At the end of rinseback:

1. Close the blue clamp on the venous blood line and the clamp on the vascular access.
2. Disconnect the venous blood line (blue clamp) from the vascular access.
3. Connect the venous blood line to the priming spike (blue clamp).

Figure 4-34: Attaching the venous blood line to the priming spike

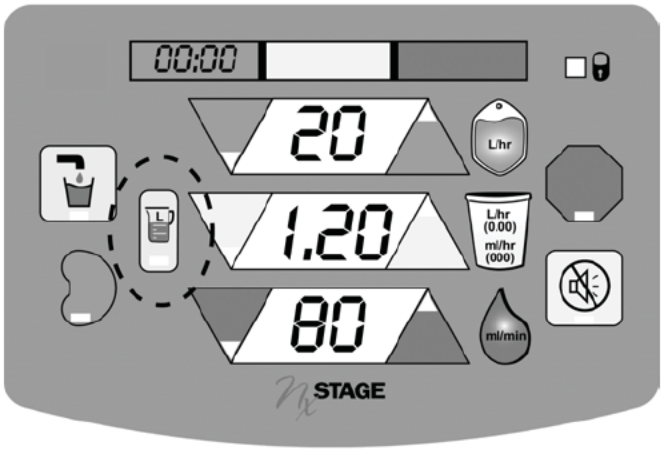


4. Press the **VOLUME TOGGLE** key to see the treatment summary.

   The treatment summary shows (from top to bottom):

   - the total treatment time.
   - the amount of dialysate used.
   - the ultrafiltration volume.
   - the amount of blood processed, in liters.

Figure 4-35: Example of treatment summary



NOTE

When you turn off the cycler, the treatment summary disappears.

5. Turn off the cycler.

To remove the disposables:

1. Disconnect the access pressure pod from the cycler.
2. Close the green clamps on the dialysate inlet line and dialysate source. Disconnect the dialysate inlet line from the dialysate source.
3. Close the yellow clamps on the waste line and drain line. Disconnect both lines.
4. Open the door of the cycler. To open, lift up the front handle until it clicks and pull the door toward you.
5. Remove the saline bag and cartridge.
6. Throw away the saline bag, cartridge, and other disposables as appropriate.

Common procedures

Re-priming a cartridge

The troubleshooting steps may ask you to re-prime the cartridge.

To re-prime the cartridge:

1. Turn off the cycler.
2. Lower the saline bag below the cycler.
3. Open the cycler door. Let the saline flow back completely into the bag.
4. Disconnect the access pressure pod. Remove the cartridge.
5. Turn on the cycler. Keep the door open and the handle up.
6. When the Yellow Caution window flashes two bars, insert the cartridge and press the lines into the three air detectors.
7. Close the door of the cycler.
8. Connect the access pressure pod and hang the saline bag.
9. Press the **ADD FLUID** key to re-prime the cartridge.

PRECAUTION

Do not reprime a Cartridge that has been used on a patient. Failure to follow the instructions for repriming a Cartridge may cause damage to the Cartridge or misloading, and may impact system performance.

Flushing the priming fluid before treatment

WARNING

Do not touch surfaces of any disposable covered by protective caps. This includes connectors and needleless access sites. Always use aseptic technique when handling connections. Touching these surfaces may make them non-sterile, which may cause patient infection.

The center may ask you to flush the priming fluid from the cartridge before starting the treatment and before connecting the blood lines to the vascular access.

Before flushing the cartridge:

1. Prepare the patient's vascular access.
2. Insert the priming spike in a fresh 1-liter bag of saline.
3. Close the blue clamps on the priming spike and venous blood line. Disconnect the venous blood line.
4. Place a luer lock syringe on the priming spike line with the blue clamp to maintain sterility. Be sure to leave the arterial blood line with the red clamp connected to the priming spike.
5. Hold the venous blood line over a clean container. Open the blue clamp.

To flush the cartridge:

1. Press the **TREATMENT** key. Drain the amount of saline determined by your center.
2. Press the **STOP** key.

After flushing the cartridge:

1. Close the blue clamp on the venous blood line. Connect the venous blood line to the vascular access.
2. Close the red clamps on the priming spike and arterial blood line. Using aseptic technique, disconnect both lines.
3. Connect the arterial blood line to the vascular access.
4. Open the red and blue clamps on the arterial and venous blood lines and the clamps on the vascular access.

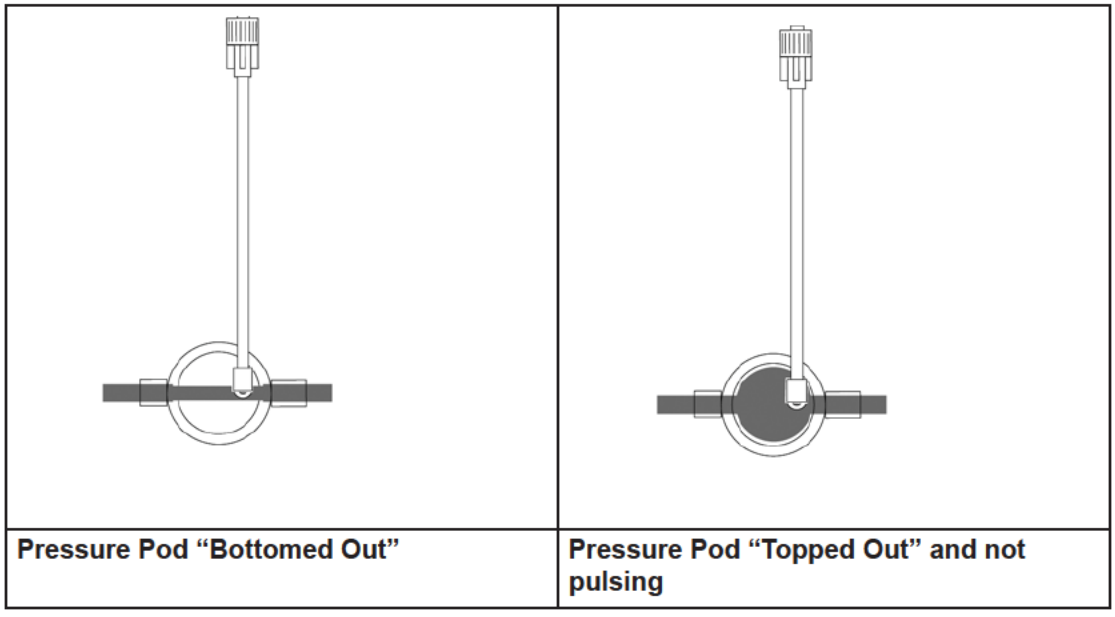
5. Place a luer lock syringe on the priming spike to maintain sterility.
6. Check that the system is ready.
7. Press the **TREATMENT** key to start treatment.

Resetting the access pressure pod

You need to reset the access pressure pod when:

- the pod is full of blood and not pulsing.
- there is no blood in the pod.
- there is no access pressure reading.

Figure 4-36: Reset access pressure pod when it tops out or bottoms out



Pressure Pod "Bottomed Out"	Pressure Pod "Topped Out" and not pulsing

To reset the access pressure pod:

1. Disconnect the access monitoring line from the cycler. The access pressure pod deflates.
2. Press the **STOP** key. If the pod fills immediately with blood, go to the procedure: **To connect the access monitoring line to the access pressure pod,** page 4-47.

If the pod does not fill immediately with blood:

1. Close the red clamp on the arterial blood line.

2. Open the white clamps on the saline line and saline "T." The pod fills with blood.
3. Close the white clamps on the saline line and saline "T."
4. Open the red clamp on the arterial blood line.

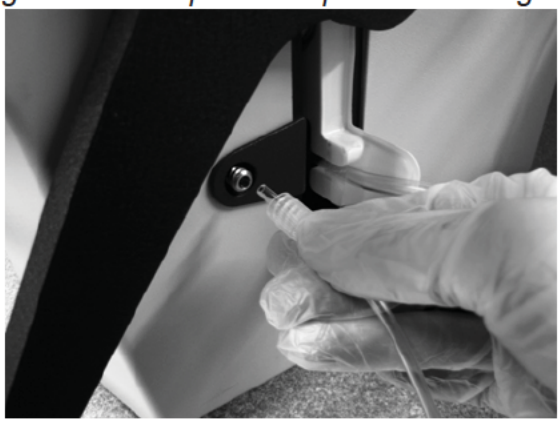
To connect the access monitoring line to the access pressure pod:

1. Hold the monitoring line behind the locking collar.
2. Insert the end of the monitoring line into the cycler. The connection is below the handle on the right side of the cycler.
3. Press the monitoring line into the connector. Twist a quarter turn to the left to seal the connection.
4. Tighten the locking collar.

To complete resetting the access pressure pod:

1. Press the **TREATMENT** key.
2. Check that the arterial pressures are within range.

Figure 4-37: Attaching the access pressure pod monitoring line



Treating low blood pressure (hypotension)

Unexpected low blood pressure may occur during treatment for a number of reasons. It may occur when the ultrafiltration is too fast or when the ultrafiltration goal is too high.

To treat low blood pressure, you can do one or both of the following:

- Deliver a manual fluid bolus.
- Stop the ultrafiltration.

Review your ultrafiltration rate and goal to determine the causes for low blood pressure during treatment. Reduce your ultrafiltration rate or goal or both if needed.

Delivering a manual fluid bolus

To deliver a manual fluid bolus:

1. Make sure there is enough saline in the saline bag for a fluid bolus.
2. While the blood pump is running, open the white clamps on the saline "T" and saline line.
3. Give the desired fluid volume.
   - Use only saline to give a fluid bolus.
   - Make sure the saline line is primed before delivering the fluid bolus.
   - Look at the markings on the saline bag to give the correct fluid volume.

Figure 4-38: Checking saline level in bag

4. Close the white clamps on the saline line and saline "T" after delivering the fluid bolus.
   - A low-pressure caution (Yellow Caution 20 or 21) may occur briefly when delivering a bolus. After delivering the bolus, the caution stops.
   - The cycler does not account for the volume of fluid given manually. You must determine if it is appropriate to add the bolus volume to the goal. Include any bolus volume not removed by ultrafiltration when you compare the weights before treatment and after treatment.

WARNING

Manual fluid boluses and fluid consumed during treatment are not included in the System One fluid balance calculations. Excessive fluid boluses, whether intentional or unintentional, or failure to account for consumed fluid during treatment, may cause patient injury. Include fluid boluses and the volume of fluid consumed in manual fluid balance calculations. Make sure that the administration lines used for manual bolus or rinseback are clamped after use.

Stopping the ultrafiltration

To stop the ultrafiltration, press and hold the **STOP** key for two seconds. The dialysate and ultrafiltration rates go to zero. The Yellow Caution window shows three zeros (**000**). The blood flow rate is not changed.

After the first treatment of low blood pressure

1. Check the patient's response to the manual bolus and stopping ultrafiltration.
2. Give another fluid bolus if needed to support the blood pressure.
3. If the blood pressure is good, continue treatment. Press the **TREATMENT** key to return to the first dialysate and ultrafiltration rates. Consider decreasing the ultrafiltration rate and volume.
4. If the blood pressure continues to be a concern, end the treatment and call your home training nurse.

NOTE

See **Ultrafiltration**, page 2-4.

Checking the dialyzer for clots

To check the dialyzer for clots by giving a manual fluid bolus with 100 to 200 milliliters of saline, follow **delivering a manual fluid bolus**, page 4-48.

The best way to check the dialyzer for clots while delivering a manual fluid bolus is to do the following:

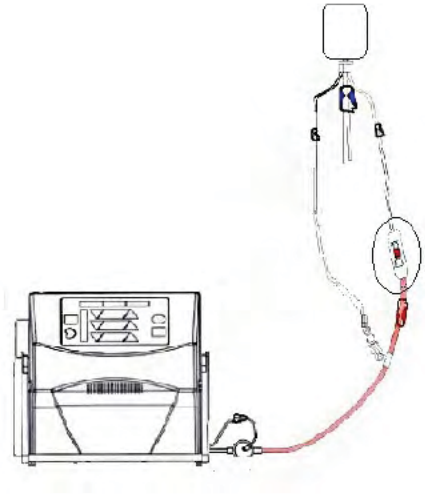
1. Press the **TREATMENT** key if the cycler is not in Treatment Mode.
2. Close the red clamp on the arterial blood line near the saline "T" (white clamp) while saline is infusing with the blood pump running.
3. Check the venous header and the arterial header for dark spots or patches. Dark spots or patches in headers are an indication of blood clotting.
4. After flushing the dialyzer, open the red clamp on the arterial blood line.
5. Close the white clamps on the saline "T" and saline line.

Temporary disconnection

To recirculate the blood circuit after rinsing back the blood:

1. After rinsing back the blood, keep the arterial blood line with the red clamp connected to the red port on the priming spike.
2. If you see clotting, throw away the cartridge.

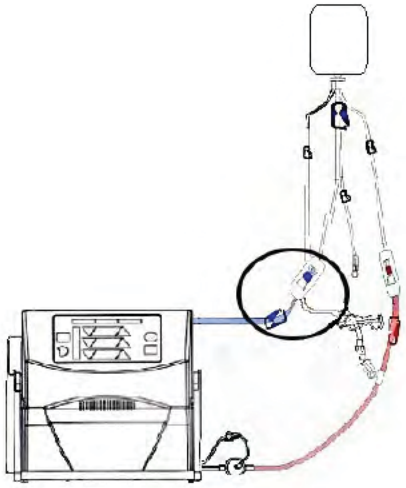
Figure 4-39: Connect the arterial blood line to the priming spike



3. Close the clamp on the venous vascular access line.
4. Close the blue clamp on the venous blood line. Disconnect it from the vascular access using aseptic technique.
5. Connect the venous blood line to the priming spike. Both have blue clamps.

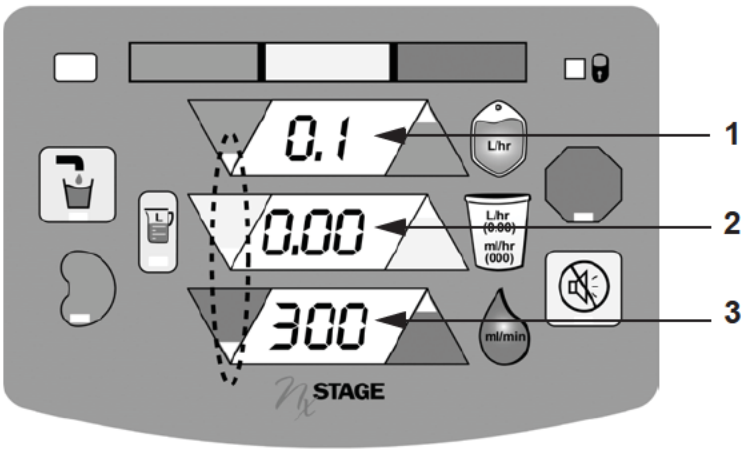
6. Open the blue clamps on the venous blood line and priming spike.

Figure 4-40: Attach the venous blood line to the priming spike



7. Press the **TREATMENT** key to recirculate the blood circuit with saline.
8. Immediately, press the **ADJUSTMENT ARROWS** keys to set the rates to the values shown in Figure 4-41.

Figure 4-41: Set the rates with the Adjustment Arrows keys



1	Dialysate rate, green arrows (top window): 0.1
2	Ultrafiltration rate, yellow arrows (middle window): 0
3	Blood flow rate, red arrows (bottom window): 300–350

Follow the instructions from your center to determine the recirculation time allowed for a temporary disconnection. If you see clotting in the blood circuit, throw away the cartridge.

To reconnect the patient after recirculation:

1. Press the **STOP** key.
2. Close the clamps on the blood lines.
3. Disconnect the blood lines from the priming spike.
4. Re-connect the blood lines to their original configuration on the vascular access.
5. Open the clamps on the blood lines and vascular access.
6. Press the **TREATMENT** key. Enter the treatment settings to resume treatment.

Manual rinseback

There are times when you can rinse back the blood manually, for example during a power failure, a recurring alarm, or any other problem that cannot be resolved. Check with your center if you are authorized to rinse back the blood manually.

Before rinsing back the blood manually, make sure that the blood circuit is not clotted or hemolyzed. Make sure there is no air in the blood circuit or blood lines.

WARNINGS

During a manual rinseback, do not apply excessive pressure or use devices that apply pressure on the saline bag (for example, blood pressure cuffs). The use of excessive pressure or a device that applies pressure to the saline bag may cause an infusion of air into the patient blood lines, which may lead to an embolism.

When performing manual rinseback, the NxStage System One Cycler door is open, which deactivates all safety systems. The operator must visually monitor for air in the patient blood lines, to prevent an infusion of air, which may lead to an embolism.

Follow your center's instructions for rinsing back blood at the end of treatment. Blood that is left in the blood lines after rinseback will result in blood loss.

Before rinsing back the blood:

1. Hang a fresh 1-liter bag of saline.
2. Make sure the saline line is primed and free of air.

NOTE

During a manual rinseback, air may enter the blood lines when squeezing a bag that is only partially filled with saline.

3. Turn off the cycler.
4. Close the yellow clamp on the waste line.
5. Close the green clamp on the dialysate inlet line to the cartridge.
6. Close the clamp on the patient's arterial vascular access line.
7. Close the red clamp on the arterial blood line. Using aseptic technique, disconnect it.
8. Connect the arterial blood line to the priming spike. Both have red clamps.

Rinsing back the blood:

1. Open the red clamps on the blood line and priming spike.
2. Open the door of the cycler. To open, lift up the handle until it clicks, then pull it toward you.
3. Squeeze the saline bag until the blood lines are clear of blood.
4. If there is pressure or resistance in the blood lines, or if there is air in the venous blood line, **do not try** to rinse back the blood.

Figure 4-42: Squeezing the saline bag for rinseback

After rinsing back the blood:

1. Close the clamp on the venous vascular access line.
2. Close the blue clamp on the venous blood line, using aseptic technique. Disconnect it from the vascular access.
3. Connect the venous blood line to the priming spike. Both have blue clamps.
4. Disconnect the access pressure pod from the cycler.
5. Close the green clamps on the dialysate inlet line and dialysate source. Disconnect the dialysate inlet line from the dialysate source.
6. Close the yellow clamps on the waste line and drain line. Disconnect both lines.
7. Remove the saline bag and the cartridge.
8. Throw away the saline bag, the cartridge, and other disposables, as appropriate.

Emergency rinseback

There are times when you need to rinse back the blood quickly. Before rinsing back the blood in an emergency, make sure that the blood circuit is not clotted or hemolyzed. Make sure there is no air in the blood circuit and blood lines.

To rinse back the blood quickly:

1. Make sure there is enough saline to rinse back the blood. You will need between 300 and 500 milliliters of saline.
2. Open the white clamps on the saline line and saline "T." Check the flow of saline.
3. Close red clamp on the arterial blood line.
4. Let saline infuse the blood lines to return the blood to the patient.

After returning the blood:

1. Press the **STOP** key on the cycler when the venous blood line (blue clamp) is clear of blood.
2. Close the clamps on the arterial and venous vascular access lines.
3. Close the blue clamp on the venous blood line. Disconnect it from the vascular access using aseptic technique.
4. Close the red clamp on the arterial blood line. Disconnect it from the vascular access using aseptic technique.
5. Connect the arterial blood line (red clamp) and venous blood line (blue clamp) to the red and blue clamps on the priming spike.
6. Turn off the cycler.
7. Open the door of the cycler. To open the door, lift up the handle until it clicks, then pull it toward you.

To remove the disposables:

1. Disconnect the access pressure pod from the cycler.
2. Close the green clamps on the dialysate inlet line and dialysate source line. Disconnect the dialysate inlet line from the dialysate source.
3. Close the yellow clamps on the waste line and drain line. Disconnect both lines.
4. Remove the saline bag and cartridge from the cycler.
5. Throw away the saline bag, cartridge and other disposables, as appropriate.

This page intentionally left blank.

NxSTAGE®
Invent. Improve. Inspire.

Chapter 5 Troubleshooting

The NxStage System One cycler delivers safe, smooth, and comfortable treatment. The cycler has features that monitor for safe operation. Alarms and cautions alert you of problems or potential problems to help you maintain safe treatments. Always have your care partner help you troubleshoot blood lines.

WARNINGS

The risk of blood clotting in the Cartridge and Dialyzer is higher during long treatments, when no anticoagulation is used, in certain patients who are more prone to excess clotting, or any time when the blood flow stops, including when the NxStage System One Cycler loses power or during an unrecoverable alarm. The risk of blood clotting increases the longer treatment continues and the longer blood flow is stopped. To reduce the risk of blood clotting and identify the early signs of clotting:

- Follow your center's instructions to give and monitor anticoagulant.
- During treatment, regularly check the Cartridge and Dialyzer for clotting by looking closely at the Cartridge and Dialyzer, and periodically flushing the Dialyzer with a manual fluid bolus.

Failure to respond to blood clotting in the Cartridge and Dialyzer may result in a blood clot being released into the patient's bloodstream and causing a blockage (thromboembolism). Failure to respond to clotting may also lead to sustained high pressures in the blood circuit and cause a dialyzer blood leak or hemolysis. These conditions may cause serious injury or death if not responded to promptly and appropriately. Regularly check the Dialyzer for any evidence of a leak. Do not return the blood if the blood flow is stopped for a long time. Discard the Cartridge and Dialyzer if they are clotted.

Manual fluid boluses and fluid consumed during treatment are not included in the System One fluid balance calculations. Excessive fluid boluses, whether intentional or unintentional, or failure to account for consumed fluid during treatment, may cause patient injury. Include fluid boluses and the volume of fluid consumed in manual fluid balance calculations. Make sure that the administration lines used for manual bolus or rinseback are clamped after use.

When a Yellow Caution is displayed, some safety systems may not be active. Monitor the system and the patient until the Green Safe Operating condition returns. Failure to do so may cause patient injury or death.

During a manual rinseback, do not apply excessive pressure or use devices that apply pressure on the saline bag (for example, blood pressure cuffs). The use of excessive pressure or a device that applies pressure to the saline bag may cause an infusion of air into the patient blood lines, which may lead to an embolism.

WARNINGS

Before starting treatment, check the patient blood lines for air. Check again before and during rinseback. Follow the instructions to remove air before starting treatment or rinseback. Failure to remove air from the patient blood lines may cause an infusion of air, which may lead to an embolism.

There are no operator or customer technician serviceable parts in any NxStage equipment. Unless otherwise instructed or authorized, NxStage or its agent must perform all maintenance and repair. No changes or modifications to any NxStage equipment are allowed without NxStage's authorization. Unauthorized changes or modifications to equipment may impact performance which may lead to patient or operator injury or death.

Re-priming the cartridge

The troubleshooting steps may ask you to re-prime the cartridge.

To re-prime the cartridge:

1. Turn off the cycler.
2. Lower the saline bag below the cycler.
3. Open the cycler door. Let the saline flow back completely into the bag.
4. Disconnect the access pressure pod. Remove the cartridge.
5. Turn on the cycler. Keep the door open and the handle up.
6. When the Yellow Caution window flashes two bars, insert the cartridge and press the lines into the three air detectors.
7. Close the door of the cycler.
8. Connect the access pressure pod and hang the saline bag.
9. Press the **ADD FLUID** key to re-prime the cartridge.

PRECAUTION

Do not reprime a Cartridge that has been used on a patient. Failure to follow the instructions for repriming a Cartridge may cause damage to the Cartridge or misloading, and may impact system performance.

Manual fluid bolus

The troubleshooting steps may ask you to give a manual fluid bolus.

To give a manual fluid bolus:

1. Make sure there is enough saline in the saline bag for a fluid bolus.
2. While the blood pump is running, open the white clamps on the saline "T" and saline line.
3. Give the desired fluid volume.
   - Use only saline to give a fluid bolus.
   - Make sure the saline line is primed before delivering the fluid bolus.
   - Look at the markings on the saline bag to give the correct fluid volume.

Figure 5-1: Checking saline level in bag

4. Close the white clamps on the saline line and saline "T" after delivering the fluid bolus.
   - A low-pressure caution (Yellow Caution 20 or 21) may occur briefly when delivering a bolus. After delivering the bolus, the caution stops.
   - The cycler does not account for the volume of fluid given manually. You must determine if it is appropriate to add the bolus volume to the goal. Include any bolus volume not removed by ultrafiltration when you compare the weights before treatment and after treatment.

General alarm events

Treatment time displays 99:99

Probable cause

System Setting 38 is set to one (**1**) and the treatment ultrafiltration rate is set to zero (**0**). The cycler cannot remove the rinseback volume if the ultrafiltration rate is set to zero (**0**) and the cycler is not able to calculate the treatment time.

Action required

Set the ultrafiltration rate to 0.5 L/hr to remove the rinseback volume. The estimated treatment time will be shown in the window. This time is based upon the dialysate rate and volume.

Cycler will not turn on

Probable cause

1. There is no AC power to the cycler.
2. The cycler is in a power protection state.

Action required

1. Make sure one end of the power cord is fully plugged into a working electrical outlet and the other end to the cycler. Make sure the cycler power switch is turned on.
2. Unplug the power cord from the electrical outlet. Wait five minutes. Plug the power cord back into the electrical outlet and turn on the cycler.

   If the recommended action does not resolve the problem, call Technical Support.

Continuous beep. Nothing on screen

Probable cause

1. Power loss.
2. Service required.

Action required

1. Check the connections of the power cord to the wall outlet and to the power input on the cycler.
2. If the recommended action does not resolve the problem, call Technical Support.

Clotting in the dialyzer or blood circuit

Blood clotting in the dialyzer or blood circuit can be a very serious risk for the dialysis patient. When the blood clots, it cannot be returned to the body and the dialysis patient loses blood. Risks from returning blood that is clotted to the patient include heart attack, stroke, and pulmonary embolism. Clotting in the cartridge can restrict the blood flow and cause damage to the red blood cells, called hemolysis.

Probable cause

Blood clotting in the dialyzer and blood circuit can occur at any time during treatment while the blood is outside the body. Access flow, blood flow rate, not enough anticoagulation and other events may cause blood clotting.

- Clotting in the dialyzer or blood circuit starts to happen as soon as the blood pump is turned off.
- Patients and their caregivers should carefully follow the instructions from their doctor or center on the use of an anticoagulant, for example heparin, as part of their treatment.
- Potential for clotting increases every time the blood flow stops, after multiple alarms, and with prolonged alarm recovery times.

Action required

- Look at the blood circuit. Make sure the blood flows freely.
- Remove air promptly from the blood circuit and dialyzer.
- Respond to all alarms promptly.
- Seek help if unable to clear multiple alarms.
- Check the dialyzer and blood circuit regularly for early signs of clotting.

When there is clotting in the blood lines, the color of the blood is very dark. If the blood stops pulsating in the access pressure pod, it is a sign of clotting in the access pressure pod.

You can check the dialyzer for clotting by giving a manual fluid bolus. See **manual fluid bolus**, page 5-5.

The best way to check the dialyzer for clotting is to do the following:

1. Press the **TREATMENT** key if the cycler is not in Treatment Mode.
2. Close the red clamp on the arterial blood line near the saline "T" (white clamp) while saline is infusing with the blood pump running.
3. Check the venous header and the arterial header for dark spots or patches. Dark spots or patches in the headers are signs of blood clotting.
4. Open the red clamp on the arterial blood line after flushing the dialyzer.
5. Close the white clamps on the saline "T" and the saline line.

WARNING

Manual fluid boluses and fluid consumed during treatment are not included in the System One fluid balance calculations. Excessive fluid boluses, whether intentional or unintentional, or failure to account for consumed fluid during treatment, may cause patient injury. Include fluid boluses and the volume of fluid consumed in manual fluid balance calculations. Make sure that the administration lines used for manual bolus or rinseback are clamped after use.

- Watch closely for any changes in venous or effluent pressure. Unless the blood lines are kinked, blocked, disconnected or the clamps are closed, changes in venous or effluent pressure are signs of blood clotting in the blood circuit.

- Check for clotting in the dialyzer or blood circuit when any of the following alarms occur:
  - Red Alarms 33 and 34 (Check Dialyzer: High TMP)
  - Red Alarm 62 (Check Dialyzer for Clotting: Arterial Pressure Unstable)
  - Red Alarms and Yellow Cautions 20 and 21 (Low Venous Pressure) and 22 (Effluent Pressure)
- If there is clotting in the dialyzer or blood circuit, end the treatment and do **not** rinse back the blood.
- If any of the following events occur, contact your center to determine if anticoagulation needs to be changed or other steps to take before the next treatment:
  - Clotting appears to occur more often.
  - There is a large amount of clotting.
  - The patient loses blood.

Arterial access flow

During hemodialysis, the cycler pulls the blood from the arterial vascular access at the set blood pump rate. If the arterial access does not have sufficient blood flow for the set blood pump rate, alarms may occur.

NOTE

The cycler displays the arterial access pressure without the negative sign. Therefore, when the arterial access pressure decreases (more negative), the arterial access pressure shown on the cycler has a higher number indicating a more restricted flow.

When the cycler tries to pull more blood from the arterial access than it can deliver, it lowers the arterial access pressure (more negative) and pulls small bubbles of air out of the blood. The more negative the arterial access pressure, the higher is the arterial pressure number reading on the cycler. A high arterial access pressure number indicates an insufficient blood flow.

WARNINGS

- Do not disconnect and reverse patient blood lines during treatment. This may cause an infusion of air into the patient blood lines, which may lead to an embolism.
- Do not adjust the vascular access while the Blood Pump is running. Adjusting the vascular access while the Blood Pump is running increases the likelihood of needle dislodgement, which may result in a significant blood loss.

Probable cause

Poor blood flow at the arterial access.

Action required

- Follow the instructions from your center on how to assess the blood flow from the arterial access.
- If there is not enough blood flow for the cycler to pump the blood at the set rate, an alarm occurs:
  - Caution and Alarm 24 usually occur first if the arterial access pressure decreases (becomes more negative).
  - Alarm 11 occurs when air is pulled out of the blood. This alarm also indicates poor blood flow or an occlusion.
  - Caution and Alarm 21 occurs when the venous pressure is low. This alarm may also occur when the blood flow is low at the arterial access because the blood reaching the venous pressure sensor has less pressure.
  - Alarm 22 (Low Effluent Pressure) may occur when there is not enough blood in the dialyzer to produce the positive effluent pressure needed to finish the treatment.

NOTE

For the complete list of alarms and how to clear the alarms see page 5-19.

To prevent arterial access flow problems:

- Follow the instructions from your center on how to insert, position, adjust, and tape the needles at the vascular access.
- Before starting your treatment, check the cartridge arterial blood line for kinks or loose connections that would prevent blood flow. Make sure that all the clamps on the line are opened or closed properly.
- When starting your treatment, watch for any signs of poor blood flow. Check and adjust the arterial vascular access:
  - If you see bubbles of air in the arterial blood line when the cycler pumps the blood.
  - If the access pressure is different from the expected range when the cycler starts pumping the blood.

When it is necessary to check and adjust the arterial access:

- Use a luer lock syringe on the access line and draw a small amount of blood to check that the blood draws easily.
- If the access needle requires more than a minor adjustment, or if it needs to be replaced, rinse back the blood unless otherwise directed by the center, as long as the blood circuit is not clotted or hemolyzed and air is not seen in the blood circuit or in the patient blood lines. Remember, clotting starts when the blood pump is off.
- After rinseback, you can either temporarily disconnect the patient and recirculate the cartridge (see page 4-50) or prime a new cartridge.

- During treatment, monitor for changes in blood circuit pressures, alarms, and cautions. These are signs of insufficient blood flow.

Observation of pink waste fluid

Hemolysis is the destruction of red blood cells. When red blood cells are destroyed, the hemoglobin inside them is released into the blood plasma. Pink-tinged effluent or waste fluid without a Blood Leak Alarm 60 may be due to hemolysis.

Destroying red blood cells releases potassium into the bloodstream. A high potassium level can lead to muscle weakness and changes in the heart rhythm and may eventually lead to cardiac arrest and possibly death. The destruction of the red blood cells may also cause low hemoglobin levels and anemia.

Identifying and responding to the risks, causes, and symptoms of hemolysis may prevent further hemolysis.

NOTE

Clinical symptoms of hemolysis include back pain, shortness of breath, burning in the venous access, and tightness of the chest. These symptoms indicate a medical emergency. Follow the guidelines from your center for help and treatment.

Probable cause

1. A medical condition or medication can cause hemolysis or change the color of the effluent fluid.
2. Hemolysis as the result of treatment occurs under the following conditions:
   - The red blood cells are forced through a narrowed, severely kinked, or obstructed catheter, blood line or needle.
   - The blood pump starts and stops frequently.
   - The pump runs when there is clotting in the dialyzer or blood lines.

Action required

1. Contact your health care provider to discuss medical conditions and medication that may cause hemolysis
2. Follow the instructions from your center on how to test for blood in the effluent fluid.
   - If the test shows blood in the effluent fluid, press the **STOP** key to end the treatment. Perform a manual rinseback to rinse back the blood, unless otherwise instructed by your center. You can rinse back the blood as long as there is no clotting, hemolysis, or air in the blood circuit and blood lines. **See manual rinseback**, page 4-52.
   - If the test does not show blood in the effluent fluid but hemolysis is still suspected, end your treatment and **do not** rinse back the blood.

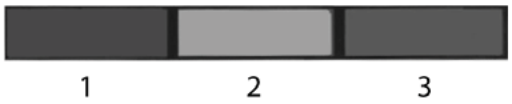
To prevent hemolysis:

1. Check every cartridge for kinks in the bloodlines. Do not use a cartridge with kinked bloodlines.
2. Follow your prescription settings from your doctor for needle size, blood flow rate and blood circuit pressures.
3. Monitor the system for clotting. **Do not try** to rinse back the blood if the blood circuit is clotted. Clotting in the dialyzer and blood line starts as soon as the blood pump is turned off.
   - If you cannot clear an alarm promptly, after two or three attempts, end your treatment. Perform a manual rinseback to rinse back the blood, unless otherwise instructed by your center. You can rinse back the blood as long as there is no clotting, hemolysis, or air in the blood circuit and blood lines. **See manual rinseback**, page 4-52.

Alarm system overview

The alarm system includes a red alarm and a yellow caution. During a red alarm, a red alarm number appears in the red alarm window. During a yellow caution, a yellow caution number appears in the yellow caution window. See Figure 5-2.

Figure 5-2: The Status Windows



1	Green Operating
2	Yellow Caution
3	Red Alarm

During a red alarm, the cycler stops the blood pump. The risk of blood clotting in the circuit and blood lines increases the longer the blood pump is stopped. Multiple alarms and long delays in alarm clearance increase the risk of clotting. To avoid clotting, it is important to identify and clear alarms promptly.

Standard response to red alarms

To respond to a red alarm:

1. Check the alarm number in the red alarm window.
2. Press the **MUTE** key to silence the alarm.
3. Look up the alarm number in the list of alarms and cautions that begins on **page 5-19**.
4. Follow the instructions in the table to identify the cause of the alarm.
5. Press the **STOP** key to clear the alarm.
   - If the red alarm occurs during treatment, press the **TREATMENT** key to continue.
   - If the red alarm occurs during the Prime or Rinseback Mode, press the **ADD FLUID** key to continue.

If you cannot correct the cause of an alarm promptly, after two or three attempts, end your treatment. Perform a manual rinseback to rinse back the blood, unless otherwise instructed by your center. You can rinse back the blood as long as there is no clotting, hemolysis, or air in the blood circuit and blood lines. **See manual rinseback**, page 4-52.

Contact your center if you cannot continue your treatment.

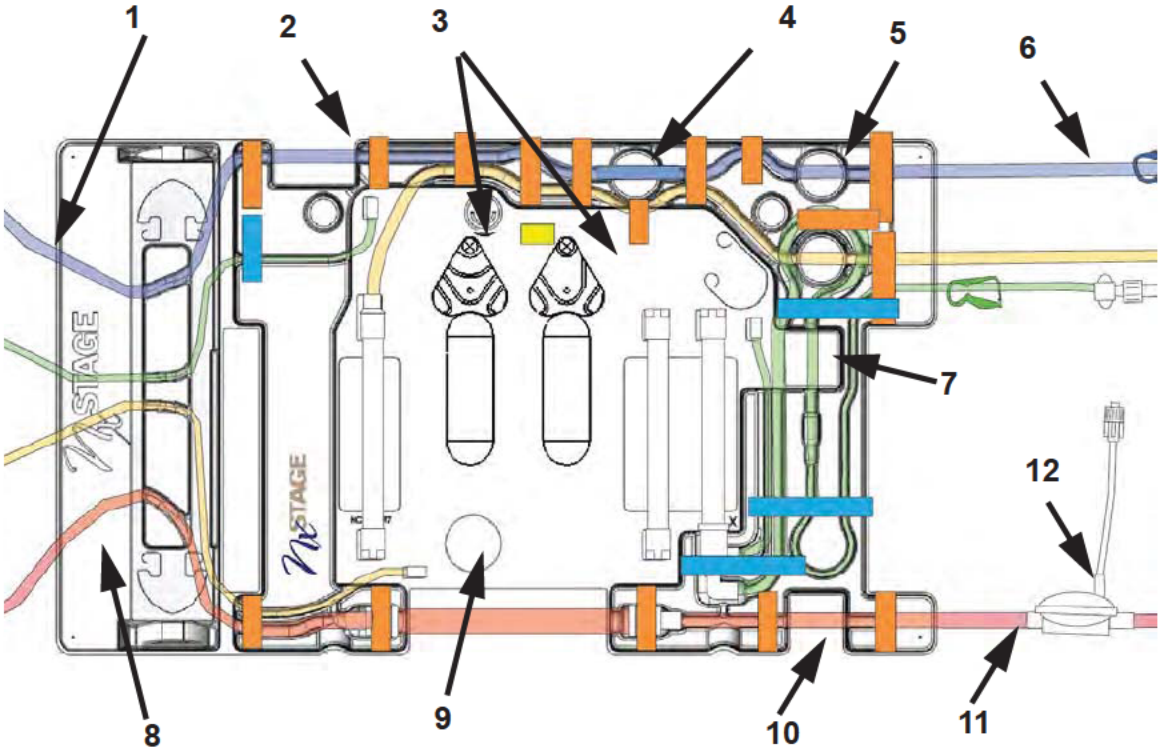
Overview of safety and control systems

Your cycler with the cartridge installed, includes the following safety and control systems:

- Air detection in the arterial and venous blood lines, and in the dialysate lines
- Balance chamber pressure sensor
- Blood leak detection
- Pressure sensors in the arterial and venous blood lines, effluent, waste bag, and in the dialyzer membrane (TMP)
- Temperature sensor

As soon as you load the cartridge into the cycler, the safety and control systems become active.

Figure 5-3: Safety and control system interfaces (location on cartridge)



1	From Dialyzer	7	Dialysate Air Detector
2	Venous Air Detector	8	To Dialyzer
3	Balance Chamber, Waste Line pressure monitoring	9	Effluent Pressure Detector, Blood Leak Detector
4	Venous Pressure Detector	10	Arterial Air Detector
5	Venous Clamp	11	From Arterial Blood Line (red clamp)
6	To Venous Blood Line (blue clamp)	12	Access Pressure Pod

Alarm types

All red alarms and yellow cautions produced by the cycler are related to the equipment or system only. The NxStage System One does not produce any alarms or cautions related to the medical condition of the patient.

Table 5-1: Alarm types include:

Change of status	**Red Alarm 000** **Yellow Caution 000** The cycler is at the end of an operational mode. Press the **STOP** key to go to the next mode of operation. Example: to go from Prime to Treatment.
Information	**Yellow Caution 1, 2, 3, 4, 5, 6, 7, 8, 9,72** This is a system status. Some events require intervention.
Air	**Red Alarm 10, 11, 13** **Yellow Caution 12, 14** Air detected in one of three locations: • in the arterial blood line (red clamp) • in the venous blood line (blue clamp) • in the dialysate inlet line (green clamp) Air must be removed to clear the alarm.
Pressure	**Red Alarm 20*, 21*, 22*, 23, 24, 30, 31, 33*, 34, 35, 62*** **Yellow Caution 20*, 21*, 23, 24, 25, 27, 30, 32** Detected pressures are higher or lower than expected. The cause must be identified and the alarm cleared before continuing the treatment. * When these alarms happen several times, it may indicate that the blood circuit or dialyzer is clotting.
Balancing system	**Red Alarm 36, 37, 38, 39, 90, 91, 92, 99** The fluid balancing system is not performing as expected or there may be a leak in the system. Check the cartridge for a leak before continuing the treatment.
Power failure	**Red Alarm 41** **Yellow Caution 40** Indicates a loss of power to the machine and whether the treatment may be started again.

Temperature	**Red Alarm 50** **Yellow Caution 51, 52, 53, 54** • The dialysate temperature has reached its alarm point. • Status of the cool down or warm up process. • Monitoring status for low temperature.
Blood leak detector	**Red Alarm 60, 61** Lets you know when to check the effluent for blood. Lets you know when the machine may not work due to a dirty detector.
Maintenance	**Yellow Caution 70, 71** Lets you know when the cartridge life has expired. Lets you know when the preventive maintenance is due.
Startup/ priming	**Red Alarm 13, 85, 86, 87, 88, 89, 92** **Yellow Caution 80, 81, 88, 93** Lets you know of the steps you are required to take during the prime and alarms test.
System	**Red Alarm between 100-999 (Except 715 and 721)** **Yellow Caution 999** Lets you know of a system error. Lets you know of a communication error. Lets you know of an incorrect setup. If these events occur, contact Technical Support.
Power loss	Within five seconds of power loss, the machine sounds an alarm tone and the control panel goes blank.

Alarm and caution priorities

Alarm and caution priorities are based on the types and if user intervention is required.

Table 5-2: Alarm priorities

Priority	Alarm type	Intervention required	Alarm/caution number
High	Red alarm	Yes	All red alarm numbers
Medium	Yellow caution	Yes	Caution 4, 6 All caution numbers above number 10
Low	Yellow caution	No	Cautions 000, 1, 2, 3, 5, 7, 8, 9, 70, and 72

The following pages list all red alarm and yellow caution events. Each alarm or caution is identified by its number, probable cause, and actions required to clear the alarm or caution. If an alarm or caution has more than one probable cause, the list gives the number for each cause and the steps to clear the alarm or caution.

NOTE

When using the list of alarms and cautions, make sure you check the next page. Some alarms and cautions have more than one cause and resolution to clear them.

List of alarms and cautions

000 - End of TREATMENT/RINSEBACK (Yellow Caution)

000 - Alarm Test Passed (Red Alarm)

Priority

- Yellow Caution - Low
- Red Alarm - High

Alarm Event

The system has reached the end of a process.

Probable Cause	Action Required
The system has successfully reached the end of a major process (Prime, Treatment, Rinseback).	None required. Press the **STOP** key if you want to go to the next mode, such as: • From Prime to Treatment • From Treatment to Rinseback

1 - Infusing Fluid Bolus (Yellow Caution)

Priority

- Yellow Caution - Low

Alarm Event

The user has pressed the **ADD FLUID** key during the treatment and an automated fluid bolus is underway.

Probable Cause	Action Required
This feature is only active when System Setting 9 is set to a value greater than **0**. System Setting 9 determines the volume of fluid bolus (see **Changing system settings**, page 9-2).	None required, or press the **STOP** key to stop infusing bolus.

PRECAUTION

The default value for System Setting #9 is zero (0) for hemodialysis which disables the automatic bolus feature. In certain geographic areas outside of the US, additional labeling provides more information on using the NxStage System One to deliver an automatic fluid bolus.

2 - Fluid Balance System Check Underway (Yellow Caution)

Priority

- Yellow Caution - Low

Alarm Event

The system is conducting a normal automated fluid balancing system check, which takes approximately two minutes.

Probable Cause	Action Required
The fluid balancing system check is performed at an interval determined by System Setting 43.	None required. If check fails, a balancing system red alarm will appear.

3 - Parameter Limit Exceeded (Yellow Caution)

Priority

- Yellow Caution - Low

Alarm Event

A setting is too low or too high.

Probable Cause	Action Required
The user has attempted to input a setting (for example, flow rate) that is too low or high.	Confirm the system settings. See **System Settings**, page 9-6 for allowable settings.

4 - Blood Pump Off Caution (Yellow Caution)

Priority

- Yellow Caution - Low

Alarm Event

The blood pump is stopped.

Probable Cause	Action Required
The user pressed the **STOP** key during Treatment Mode and the blood pump is stopped. Blood flow rate equals zero (**0**).	• Press the **TREATMENT** key to continue during Treatment Mode. • Press the **ADD FLUID** key to continue during Rinseback Mode. Clotting risk increases if the blood pump is stopped for a long time.

5 - Target Volume Achieved (Yellow Caution)

Priority

- Yellow Caution - Low

Alarm Event

The target volume has been achieved.

Probable Cause	Action Required
Dialysate or ultrafiltration volume target reached.	Reset target volumes (if necessary). Press the **MUTE** key to clear caution.

6 - Blood Circulation Only (Yellow Caution)

Priority

- Yellow Caution - Medium

Alarm Event

No therapy is being delivered but the target volume has not been reached.

Probable Cause	Action Required
The dialysate rate and the ultrafiltration rates are set to zero (**0**), but at least one target volume is non-zero. Blood is flowing through the cartridge, but no therapy is being delivered.	Reset rates or end the treatment and perform an automated rinseback, page 4-39, as appropriate.

7 - Alarms Overridden Caution (Yellow Caution)

Priority

- Yellow Caution - Low

Alarm Event

System is stabilizing.

Probable Cause	Action Required
One or more alarms are temporarily overridden as the system stabilizes, such as after a change in commanded flow rates.	Monitor treatment closely until a Green Operating Condition returns.

8 - Pressure Limits Not Locked (Yellow Caution)

Priority

- Yellow Caution - Low

Alarm Event

System adjusting to commanded change in flow rates.

Probable Cause	Action Required
The user has changed flow rates using the **ADJUSTMENT ARROWS** keys and the adjustable pressure limit windows have not yet "locked" (see Chapter 9, System Settings).	Monitor treatment closely until a Green Operating Condition returns.

9 - Automated High Pressure Recovery (Yellow Caution)

Priority

- Yellow Caution - Low

Alarm Event

Pressure-related alarm recovery.

Probable Cause	Action Required
Alarm reset condition after pressure-related alarm condition (Red Alarm 20–39).	None required. Do **not** press the **STOP** key during the alarm recovery process.

NOTE

TREATMENT key remains lit during high pressure recovery.

10 - Check for Venous Air During PRIME, Not including recirculation Step 23.0 (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

Air is detected in the cartridge tubing after the dialyzer and before the venous blood line (blue clamp). All pumps stop when the alarm is displayed.

1. Press **MUTE** to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
Air entering the blood circuit from:	
1. Priming spike tip is not fully inserted into saline bag. (For example, the tip is not visible within the saline bag).	Push the priming spike into the saline bag using a twisting motion until tip is visible.
2. Saline bag is empty of fluid.	Replace the empty saline bag with new bag.
3. Saline "T" cap is loose.	Secure the cap on the saline "T."

After probable cause is resolved:

Press the **STOP** key to clear the alarm. Remove the air using a luer lock syringe (for a small amount of air) or reprime the cartridge, see page 5-4.

PRECAUTION

Do not reprime a Cartridge that has been used on a patient. Failure to follow the instructions for repriming a Cartridge may cause damage to the Cartridge or misloading, and may impact system performance.

To remove the air using a syringe:

1. Close the blue clamp on the post-dialyzer port.
2. Attach a 20 ml luer lock syringe to the post-dialyzer port, then open the blue clamp. Slowly pull back on the syringe to remove air. When air is removed, close the blue clamp.
3. If no air is seen, press the **ADD FLUID** key to resume.
4. Observe blood circuit lines and venous header for air. Repeat Steps 1 and 2 if air is seen.

10 - Check for Venous Air During TREATMENT (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

Air is detected in the cartridge tubing after the dialyzer and before the venous blood line (blue clamp).

All pumps stop and air must be removed before continuing. If air is present in the venous blood line, **do not** rinse back blood.

Air in the blood circuit during treatment can be dangerous. If air enters the blood stream, it can lead to an air embolism that can result in serious injury or even death. If an air embolism is suspected, follow the emergency interventions according to your center's policy. Call emergency medical personnel immediately, and then notify the doctor and center.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
Air entering the blood circuit from:	
1. Arterial connection loose or disconnected between patient and blood pump.	Secure and/or reconnect all arterial connections.
2. Arterial access dislodged.	Re-establish arterial access following your center's procedure.

Probable Cause	Actions Required
3. Air in saline line from empty saline bag.	Remove air from the saline line: • Replace the saline bag with a new bag. • Make sure the saline "T" is clamped. • If air is seen in the saline line, disconnect the saline line from the saline "T." Open the clamp on the saline line to prime the line with saline, then close the clamp the saline line and reconnect to the saline "T."
4. Air not removed during priming.	Follow the instructions below to remove air from the venous line.
5. Air not completely removed from venous header.	Follow the instructions below to remove air from the venous line.
6. Air in replacement fluid (hemofiltration therapy only).	Follow the instructions below to remove air from the venous line.

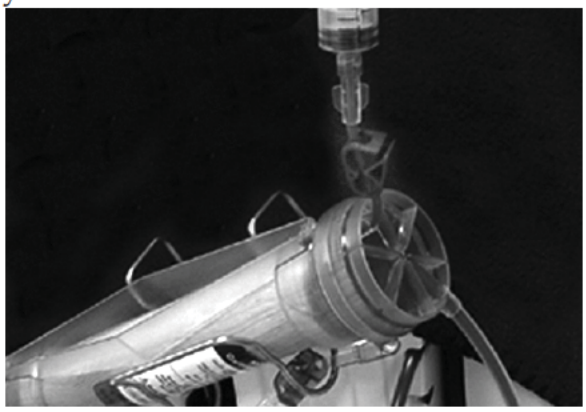
WARNING

Do not disconnect and reverse patient blood lines during treatment. This may cause an infusion of air into the patient blood lines, which may lead to an embolism.

After probable cause is resolved, remove air from the venous line:

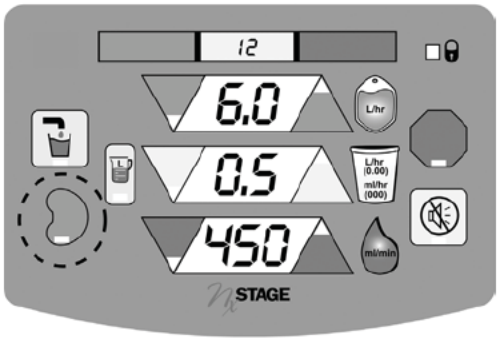
1. Press the **STOP** key.
2. Attach a 20 ml luer lock syringe to the post-dialyzer port, then open the blue clamp. Slowly pull back on the syringe to remove air.

3. Inject the blood (not the air) back through the post-dialyzer port. Close the clamp securely.



- Hold the luer lock syringe upright to prevent the return of air.
- When complete, check that the post-dialyzer port is clamped securely.

4. Press the **TREATMENT** key. The Yellow Caution window will display the number **12**.



- Watch for the Yellow Caution window to show the number 12. This means the blood pump is running slowly (50 ml/min) so that you can make sure there is no air.
- Observe for air in the venous blood line (blue clamp).

5. If air is seen, press the **STOP** key immediately. Repeat Steps 2 through 4.
   - If necessary, disconnect the blood lines and recirculate blood to remove air.
   - If unable to remove air from the venous blood line, press the **STOP** key and end the treatment. Do **not** rinse back blood.
6. If no air is seen, press the **TREATMENT** key again to continue treatment.
   - At this time, the blood flow will return to the previous rate.

7. Flush the post-dialyzer port with 3 ml of saline to clear blood, and then close the clamp on the port securely. Continue to observe the venous header for air.

10 - Check for Venous Air During RINSEBACK (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

Air is detected in the cartridge tubing after the dialyzer and before the venous blood line (blue clamp).

All pumps stop and air must be removed before continuing. If air is present in the venous blood line, **do not** rinse back blood.

Air in the blood circuit during treatment can be dangerous. If air enters the blood stream, it can lead to an air embolism that can result in serious injury or even death. If an air embolism is suspected, follow the emergency interventions according to your center's policy. Call emergency medical personnel immediately, and then notify the doctor and center.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
Air entering the blood circuit from: • Air not completely removed from venous header. • Air entering the blood circuit while making cartridge connections for rinseback.	To remove the air with a syringe: 1. Press the **STOP** key to clear the alarm.
	2. Attach a 20 ml luer lock syringe to the post-dialyzer port, then open the blue clamp. Slowly pull back on the syringe to remove air.
	3. Inject the blood (not the air) back through the post-dialyzer port, then close the blue clamp securely.
	4. Press the **ADD FLUID** key. The Yellow Caution window will display **12** Yellow Caution (air recovery underway).
	5. Observe venous blood line (blue clamp) for air and repeat steps 1 through 4 if air is seen.
	6. If no air is seen, press the **ADD FLUID** key again to resume treatment. • If unable to remove air from the venous blood line, press the **STOP** key and end the treatment. Do **not** rinse back blood.

11 - Check for Arterial Air During PRIME, Not Including Recirculation Step 23.0 (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

Air is detected in the arterial blood line (red clamp) before the dialyzer.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
Air entering the blood circuit from:	
1. Priming spike tip not visible in the saline bag.	Push the priming spike into the saline bag using a twisting motion until the tip is visible.
2. Kinked/clamped saline or arterial blood line.	Unkink or unclamp the saline or arterial blood line. NOTE Air is pulled out of solution (saline/blood) when negative pressure is increased from the kinked or clamped arterial blood line.
3. Saline bag is empty of fluid.	Replace the empty saline bag with a new bag.
4. Saline "T" cap is loose.	Secure the "T" cap.

After the probable cause is resolved

1. Press the **STOP** key to clear the alarm.
2. Press the **ADD FLUID** key to resume priming.

11 - Check for Arterial Air During TREATMENT (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

Air is detected in the cartridge tubing before the dialyzer.

All pumps stop and air must be removed before continuing.

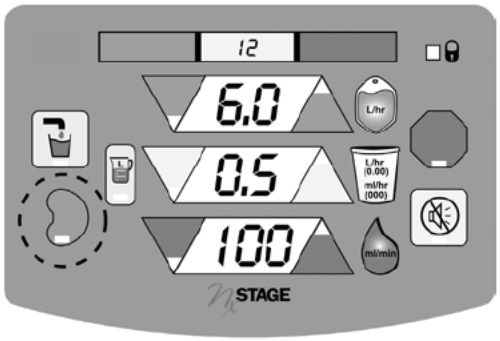
1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
1. Air is entering the blood circuit from: • Loose connection at arterial vascular access. • Arterial vascular access disconnection. • Reversing patient blood lines.	Secure connection and make sure no air is in the saline line.
2. Poor flow through arterial vascular access or clamped blood line.	Adjust the vascular access or unclamp the blood line.
3. Access pressure pod is clotted.	Perform a **manual fluid bolus,** page 5-5, to view the access pressure pod. • If the pod is clotted, end the treatment and **do not** rinse back blood. • If pod is **not** clotted, follow the instructions perform arterial air recovery, see page 5-35.

Probable Cause	Actions Required
4. Air in the saline line from empty saline bag.	Remove air from the saline line: • Replace the empty saline bag with a new bag. • Make sure the clamp on the saline "T" is closed. • If air is seen in the saline line, disconnect the saline line from the saline "T." Open the clamp on the saline line to prime the line with saline. Then close the clamp on the saline line and reconnect to the saline "T."

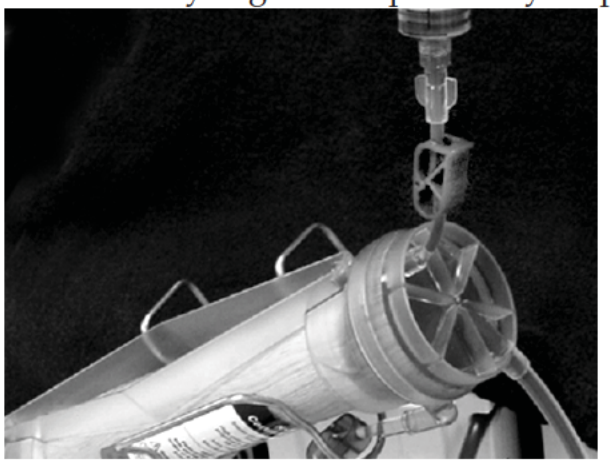
After probable cause is resolved, perform arterial air recovery:

1. Press the **STOP** key.
2. Identify and correct the source of air in the arterial blood line (red clamp).
3. Press the **TREATMENT** key.
   - The Yellow Caution window will display **12**.
   - The blood pump will now run at 100 ml/min.



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

4. Attach a 20 ml luer lock syringe to the post-dialyzer port.



5. Press the **TREATMENT** key. The blood pump will now return to the pre-alarm rate.

   If/when air is observed in the venous header of the dialyzer:

   - Open the clamp on the post-dialyzer port. Slowly pull back on the syringe to remove air.
   - Hold the syringe upright (to allow bubbles to rise) and inject the blood (but not the air) back through the post-dialyzer port. Close the clamp the on the port securely.

6. Flush post-dialyzer port with 3 ml of saline to clear the blood and then close the clamp on the port securely.

   - Continue to observe the venous header of the dialyzer for air and remove as needed.
   - If this alarm occurs again, lower the blood flow rate. The arterial vascular access may not be able to deliver the commanded blood flow.

11 - Check for Arterial Air During RINSEBACK (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

Air is detected in the arterial blood line before the dialyzer.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
1. Clamp is closed on the arterial blood line, or the arterial blood line is kinked.	Open the clamp or unkink the arterial blood line. NOTE Air is pulled out of solution (saline / blood) when negative pressure is increased from the kinked or clamped arterial blood line.
2. Insufficient fluid volume in saline bag for programmed Rinseback (Empty saline bag).	Hang a new saline bag.
3. After disconnection from arterial vascular access, the arterial blood line tip may have a small air bubble that travels past and is detected by the arterial air detector when Rinseback begins.	Remove air using the instructions below.

After probable cause is resolved, remove air:

1. Press the **STOP** key.

2. Press the **ADD FLUID** key.
   - The Yellow Caution window will display **12**.
   - The blood pump rate will now run at 100 ml/min.
   - Verify that the source of air is corrected by observing the arterial blood line (red clamp) for air (5 to 10 seconds).
3. Attach a 20 ml luer lock syringe to the post-dialyzer port.
4. Press the **ADD FLUID** key.
   - The blood pump will now return to the pre-alarm rate.
   - If air is observed in the venous header of the dialyzer:
     – Open the clamp on the post-dialyzer port. Slowly pull back on the syringe to remove air.
     – Hold the syringe upright to allow bubbles to rise. Inject the blood (but not the air) back through the post-dialyzer port. Close the clamp on the port securely.
5. Flush the post-dialyzer port with 3 ml of saline to clear the blood, and then close the clamp on the port securely. Continue to observe the venous header of the dialyzer for air and remove as needed.
6. If unable to remove air, press the **STOP** key and end Rinseback Mode.

12 - Air Recovery Underway (Yellow Caution)

Priority

- Red Alarm - High

Alarm Event

Previous Red Alarm 10 or 11 in Treatment or Rinseback Mode.

The system reduces the blood flow rate to allow time to confirm successful air removal.

Probable Cause	Actions Required
This caution will always occur after a Red Alarm 10 or 11 in Treatment or Rinseback Mode.	1. Check the following sites for air entering the system: • Arterial blood line (red clamp) (Red Alarm 11). • Venous blood line (blue clamp) (Red Alarm 10). 2. If air is observed, press the **STOP** key and repeat the air removal process. If no air is observed, press the **TREATMENT** key to resume Treatment or press the **ADD FLUID** key to resume Rinseback.

NOTES

- A Low Venous Pressure Caution or Alarm (20, 21) may occur before the **TREATMENT** key or **ADD FLUID** key is pressed due to the reduced blood flow rate.
- Do not adjust the blood flow rate at this time unless resetting the rates is desired. Prior rates will be restored once Treatment or Rinseback Mode is resumed.

13 - Check Fluid Line Inlet: Air Detected in Fluid Line Inlet (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

Air is detected in the dialysate circuit during the prime and alarms test.

Prime and alarms tests will be stopped until the situation is resolved.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
1. Insufficient priming fluid.	Verify that sufficient priming fluid is available.
2. Blocked or kinked tubing.	Unblock or unkink fluid inlet tubing.
3. Cartridge was not loaded correctly.	Prime a new cartridge. Make sure that all cartridge lines are manually pressed into air detectors.

When the probable cause is resolved, press the **STOP** key to clear the alarm, and then press the **ADD FLUID** key to resume.

14 - Check Fluid Line Inlet: Air Detected in Fluid Line Inlet (Yellow Caution)

Priority

- Yellow Caution - Medium

Alarm Event

Air is detected in the dialysate circuit.

PRECAUTION

Make sure that premixed Dialysate is at room temperature before using. If it is not at room temperature, outgassing of air may occur as the fluid is warmed, which may cause NxStage System One Cycler air alarms.

The blood pump and the ultrafiltration pump will continue to run. The dialysate pump will stop until the situation is resolved and the **TREATMENT** key is pressed.

1. Press the **MUTE** key to silence the caution.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
1. Dialysate source empty or fluid volume low.	If dialysate source is empty or low, add more dialysate: • If using a warmer, replace the dialysate bags. • If using PureFlow SL: – Check for sufficient fluid volume in the SAK. – Reposition the SAK by carefully lifting up the back end. Line inlets must be at or near the base of the tub.
2. Loose dialysate line connection(s).	Verify dialysate line connection(s) are tight.

Probable Cause	Actions Required
3. Occluded, kinked/clamped dialysate line(s).	Check dialysate line(s) and unkink/unclamp/unfold the affected lines: • On the cartridge: cartridge dialysate inlet (green clamp) • If using a warmer: Check warmer disposable (green clamps) • If using PureFlow SL, check: – Dialysate outlet (green clamp) – SAK lines within the PureFlow SL tub – Dialysate line filter. If it is plugged, discard the SAK and make another batch
4. If using a fluid warmer, the dialysate bags are not hung properly.	Verify that the dialysate bags are hung using both corner holes (two holes in each bag) and that the dialysate outlet port is located at the very bottom of the bag.

Probable Cause	Actions Required
5. If using ComfortMate Fluid Warmer: • Warmer air trap is full of air. • Warmer bag fitments not properly seated in the fluid warmer.	Remove air from the air vent on the disposable: • Unclamp the air vent line. • Loosen the protective cap to expel air. • When air is removed, tighten the cap and reclamp.  1 Air Vent Line 2 Air Trap 3 Warmer Outlet Line • Make sure bag fitments are seated properly in the ComfortMate Fluid Warmer.

Probable Cause		Actions Required
6.	If using PureFlow SL: • The **TREATMENT** key on the cycler was pressed before pressing the **GO** key on the PureFlow SL. • PureFlow SL was paused. • Air in the SAK lines.	If using PureFlow SL: • Verify that the PureFlow SL is in Batch in Use Mode. If not, press the **GO** key on the PureFlow SL twice to go to Batch in Use Mode. Then press the **TREATMENT** key on the cycler. • If PureFlow is paused, press the **GO** key to enter Config To Use Batch Mode. • If there is air is in the SAK lines, slightly open the connection between the SAK and cartridge dialysate inlet line to remove air.
When the probable cause is resolved, press the **TREATMENT** key on the cycler to resume the treatment.		
7.	Cartridge was not loaded correctly.	End the treatment and rinse back the patient's blood unless otherwise directed by the center, as long as the blood circuit is not clotted or hemolyzed and air is not seen in the blood circuit or in the patient blood lines.

20 - Check Blood Circuit: Venous Pressure Low During RINSEBACK (Yellow Caution)

Priority

- Yellow Caution - Medium

Alarm Event

Pressure is lower than expected at the venous pressure detector.

All pumps will continue to run. If, during the treatment, the venous pressure drops further, then a Red Alarm (20, 21) will occur.

Probable Cause	Actions Required
1. Arterial access flow problem.	Reposition the arterial access.
2. Venous blood line (blue clamp) leak, disconnection, or access extraction.	Secure the venous access and/or the venous blood line (blue clamp).
3. Clotting dialyzer.	If clotting is suspected, flush the dialyzer by performing a **manual fluid bolus**, page 5-5. If the dialyzer is clotted, end the treatment and **do not** rinse back blood. Failure to appropriately respond to a clotted dialyzer or blood circuit may contribute to hemolysis or thromboembolism.
When the venous pressure increases, the caution condition will clear automatically.	

20 - Check Blood Circuit: Venous Pressure Low (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

Pressure is lower than expected at the venous pressure detector.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the caution.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
1. Blood pump speed is lower than the prescribed rate. For example, too much time taken to increase blood flow rate at the start of the treatment or during air alarm recovery.	Increase blood pump speed.
2. Arterial vascular access flow problems, kinked or clamped arterial blood line (red clamp).	Reposition the arterial access and unkink or unclamp the arterial blood line (red clamp).
3. Venous blood line (blue clamp) leak, disconnection, or access extraction.	Secure the venous access and/or the venous blood line (blue clamp).
4. Manual fluid bolus caused a decrease in venous pressure.	Resume prescribed blood flow.
5. Clotted dialyzer.	If clotting is suspected, press the **STOP** key to clear the alarm, then press the **TREATMENT** key and flush the dialyzer by performing a **manual fluid bolus,** page 5-5. If the dialyzer is clotted, end the treatment and **do not** rinse back blood. Failure to appropriately respond to a clotted dialyzer or blood circuit may contribute to hemolysis or thromboembolism.
When the probable cause is resolved, press the **STOP** key to clear the alarm. Press the **TREATMENT** key to resume the treatment.	

21—Check Blood Circuit: Venous Pressure Decreasing (Yellow Caution)

Priority

- Yellow Caution- Medium

Alarm Event

Pressure is lower than expected at the venous pressure detector.

All pumps will continue to run. If, during the treatment, the venous pressure drops further, then a Red Alarm (20, 21) will occur.

Probable Cause	Actions Required
1. Arterial vascular access flow problem.	Reposition the arterial vascular access.
2. Venous blood line (blue clamp) leak, disconnection, or access extraction.	Secure the venous vascular access and/or the venous blood line (blue clamp).
3. Clotting dialyzer.	If clotting is suspected, flush the dialyzer by performing a **manual fluid bolus,** page 5-5. If the dialyzer is clotted, end the treatment and **do not** rinse back blood. Failure to appropriately respond to a clotted dialyzer or blood circuit may contribute to hemolysis or thromboembolism.
When the venous pressure increases, the caution will clear automatically.	

21 - Check Blood Circuit: Venous Pressure Decreasing (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

Pressure is lower than expected at the venous pressure detector.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
1. Arterial vascular access flow problems, kinked or clamped arterial blood line (red clamp).	To resolve arterial access flow, use either or both of the following methods: • Reposition the arterial access. • Unkink or unclamp the arterial blood line (red clamp).
2. Venous blood line (blue clamp) leak, disconnection, or access extraction.	Secure the venous access and/or the venous blood line (blue clamp).
3. Clotted dialyzer.	If clotting is suspected, press the **STOP** key to clear the alarm then press the **TREATMENT** key and flush the dialyzer by performing a **manual fluid bolus,** page 5-5. If the dialyzer is clotted, end the treatment and **do not** rinse back blood. Failure to appropriately respond to a clotted dialyzer or blood circuit may contribute to hemolysis or thromboembolism.
When the probable cause is resolved, press the **STOP** key to clear the alarm. Press the **TREATMENT** key to resume the treatment.	

22 - Check Blood Circuit: Effluent Pressure Low (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

Pressure is lower than expected at the effluent pressure circuit.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
1. Arterial access flow problem, kinked or clamped arterial blood line (red clamp).	Reposition the arterial vascular access and unkink or unclamp the arterial blood line (red clamp).
2. Effluent line clamped or disconnected from dialyzer.	Reconnect or unclamp and secure the effluent line.
3. Clotted dialyzer.	If clotting is suspected, press the **STOP** key to clear the alarm then press the **TREATMENT** key and flush the dialyzer by performing a **manual fluid bolus,** page 5-5. If the dialyzer is clotted, end the treatment and **do not** rinse back blood. Failure to appropriately respond to a clotted dialyzer or blood circuit may contribute to hemolysis or thromboembolism.
4. Flow fraction is too high.	Decrease the flow fraction by reducing the dialysate exchange or ultrafiltration rate, or by increasing the blood flow rate.
When the probable cause is resolved, press the **STOP** key to clear the alarm. Press the **TREATMENT** key to resume the treatment.	

23 - Check Blood Circuit: Effluent Pressure Decreasing (Yellow Caution)

Priority

- Yellow Caution - Medium

Alarm Event

Pressure is lower than expected in the effluent pressure circuit.

All pumps will continue to run. If the effluent pressure drops further, a Red Alarm (22 or 23) will occur.

Probable Cause	Actions Required
1. Arterial access flow problem.	Reposition the arterial access.
2. Clotting dialyzer.	If clotting is suspected, flush the dialyzer by performing a **manual fluid bolus,** page 5-5. If the dialyzer is clotted, end the treatment and **do not** rinse back blood. Failure to appropriately respond to a clotted dialyzer or blood circuit may contribute to hemolysis or thromboembolism.
3. Flow fraction is too high.	Decrease the flow fraction by reducing dialysate exchange or ultrafiltration rate, or by increasing the blood flow rate.
When the effluent pressure increases, the caution will clear automatically.	

23 - Check Blood Circuit: Effluent Pressure Decreasing (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

Pressure is lower than expected in the effluent circuit.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
1. Arterial vascular access flow problem, kinked or clamped arterial blood line (red clamp).	Reposition the arterial vascular access and unkink or unclamp the arterial blood line (red clamp).
2. Effluent line clamped or disconnected from dialyzer.	Reconnect or unclamp and secure the effluent line.
3. Clotted dialyzer.	If clotting is suspected, press the **STOP** key to clear the alarm then press the **TREATMENT** key and flush the dialyzer by performing a **manual fluid bolus,** page 5-5**.** If the dialyzer is clotted, end the treatment and **do not** rinse back blood. Failure to appropriately respond to a clotted dialyzer or blood circuit may contribute to hemolysis or thromboembolism.
4. Flow fraction is too high.	Decrease the flow fraction by reducing the dialysate exchange or ultrafiltration rate, or by increasing the blood flow rate.
When the probable cause is resolved, press the **STOP** key to clear the alarm. Press the **TREATMENT** key to resume the treatment.	

24 - Check Arterial Access: Access Pressure Decreasing to Low Limit (Yellow Caution)

Priority

- Yellow Caution - Medium

Alarm Event

Pressure is lower than expected in the arterial blood circuit.
All pumps will continue to run. If the arterial pressure decreases further, a Red Alarm 24 will occur.

- Identify and resolve the probable cause.

Probable Cause	Actions Required
Arterial access problem	Reposition the arterial access or reduce the blood flow.

When the arterial pressure increases, the caution will clear automatically.

WARNING

Do not disconnect and reverse patient blood lines during treatment. This may cause an infusion of air into the patient blood lines, which may lead to an embolism.

24 - Check Arterial Access: Access Pressure at Low Limit (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

Pressure is lower than expected in the arterial blood circuit.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
1. Arterial access flow problem, kinked or clamped arterial blood line (red clamp).	Reposition the arterial access, or reduce blood flow, or unkink or unclamp arterial blood line (red clamp).
2. Access or access pressure pod clotting.	Follow your center's procedures to assess and treat access pressure pod or vascular access clotting. Rinseback may be performed unless otherwise directed by the center, as long as the blood circuit is not clotted or hemolyzed and air is not seen in the blood circuit or in the patient blood lines.
3. May be related to the tip of the vascular access needle/catheter touching the vascular wall.	Consider repositioning vascular access catheter/needle to improve blood flow.
4. If using a catheter for vascular access, compromised blood flow may be related to patient position.	Consider repositioning patient to improve blood flow.
When the probable cause is resolved, press the **STOP** key to clear the alarm. Press the **TREATMENT** key to resume the treatment.	

WARNING

Do not disconnect and reverse patient blood lines during treatment. This may cause an infusion of air into the patient blood lines, which may lead to an embolism.

25 - Access Pressure Pod Error: Reset Access Pressure Pod (Yellow Caution)

Priority

- Yellow Caution - Medium

Alarm Event

Pressure in the arterial blood circuit is stagnant.

All pumps will continue to run. However, access pressure readings may not be available until the situation is resolved.

Probable Cause	Actions Required
1. Access pressure pod monitor line is kinked.	Unkink access pressure pod monitoring line.

Probable Cause	Actions Required
2. Access pressure pod connection error: monitor line leaking, poorly connected, or not connected.	Reset the access pressure pod. 1. Disconnect the access monitoring line from the cycler. The access pressure pod deflates. 2. Press the **STOP** key. If pod fills immediately, go directly to Step 3. If pod does **not** fill immediately: • Close the red clamp on the arterial blood line • Open the white clamps on the saline line and saline "T." The pod fills with blood. • Close the white clamps on the saline line and saline "T." • Open the red clamp on the arterial blood line. 3. Attach the access pressure pod monitoring line to the connection point located below the front handle on the right side of the cycler as instructed below: • Hold the line behind the locking collar. • Insert the tip into the connection point until it stops. • Maintain firm pressure and twist the tip ¼ turn counterclockwise to properly seal the connection. • Tighten the locking collar. 4. Press the **TREATMENT** key. 5. Check that the arterial pressures are within range.

30 - Check Blood Circuit: Venous Pressure Approaching High Alarm Limit (Yellow Caution)

Priority

- Yellow Caution - Medium

Alarm Event

Pressure is higher than expected in the venous blood circuit.

All pumps will continue to run. If the venous pressure increases further, a Red Alarm 30 will occur.

Probable Cause	Actions Required
1. Venous blood line (blue clamp) or venous access problem.	Reposition the venous access.
2. Venous access infiltration.	Correct the venous access infiltration.
3. Commanded blood flow rate is too high for the vascular access.	Decrease the blood flow rate.
4. Fluid imbalance or UF removed too quickly leading to hemoconcentrated blood.	Perform a **manual fluid bolus,** page 5-5, to check the dialyzer for clotting. If there is no clotting, adjust UF rate or goal accordingly. If clotting is present, end the treatment and **do not** rinse back blood.
• When the venous pressure decreases, the caution condition will clear automatically. • Consider weighing the patient after the treatment is restarted to evaluate UF status.	

30 - Check Blood Circuit: Venous Pressure High During PRIME, Including Recirculation Step 23.0 (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

Pressure is higher than expected in the venous blood circuit.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
1. Kinked or clamped venous blood line (blue clamp) or priming line (blue clamp).	Unkink or unclamp venous blood line (blue clamp) or priming line (blue clamp).
2. Priming spike occluded or bent.	Replace the priming line.
When the probable cause is resolved, press the **STOP** key to clear the alarm. Press the **ADD FLUID** key to resume.	

30 - Check Blood Circuit: Venous Pressure High During TREATMENT (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

Pressure is higher than expected in the venous blood circuit.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
1. Venous blood line (blue clamp) or venous access is kinked or clamped.	Unkink or unclamp venous blood line (blue clamp) or venous access.
2. Venous access infiltration.	Correct the venous access infiltration.
3. Venous blood line (blue clamp) or venous access is clotted.	If venous blood line (blue clamp) or venous access is clotted, end the treatment. **Do not** attempt to rinse back blood through the venous access.
4. Commanded blood flow rate is too high for the vascular access.	Decrease the blood flow rate.
5. Fluid imbalance or UF removed too quickly leading to hemoconcentrated blood.	End the treatment. **Do not** rinse back the patient's blood. Weigh the patient to assess UF status.
When the probable cause is resolved, press the **STOP** key to clear the alarm. Press the **TREATMENT** to resume the treatment.	

30 - Check Blood Circuit: Venous Pressure High During RINSEBACK (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

Pressure is higher than expected in the venous blood circuit.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
1. Kinked / clamped venous blood line (blue clamp).	Unkink/unclamp the venous blood line (blue clamp). • Press the **STOP** key to clear the alarm. • Press the **ADD FLUID** key to continue.
2. Venous blood line (blue clamp) is clotted.	Press the **STOP** key and end the treatment. **Do not** rinse back blood.
3. Venous vascular access is clotted.	Press the **STOP** key and end the treatment. **Do not** rinse back blood.

32 - Check Blood Circuit: Venous Pressure Increasing (Yellow Caution)

Priority

- Yellow Caution - Medium

Pressure is higher than expected in the venous blood circuit.

All pumps will continue to run. If the venous pressure increases further, a Red Alarm 30 will occur.

- Identify and resolve the probable cause.

Probable Cause	Actions Required
1. Venous blood line (blue clamp) or venous access problem.	Reposition the venous access.
2. Venous access infiltration.	Correct the venous access infiltration.
3. Commanded blood flow rate is too high for the vascular access.	Decrease the blood flow rate.
4. Fluid imbalance or UF removed too quickly leading to hemoconcentrated blood.	Perform a **manual fluid bolus**, page 5-5 to check the dialyzer for clotting. If there is no clotting, adjust UF rate or goal accordingly. If clotting is present, end the treatment and **do not** rinse back blood.

- When the venous pressure decreases, the caution condition will clear automatically.
- Consider weighing the patient after the treatment is restarted to evaluate UF status.

33, 34 - Check Dialyzer: High TMP During PRIME, Including Recirculation Step 23.0 (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

Transmembrane Pressure (TMP) is higher than expected.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
Cartridge not aligned correctly in the cycler.	Reprime the cartridge, see page 5-4.

33, 34 - Check Dialyzer: High TMP During TREATMENT (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

Transmembrane Pressure (TMP) is higher than expected.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
1. Venous blood line is kinked between the dialyzer and the cartridge venous air detector.	Unkink the venous blood line between the dialyzer and the cartridge venous air detector.
2. Pooling/clotting of blood in the venous header of the dialyzer.	If clotting is suspected, press the **STOP** key to clear the alarm then press the **TREATMENT** key and flush the dialyzer by performing a **manual fluid bolus,** page 5-5. If the dialyzer is clotted, end the treatment and **do not** rinse back blood. Failure to appropriately respond to a clotted dialyzer or blood circuit may contribute to hemolysis or thromboembolism.
• When the probable cause is resolved, press the **STOP** key to clear the alarm. Press the **TREATMENT** key to resume the treatment. • Consider weighing the patient after the treatment is restarted to evaluate UF status.	

35 - Check Waste Line: Waste Line Pressure High (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

Waste line pressure is higher than expected.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
1. Waste or drain lines or SAK dialysate line kinked, clamped, pinched, occluded, submerged, or not connected.	1. Check the waste and drain lines to clear the occlusion. Reposition, unkink/unclamp, and connect as required to ensure proper routing and free flow of waste fluid to the drain. The affected line(s) may include: • Waste line (yellow clamp) • Waste line extension (yellow clamp) 2. If using PureFlow SL: • Control Unit Adapter (yellow clamp) • Drain line - Reposition the drain line. If necessary, flush the drain line. If unsuccessful, disconnect the cartridge waste line from the PureFlow SL and connect to waste line extension. • SAK dialysate line – Check all lines and connections in the SAK for leaks or kinks and adjust any line that is kinked. – Slide line collars all the way towards the SAK. – Verify the SAK has been installed and unfolded correctly. 3. Lower dialysate rate.
2. If using a waste bag, waste bag is full.	Replace the waste bag.
3. Low effluent pressure due to poor arterial flow.	Adjust the vascular access to improve the blood flow.
When the probable cause is resolved, press the **STOP** key to clear the alarm. Press the **TREATMENT** key to resume the treatment.	

36 - Check Dialysate Source: Dialysate Inlet Pressure Exceeded (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

Dialysate inlet pressure exceeded.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
1. If using a warmer, this alarm is unlikely to occur.	End the treatment and rinse back the patient's blood unless otherwise directed by the center, as long as the blood circuit is not clotted or hemolyzed and air is not seen in the blood circuit or in the patient blood lines.

Probable Cause	Actions Required
2. If using PureFlow SL: Kinked SAK Line.	If using PureFlow SL: 1. Open the cabinet door and slide out the tub so you can see the SAK lines. 2. Check all lines and connections on the PAK and SAK for leaks or kinks. Adjust any line that is kinked. 3. Slide line collars all the way towards the SAK. 4. Verify the SAK has been installed and unfolded correctly. 5. Press the **GO** key twice on the PureFlow SL to go to Batch In Use Mode before you press the **TREATMENT** key on the cycler. 6. Press the **STOP** key on the cycler to clear the alarm and then press the **TREATMENT** key to resume the treatment. If you cannot recover from the alarm after multiple attempts, or a SAK leak is found, you must drain the SAK.

37, 38 - Check Fluid Circuit: High Balance Chamber Pressure During PRIME, Including Recirculation Step 23.0 (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

Pressure is higher than expected in the fluid balance chambers.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
1. Clamped or kinked cartridge lines.	Unclamp/unkink the cartridge lines.
2. Priming spike is occluded or the tip is bent.	Replace the priming line.
3. Priming spike tip is not fully inserted into the saline bag (the tip is not visible within the saline bag).	Push the priming spike into saline bag using a twisting motion until tip is visible.
4. Air in fluid balance system from an empty saline bag.	Hang a new saline bag.
When the probable cause is resolved, press the **STOP** key to clear the alarm and then press the **ADD FLUID** key to resume.	

NOTES

- A Yellow Caution 9 may be displayed indicating the system is recovering from a high pressure condition. **Do not** press the **STOP** key at this time. Prime will resume when the Yellow Caution 9 disappears.
- The Red Alarm 37, 38 may recur a few times after the Yellow Caution 9 disappears if the pressure remains high. Repeat steps above to resolve.

37, 38 - Check Fluid Circuit: High Balance Chamber Pressure During TREATMENT (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

Pressure is higher than expected in the fluid balancing circuit.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
1. Occluded, kinked or clamped fluid line(s).	Check fluid lines and clear occlusion. Unkink/unclamp the affected line(s) which may include: • On the cartridge: – Cartridge dialysate inlet (green clamp) – Cartridge dialysate outlet (green clamp) – Waste line (yellow clamp) (following Alarm 35) • If using a Warmer: – Warmer disposable (green clamps) – Waste line extension (yellow clamp) • If using the PureFlow SL: – Dialysate outlet (green clamp) – SAK lines (within the PureFlow SL tub) – Control unit adapter (yellow clamp) – Control unit adapter is plugged; replace the control unit adapter. – Dialysate line filter is plugged; discard the SAK and make another batch.

Probable Cause	Actions Required
2. Dialysate source low or empty.	If dialysate source is low or empty, add more dialysate: • If using a warmer, replace empty dialysate bags. • If using the ComfortMate Fluid Warmer, remove air from the air vent of the disposable: – Unclamp the air vent line. – Loosen the protective cap to expel air. – When air is removed, tighten the cap and reclamp. • If using PureFlow SL: – Check for sufficient fluid volume in the SAK. – Reposition SAK by carefully lifting up the back end. The line inlets must be at or near the base of the tub.
3. The **TREATMENT** key pressed on the cycler before the **GO** key pressed on PureFlow SL.	Verify the PureFlow SL is in Batch In Use Mode. If it is not press the **GO** key twice on the PureFlow SL to go to Batch In Use before pressing the **TREATMENT** key on the cycler.
4. Using the wrong SAK type in the PureFlow SL while running the CYC-D2E (NX1000-3) or higher at dialysate rates higher than 12 L/hr.	Lower dialysate rate to 12 L/hr or less. Load a 400 series SAK into the PureFlow SL for the next treatment to return to higher flow rates.

Probable Cause	Actions Required
5. Dialyzer clotted.	If clotting is suspected, press the **STOP** key to clear the alarm then press the **TREATMENT** key and flush the dialyzer by performing a **manual fluid bolus,** page 5-5. If the dialyzer is clotted, end the treatment and **do not** rinse back blood. Failure to appropriately respond to a clotted dialyzer or blood circuit may contribute to hemolysis or thromboembolism.
6. Air is in fluid balancing system.	Verify dialysate is flowing from the warmer or PureFlow SL to the cartridge.
When the probable cause is resolved, press the **STOP** key to clear the alarm. Press the **TREATMENT** key to resume the treatment.	

NOTES

- A Yellow Caution 9 may be displayed indicating the system is recovering from a high pressure condition. **Do not** press the **STOP** key at this time. Treatment will resume when the Yellow Caution 9 disappears.
- The Red Alarm 37, 38 may recur a few times after the Yellow Caution 9 disappears if the pressure remains high. Repeat steps above to resolve.

39 - Check Fluid Inlet: Dialysate Inlet Occlusion (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

Pressure is lower than expected at the dialysate inlet.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
1. (During Prime Mode) Priming spike is not fully inserted into saline bag.	Push and twist the saline spike to ensure it is fully inserted into the saline bag.
2. Kinked/clamped or folded dialysate fluid line(s).	Check fluid lines and unkink/ unclamp the affected line(s) which may include: • On the cartridge: cartridge dialysate inlet (green clamp) • If using a warmer: warmer disposable (green clamps) • If using the PureFlow SL: – Dialysate outlet (green clamp) – SAK lines (in the PureFlow SL tub)

Probable Cause	Actions Required
3. Dialysate source low or empty.	If dialysate source is low or empty, add more dialysate: • If using a warmer, replace the empty dialysate bags. • If using ComfortMate Fluid Warmer, remove air from the air vent on the disposable: – Unclamp the air vent line. – Loosen the protective cap to expel air. – When air is removed, tighten the cap and reclamp. • If using the PureFlow SL: – Check for sufficient fluid volume in the SAK. – Reposition SAK by carefully lifting up the back end. The line inlets must be at or near the base of the tub.
4. If using PureFlow SL: The **TREATMENT** key pressed on the cycler before the **GO** key pressed on PureFlow SL.	Verify the PureFlow SL is in Batch In Use Mode. If it is not press the **GO** key twice on the PureFlow SL to go to Batch In Use before pressing the **TREATMENT** key on the cycler.
5. If using PureFlow SL: SAK dialysate line filter is plugged.	Discard the SAK and make another batch.
6. Using the wrong SAK type in the PureFlow SL while running the CYC-D2E (NX1000-3) or higher at dialysate rates higher than 12 L/hr.	Lower dialysate rate to 12 L/hr or less. Load a 400 series SAK into the PureFlow SL for the next treatment to return to higher flow rates.
7. Air in fluid balancing system.	Verify dialysate is flowing through the warmer or PureFlow SL to the cartridge.

Probable Cause	Actions Required
When the probable cause is resolved, press the **STOP** key to clear the alarm. Press the **TREATMENT** key to resume the treatment.	

NOTES

- A Yellow Caution 9 may be displayed indicating the system is recovering from a high pressure condition. **Do not** press the **STOP** key at this time. Treatment will resume when the Yellow Caution 9 disappears.
- The Red Alarm 37, 38 may recur a few times after the Yellow Caution 9 disappears if the pressure remains high. Repeat steps above to resolve.

40 - Perform Power Recovery: Power Failure (Yellow Caution)

WARNING

The risk of blood clotting in the Cartridge and Dialyzer is higher during long treatments, when no anticoagulation is used, in certain patients who are more prone to excess clotting, or any time when the blood flow stops, including when the NxStage System One Cycler loses power or during an unrecoverable alarm. The risk of blood clotting increases the longer treatment continues and the longer blood flow is stopped. To reduce the risk of blood clotting and identify the early signs of clotting:

- Follow your center's instructions to give and monitor anticoagulant.
- During treatment, regularly check the Cartridge and Dialyzer for clotting by looking closely at the Cartridge and Dialyzer, and periodically flushing the Dialyzer with a manual fluid bolus.

Failure to respond to blood clotting in the Cartridge and Dialyzer may result in a blood clot being released into the patient's bloodstream and causing a blockage (thromboembolism). Failure to respond to clotting may also lead to sustained high pressures in the blood circuit and cause a dialyzer blood leak or hemolysis. These conditions may cause serious injury or death if not responded to promptly and appropriately. Regularly check the Dialyzer for any evidence of a leak. Do not return the blood if the blood flow is stopped for a long time. Discard the Cartridge and Dialyzer if they are clotted.

Priority

- Yellow Caution - Medium

Alarm Event

Previous loss of power to cycler.

Probable Cause	Actions Required
1. During the recirculation step of Prime Mode (**000** in Red Alarm window, **23.0** in top window): Power is restored following a power failure or cycler being turned off) during recirculation and the cartridge life has not expired.	1. Press the **TREATMENT** key. 2. Monitor the cycler screen (**20.0** to **23.0** in top window) indicating the system is rechecking the fluid balance system. 3. When **23.0** is shown, continue with air removal steps as instructed in **Removing air from the blood circuit**, page 4-19.
2. During Treatment or Rinseback Mode: Power is restored following a power failure (or cycler being turned off) for less than the preset number of minutes allowed (set by System Setting 16; see Chapter 9).	• During Treatment Mode, press the **TREATMENT** key to resume. • During Rinseback Mode, press the **ADD FLUID** key to resume.

41 - Failed Power Recovery During TREATMENT or RINSEBACK (Red Alarm)

WARNING

The risk of blood clotting in the Cartridge and Dialyzer is higher during long treatments, when no anticoagulation is used, in certain patients who are more prone to excess clotting, or any time when the blood flow stops, including when the NxStage System One Cycler loses power or during an unrecoverable alarm. The risk of blood clotting increases the longer treatment continues and the longer blood flow is stopped. To reduce the risk of blood clotting and identify the early signs of clotting:

- Follow your center's instructions to give and monitor anticoagulant.
- During treatment, regularly check the Cartridge and Dialyzer for clotting by looking closely at the Cartridge and Dialyzer, and periodically flushing the Dialyzer with a manual fluid bolus.

Failure to respond to blood clotting in the Cartridge and Dialyzer may result in a blood clot being released into the patient's bloodstream and causing a blockage (thromboembolism). Failure to respond to clotting may also lead to sustained high pressures in the blood circuit and cause a dialyzer blood leak or hemolysis. These conditions may cause serious injury or death if not responded to promptly and appropriately. Regularly check the Dialyzer for any evidence of a leak. Do not return the blood if the blood flow is stopped for a long time. Discard the Cartridge and Dialyzer if they are clotted.

Priority

- Red Alarm - High

Alarm Event

Previous loss of power to cycler.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.
3. Regardless of cause, the treatment must be ended.

Probable Cause	Actions Required
1. Power failure or cycler turned off during Treatment or Rinseback Mode for longer than the preset number of minutes allowed (set by System Setting 16; see Chapter 9) after recovering from a power failure.	If the circuit is not clotted, perform a **manual rinseback,** page 4-52, unless otherwise instructed by your center, as long as the blood circuit is not clotted or hemolyzed and air is not seen in the blood circuit or in the patient blood lines.
2. Cycler door was opened during power failure (or while the cycler power was turned off) that occurred while in Treatment or Rinseback Mode and remained open when the power returned.	If the circuit is not clotted, perform a **manual rinseback,** page 4-52, unless otherwise instructed by your center, as long as the blood circuit is not clotted or hemolyzed and air is not seen in the blood circuit or in the patient blood lines.

50 - Check Fluid Temp: Fluid Temp High (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

Fluid temperature is above fluid temperature alarm point.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
1. Heater setting too high on the fluid warmer or PureFlow SL.	Reduce the dialysate heater setting: • If using the ComfortMate Fluid Warmer: – Turn the Fluid Warmer knob counter-clockwise. • If using the Express Fluid Warmer: – Press the **DOWN ARROW** key to decrease the comfort setting. • If using PureFlow SL: – Reduce the heater setting. – Open the PureFlow SL cabinet door to help fluid cool.
2. Dialysate bags too warm prior to set up.	Cool or replace the dialysate bags.
3. Treatment environment too warm.	Cool room with air conditioning or fan.
When the probable cause is resolved, press the **STOP** key to clear the alarm. Press the **TREATMENT** key to resume the treatment.	

51 - Fluid Cooldown Underway (Yellow Caution)

Priority

- Yellow Caution - Medium

Alarm Event

Previous Red Alarm 50. The fluid temperature is cooling down.

The blood pump and ultrafiltration pump will continue to run. However, the dialysate pump will stop until the temperature of the dialysate has cooled down.

Probable Cause	Actions Required
Previous Alarm 50.	None required. Look for Yellow Caution 52.

NOTE

If Yellow Caution 52 does not occur within a reasonable amount of time, this means the dialysate temperature remains too high. Consider ending the treatment and rinsing back blood.

52 - Continue Treatment: Fluid Cooldown Complete (Yellow Caution)

Priority

- Yellow Caution - Medium

Alarm Event

Dialysate has cooled down sufficiently following a previous Red Alarm 50 and Yellow Caution 51.

The dialysate pump remains stopped.

Probable Cause	Actions Required
Fluid temperature has dropped 0.5°C or more below the fluid temperature alarm point after a Red Alarm 50 and subsequent Yellow Caution 51.	Press the **TREATMENT** key to resume the treatment.

53 - Caution: Low Fluid Temperature (Yellow Caution)

Priority

- Yellow Caution - Medium

Alarm Event

Fluid Temperature is below 33.3°C.

Blood pump and ultrafiltration pump will continue to run. This caution will occur if the fluid temperature is less than 17.1°C or remains between 17.1°C and 24.4°C for at least 20 minutes.

Probable Cause	Actions Required
1. Fluid warmer is not turned on, is set too low or is not working.	Turn on the fluid warmer or increase the dialysate heater setting: • If using the ComfortMate Fluid Warmer: – Turn the Fluid Warmer knob clockwise. • If using the Express Fluid Warmer: – Press the **UP ARROW** key. • If using PureFlow SL: – Refer to the *PureFlow SL User Guide* to change heater setting.
2. Dialysate too cold prior to set-up.	Allow warmer sufficient time to warm fluid. Press the **TREATMENT** key to continue. If patient is experiencing discomfort, end treatment.
3. Room temperature too low.	Increase room temperature.
When the probable cause is resolved, press the **TREATMENT** key to resume the treatment.	

54 - Caution: Low Temperature Monitor Disabled (Yellow Caution)

Priority

- Yellow Caution - Medium

Alarm Event

System Setting 79 has been set to **0**.

Probable Cause	Actions Required
System Setting 79 has been set to **0**.	Press **MUTE** to acknowledge the caution, or If low temperature should be enabled, see the instructions in Chapter 9, System Settings to change System Setting 79 to **1**.

60 - Check for Blood Leak: Blood Detected in Waste Line (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

The system suspects that blood may be present in the effluent.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
1. Dialyzer fiber leak.	Check the color of your waste fluid. Follow your center's instructions for testing waste fluid for the presence of blood. • If visual presence of blood (which may appear as red streaks as the fluid leaves the dialyzer) or if testing shows the presence of blood, end the treatment and perform a **manual rinseback,** page 4-52, unless otherwise instructed by your center, as long as the blood circuit is not clotted or hemolyzed and air is not seen in the blood circuit or in the patient blood lines. • If pink-tinged effluent is observed in the drain line and testing shows the presence of blood, end the treatment and perform a **manual rinseback,** page 4-52, unless otherwise instructed by the center, as long as the blood circuit is not clotted or hemolyzed and air is not seen in the blood circuit or in the patient blood lines. • If normal yellow color and if testing does not show the presence of blood, see probable cause 2.

Probable Cause	Actions Required
2. Air in effluent or flow fraction set too high.	Do one or both of the following: • Correct the source of air entering the effluent. • Lower the flow fraction. If the alarm recurs, end the treatment and perform a **manual rinseback,** page 4-52, unless otherwise instructed by the center, as long as the blood circuit is not clotted or hemolyzed and air is not seen in the blood circuit or in the patient blood lines.
3. Ultrafiltration rate at zero (**0**).	Press the **STOP** key, then press the **TREATMENT** key. Set the ultrafiltration rate to 0.1 L/hr (at least) for approximately two minutes and reset the alarm.

NOTE

Pink tinged or red effluent not associated with a blood leak (confirmed by testing) may be attributed to certain medical conditions, medications, or treatment-related hemolysis. In any case, the presence of pink effluent should be discussed with your health care provider (HCP). See the section **Observation of pink waste fluid**, page 5-12, for additional information.

61 - Check BLD: Failed Blood Leak Detector (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

The detector or detector mirror are not clean.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
One or both of the following require cleaning: • Detector • Detector mirror	Follow the instructions below: 1. Turn off the power switch to the cycler. 2. Lower the saline bag below the cycler. 3. Open the cycler door and allow the fluid to flow back into the saline bag. 4. Clean mirror and detector. See **Cleaning the blood leak detector**, page 6-5. 5. Turn on the power switch to the cycler with the door open and the handle raised. 6. When the Yellow Caution window flashes, insert the cartridge, close the door, and hang the saline bag. 7. When the **ADD FLUID** key is lit, restart Prime.

⚠ PRECAUTION

Do not reprime a Cartridge that has been used on a patient. Failure to follow the instructions for repriming a Cartridge may cause damage to the Cartridge or misloading, and may impact system performance.

62 - Check Dialyzer for Clotting (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

Arterial pressure is unstable.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
1. Arterial blood line is kinked between the cartridge and the dialyzer.	1. Unkink the arterial blood line between the cartridge and the dialyzer. 2. Press the **STOP** key to clear the alarm. 3. Press the **TREATMENT** key to resume.
2. A clot has formed in the arterial header of the dialyzer.	1. Press the **STOP** key to clear the alarm. 2. Press the **TREATMENT** key and perform a **manual fluid bolus**, page 5-5 to observe the arterial header of the dialyzer for clotting. 3. If clotting is seen, end the treatment and do not rinse back blood. Failure to appropriately respond to a clotted dialyzer or blood circuit may contribute to hemolysis. 4. If no clotting is seen, continue the treatment. If the alarm recurs, end the treatment and do not rinse back blood.

NOTE

System Setting 53 must be set to **1** and System Setting 78 must be set to **1** to enable this alarm.

70 - Change Cartridge: Cartridge Life Exceeded (Yellow Caution)

Priority

- Yellow Caution - Low

Alarm Event

The cycler has determined that the cartridge has exceeded its life expectancy.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
1. The cartridge has been used for greater than 864 L of blood processed or for longer than 72 hours of operation.	If the caution is due to exceeded cartridge life, press the **MUTE** key to clear or end the treatment and replace the cartridge.
2. The priming bag was spiked before the cycler door was closed after a new cartridge was inserted and the tubing pressed into all three air detectors.	If the caution occurred with a new cartridge as priming was initiated, clear the caution and reprime the same cartridge, see page 5-4.

71 - Schedule Preventive Maintenance: Preventive Maintenance Due (Yellow Caution)

Priority

- Yellow Caution - Medium

Alarm Event

Preventive maintenance is due on the cycler.

Probable Cause	Actions Required
Normal maintenance notification.	Complete the treatment. Schedule preventive maintenance with Technical Support.

72 - Treatment Complete (Yellow Caution)

Priority

- Yellow Caution - Low

Alarm Event

The cycler door opened at the end of Rinseback Mode.

All keys and alarms are disabled. The user may not resume Treatment or Rinseback.

Probable Cause	Actions Required
User has opened the cycler door at end of Rinseback Mode.	Turn the power switch to the cycler off. Prime a new cartridge if additional treatment is desired.

80 - Reconfigure Cartridge Line (Yellow Caution)

Priority

- Yellow Caution - Medium

Alarm Event

The venous blood line of a cartridge without pre-attached dialyzer must be reconfigured.

Probable Cause	Actions Required
Cycler has paused during the priming of a cartridge without pre-attached dialyzer and System Setting 25 (see Chapter 9) is set to **1**.	Move the venous blood line (blue clamp) of the cartridge without pre-attached dialyzer. See the cartridge without pre-attached dialyzer Instructions for Use (IFU).
Press the **ADD FLUID** key to continue.	

81 - Tap Dialyzer to Remove Air (Yellow Caution)

Priority

- Yellow Caution - Medium

Alarm Event

Priming procedure.

Probable Cause	Actions Required
System Setting 64 (see Chapter 9**)** is set to **1**. The cycler has paused during priming to give the user time to remove air from the dialyzer.	Tap the dialyzer to dislodge trapped air until the Yellow Caution disappears. For specific priming directions for the cartridge without pre-attached filter. Refer to cartridge without pre-attached filter instructions for use (IFU).

85 - Check Cartridge Loading: Waste Line Check Failure (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

During Prime, the cycler determined that the cartridge is not properly loaded.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
The cartridge is not properly loaded.	Follow the instructions below: 1. Press the **STOP** key, and then press the **ADD FLUID** key. 2. If the alarm recurs, reprime the cartridge, see page 5-4. 3. If the alarm recurs, replace the cartridge and restart Prime. 4. If the alarm recurs, record the alarm number and Prime step when the alarm occurs, then call Technical Support.

86 - Reprime (Replace) Cartridge: Failed Alarm Test (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

The system failed an alarm test during Prime.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
1. Improper priming.	For all probable causes, follow the instructions: 1. Press the **STOP** key, and then press the **ADD FLUID** key. 2. If the alarm recurs, reprime the cartridge, see page 5-4. 3. If the alarm occurs again, replace the cartridge and restart Prime. 4. If the alarm recurs a third time, record the alarm number and Prime step when the alarm occurs, then call Technical Support.
2. Faulty cartridge.	
3. Cycler malfunction.	

87 - Check Cartridge Loading: UF Occlusion Test Failure (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

The system failed an alarm test during Prime.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
1. Loose post-dialyzer port cap.	Tighten post-dialyzer port cap.
2. The cartridge is not properly loaded.	1. Press the **STOP** key, and then press the **ADD FLUID** key. 2. If the alarm recurs, reprime the cartridge, see page 5-4. 3. If the alarm recurs, replace the cartridge and restart Prime. 4. If the alarm recurs, record the alarm number and Prime step when the alarm occurs, then call Technical Support.

88 - Pressure Offset Rezeroing Needed (Yellow Caution)

Priority

- Yellow Caution - Medium

Alarm Event

Priming cannot begin until the pressure offset rezeroing procedure is done.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
1. The cycler power was turned on with the door closed.	Rezero pressure offset by doing the following: 1. Turn off the cycler power switch. 2. Lift the front door handle of the cycler up completely until it clicks. 3. Open the cycler door. 4. Turn on the cycler power switch with the door open and handle raised. Pressure offset rezeroing will be done automatically. 5. When the Yellow Caution window flashes, insert the cartridge and close the cycler door.
2. A used cartridge was installed before turning the cycler power on.	Discard the cartridge and prime a new cartridge. Pressure offset rezeroing will be done automatically.
3. A partially primed cartridge was installed before turning the cycler power on.	Reprime the cartridge, see page 5-4. Pressure offset rezeroing will be done automatically.

88 - Pressure Offset Rezeroing Needed (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

The system failed when attempting to lower the pressures during Prime.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
1. Blocked or kinked dialysate lines.	Unblock or unkink the dialysate line.
2.. Pressure offset error.	Press the **STOP** key then press the **ADD FLUID** key. • If the alarm recurs, reprime the cartridge, see page 5-4. • If the alarm recurs a second time, record the alarm number and Prime step when the alarm occurs, then call Technical Support.

89 - Pressure Offset Rezeroing Failed (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

Cycler was unable to rezero the pressure sensor offsets on startup.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
Cycler was unable to adjust a variable pressure offset on startup.	Rezero pressure offset by doing the following. 1. Turn off the cycler power switch. 2. Lift the front door handle of the cycler up completely until it clicks. 3. Disconnect the access pressure pod monitoring line (if present) from the side of the cycler. 4. Open the cycler door. 5. Turn on the cycler power switch with the door open and handle raised. (Pressure offset rezeroing will be done automatically.) 6. When the Yellow Caution window flashes, insert the cartridge and close the cycler door.

90 - Check Cartridge For Leak: Fluid Circuit Test Failure (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

The cycler detected a malfunction in the fluid balancing system.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
Malfunction of fluid balancing system.	Follow the instructions below: 1. End the treatment and perform an **automated rinseback**, see page 4-39. 2. Thoroughly check cartridge for fluid leaks, for example, at the bottom of the cartridge. If leaking, contact Technical Support.

NOTES

- For all fluid balance failure alarms, check patient weight.
- Setting the UF rate to **0** will not resolve a fluid balance system problem.

91 - Check Fluid Balance: Fluid Circuit Leak Probable (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

The cycler detected a malfunction in the fluid balancing system.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
Malfunction of fluid balancing system.	Follow the instructions below: 1. End the treatment and perform an **automated rinseback**, see page 4-39. 2. Thoroughly check cartridge for fluid leaks, for example, at the bottom of the cartridge. If leaking, contact Technical Support.

NOTES

- For all fluid balance failure alarms, check patient weight.
- Setting the UF rate to **0** will not resolve a fluid balance system problem.

92 - Check for Cartridge Leak, During PRIME or Recirculation (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

During PRIME or recirculation, the cycler detected a malfunction in the fluid balancing system.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
Cartridge integrity compromised.	Confirm the integrity of the fluid balancing system by performing all of the following steps: 1. Thoroughly check cartridge for fluid leaks, for example, at the bottom of the cartridge. Notify Technical Support of cartridge leak. Return or discard cartridge as directed. 2. If no leak is observed, press the **STOP** key and then press the **ADD FLUID** key to continue.

93 - Correct Parameters: System Settings Conflict (Yellow Caution)

Priority

- Yellow Caution - Medium

Alarm Event

The cycler detected conflicting settings.

This caution can only occur in Service or System Setting Mode — not regular start-up or Prime.

Probable Cause	Actions Required
A setting is set to a value that conflicts with the values of other settings.	Re-enter/review System Settings (see Chapter 9).

99 - Fluid Balance System Failed: Terminate Treatment (Red Alarm)*

**Not applicable in Software version 4.3*

Priority

- Red Alarm - High

Alarm Event

The system detected a malfunction of fluid balancing system.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
Malfunction of fluid balancing system.	Press the **STOP** key, then press the **TREATMENT** key, and observe **000** in the Yellow Caution window. End the treatment and perform an automated rinseback, page 4-39.

NOTE

For all fluid balance failure alarms, check patient weight.

100 - 999 System Alarm* (Red Alarm)

** Except for alarm numbers 600, 601, 602, 603, 715 and 721*

Priority

- Red Alarm - High

Alarm Event

The cycler detected a system or communications error or may be in Service Mode.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
Indicates a system error or internal communications error. Also, the cycler may be in Service Mode.	Use the following instructions: *During Prime Mode before Step 23.0* • Reprime the cartridge, see page 5-4. *During Recirculation of Prime (23.0 in top window), Treatment or Rinseback Mode:* 1. Note alarm number displayed in the Red Alarm window. • Write down the alarm number for future reference. • If **999** is shown in the Yellow Caution window, the cycler is in Service Mode. Call Technical Support immediately. Do not initiate or continue treatment.

Probable Cause	Actions Required
	2. Turn off power switch to the cycler, and then turn it on again immediately. • Watch for the number **40** in the Yellow Caution window. 3. If the cycler repeats the alarm or has a blank window after Step 2, turn off the power, wait approximately one minute, and then turn on the power again. 4. If **40** appears in the Yellow Caution window, press the **TREATMENT** key or the **ADD FLUID** key to continue. 5. If the system alarm recurs, or Red Alarm 41 appears, perform a **manual rinseback**, see page 4-52, unless otherwise instructed by your center, as long as the blood circuit is not clotted or hemolyzed and air is not seen in the blood circuit or in the patient blood lines. Contact Technical Support and provide the system alarm number.

600 - System Alarm (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

The cycler detected pump movement while cycler door was closing.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
1. After spiking the saline bag, a pump might have moved while the cycler door was being closed.	Reprime the cartridge, see page 5-4.
2. Before spiking the saline bag, a pump might have moved while the cycler door was being closed.	Follow the instructions below: 1. Turn off the power to the cycler. 2. Lift the front door handle of the cycler up completely (until it clicks) and pull toward you to open the door. 3. Remove the cartridge completely from the cycler. 4. Turn on the power to the cycler. 5. When the Yellow Caution window flashes, insert the cartridge and close the cycler door. 6. Press the **ADD FLUID** key. 7. If alarm recurs, contact Technical Support.

601, 602, 603 - System Alarm (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

The cycler detected that the pumps are not running at the proper speed.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
1. Kinked, clamped, or pinched fluid or blood lines.	*During Prime Mode before Step **23.0:*** • Check and resolve any kinked, clamped, or pinched fluid or blood lines. • Reprime the cartridge, see page 5-4. • If unable to resolve, contact Technical Support. *During Recirculation of Prime (**23.0** in top window), Treatment or Rinseback Mode:* • Check and resolve any kinked, clamped, or pinched fluid or blood lines.

Probable Cause	Actions Required
2. Pump failure.	If pump failure is suspected: 1. Turn off the cycler. 2. Wait for three seconds and then turn on the cycler. 3. When **40** appears in the Yellow Caution window, press the **TREATMENT** key to continue. 4. If alarm recurs, repeat Steps 1 through 3. Press and hold the **STOP** key**.** Perform an **automated rinseback**, see page 4-39. 5. If alarm occurs a third time, perform a **manual rinseback**, see page 4-52 unless otherwise instructed by the center, as long as the blood circuit is not clotted or hemolyzed and air is not seen in the blood circuit or in the patient blood lines. Contact Technical Support.

715 - Check Blood Leak Detector (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

The cycler detected a problem with the blood leak detector.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
1. Blood leak detector malfunction. 2. Fluid has interfered with the blood leak detector signal. 3. Improper automated calibration of blood leak detector during Prime.	Follow steps below for all probable causes: 1. Turn power off, then on again immediately. 2. If the number **40** appears, press the **TREATMENT** key to continue. 3. If the alarm recurs, or a leak is observed, end the treatment and perform a **manual rinseback**, see page 4-52, unless otherwise instructed by your center, as long as the blood circuit is not clotted or hemolyzed and air is not seen in the blood circuit or in the patient blood lines. • After rinseback is complete, check for cartridge leak. If a leak is observed, clean and dry all cycler surfaces affected by the leak. Weigh the patient to assess UF status. • Even if no leak is observed, clean and dry the blood leak detector. For the proper procedure, see **Cleaning the blood leak detector**, page 6-5. • Reinitiate Prime with a new cartridge.

721 - Door is Ajar (Red Alarm)

Priority

- Red Alarm - High

Alarm Event

Door movement.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
Door handle was lifted any time after priming was initiated. • Indicates door locking mechanism may be damaged.	1. Clamp dialysate inlet line immediately. 2. Turn the cycler power off. 3. Perform a a **manual rinseback**, see page 4-52, unless otherwise instructed by your center, as long as the blood circuit is not clotted or hemolyzed and air is not seen in the blood circuit or in the patient blood lines. 4. Call Technical Support and report the alarm number.

999 - Service Mode Active (Yellow Caution)

Priority

- Yellow Caution - Medium

Alarm Event

The cycler is in Service Mode.

All pumps stop when the alarm is displayed.

1. Press the **MUTE** key to silence the alarm.
2. Identify and resolve the probable cause.

Probable Cause	Actions Required
The cycler is in Service Mode.	Do not initiate the treatment. Call Technical Support immediately.

NxSTAGE® Invent. Improve. Inspire.

Chapter 6 Maintenance

To reduce the risk of infection, follow the instructions in this user guide to clean and disinfect the cycler. The care and servicing of your cycler is discussed under preventive maintenance.

Cleaning and disinfection

Clean and disinfect the cycler after each treatment. Clean the blood leak detector at least once a month. The cartridge is single use. It does not need to be cleaned or disinfected.

The following steps for cleaning and disinfecting NxStage equipment were developed in accordance with the Centers for Disease Control (CDC) and the Centers for Medicare and Medicaid Services (CMS) "Conditions for Coverage for End-Stage Renal Disease Facilities."

WARNINGS

- There are no operator or customer technician serviceable parts in any NxStage equipment. Unless otherwise instructed or authorized, NxStage or its agent must perform all maintenance and repair. No changes or modifications to any NxStage equipment are allowed without NxStage's authorization. Unauthorized changes or modifications to equipment may impact performance which may lead to patient or operator injury or death.
- Always follow universal precautions when operating the NxStage System One, cleaning or disinfecting equipment, or observing patient treatment, to avoid infection.
- Clean and disinfect NxStage equipment in a well-ventilated environment in accordance with instructions included in this User Guide. Failure to follow these instructions increases the risk of exposure to infectious diseases and may also cause damage to the equipment.

PRECAUTIONS

- Keep all equipment free of dust by regularly cleaning around and under the equipment. Excessive dust on equipment can lead to poor system performance.
- Keep all equipment out of direct sunlight to prevent the device from overheating.
- Keep children and pets away from all equipment to prevent damage that may lead to poor system performance.

NOTE

If you are not familiar with a specific cleaning or disinfection procedure on your cycler, contact Technical Support.

Follow universal precautions when cleaning and disinfecting the cycler. Use the protective clothing and supplies your center advises to avoid cross-contamination when cleaning and disinfecting the cycler. The protective clothing also protects you from cleaning solutions and fumes.

Before cleaning and disinfecting your cycler, filter holder, and computer

1. Unplug the cycler from its electrical power source.
2. Remove all disposables from the cycler.
3. Close the door of the cycler. Push the handle down until it clicks to close the door.

When cleaning and disinfecting the cycler, filter holder, and computer

- Moisten a cloth with the cleaning solution or disinfectant. Do not saturate the cloth to prevent drips.
- Do not immerse any parts of the cycler into the cleaning solution or disinfectant.
- Avoid the metal connections under the computer.

Figure 6-1: Underside of the Jewel Box computer

Cleaning and disinfecting the cycler, filter holder, and computer after each treatment

To clean and disinfect the cycler after each treatment:

1. Use a soft and dry brush to remove gross debris, if needed.
2. Use a soft cloth and mild detergent to wipe the exterior of the cycler. Follow the instructions from the detergent manufacturer.

If the cycler is soiled with blood, or suspected of contamination with pathogens (bacteria, viruses, or fungi):

1. Use a bleach solution of 1:100 (1 part EPA-registered household bleach to 99 parts clean water).

   Mix 60 milliliters of bleach (2 oz/ ¼ cup) with 3.78 liters of water (128 oz/one gallon). Moisten a soft cloth with the bleach solution.

   You can also make less solution by mixing 15 milliliters (0.5 oz/ one tablespoon) of bleach in 0.95 liters (32 oz/one quart) of water.
2. Wipe the external parts of the cycler with the bleach solution.
3. Let the bleach solution remain on the equipment for 10 minutes before wiping it out.

NOTE

Use the freshly made bleach solution within 24 hours. Some blood pathogens may require a different solution and contact time for disinfection. Follow the directions from the bleach manufacturer to disinfect the suspected blood pathogen.

4. After cleaning up the blood, use a clean cloth to apply the bleach solution a second time. Let the bleach solution remain on the equipment for another ten minutes.
5. Use another clean cloth with water to rinse off the bleach solution. Air-dry.
6. Throw away the cleaning cloths and protective clothing, as appropriate.
7. Make sure the door of the cycler is closed before storage.

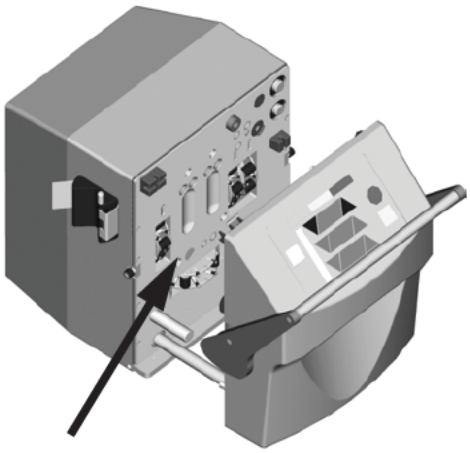
Cleaning the blood leak detector

Clean the detector at least once a month or more frequently if needed.

To clean the blood leak detector:

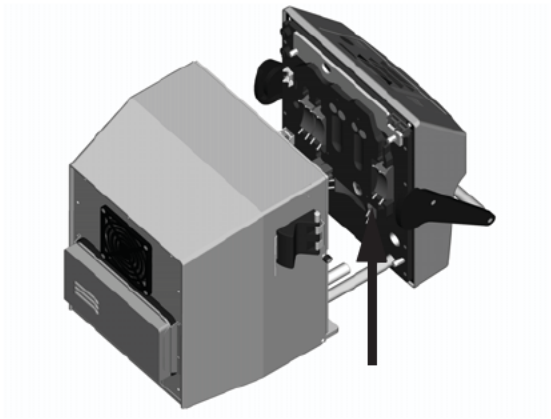
1. Open the door of the cycler. To open, lift up the handle until it clicks, and then pull it toward you. The blood leak detector is inside the cycler, on the left.

Figure 6-2: Location of blood leak detector



2. Look for the mirror directly across the blood leak detector. See Figure 6-3.

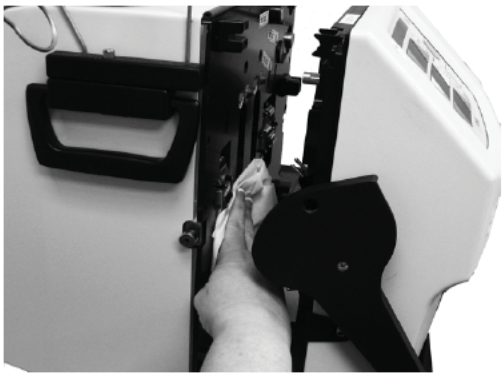
Figure 6-3: Location of the mirror



3. Moisten a soft lint-free cloth with tap water, wipe the blood leak detector and mirror to remove dust and debris.

4. Dry the blood leak detector and mirror with a clean, soft, and ultra, low-lint cloth.

Figure 6-4: Wiping the blood leak detector and mirror



- Be sure to remove all jewelry before putting your hand inside the cycler.
- Do not touch other sensors during this procedure.
- It is safest to reach inside the cycler from the side as shown in Figure 6-4.
- Camera or eyeglasses cloths can be used for cleaning the detector and mirror.

Preventive maintenance

The cycler is designed to require low preventive maintenance. There is no repair to be done by the user on the cycler.

WARNING

There are no operator or customer technician serviceable parts in any NxStage equipment. Unless otherwise instructed or authorized, NxStage or its agent must perform all maintenance and repair. No changes or modifications to any NxStage equipment are allowed without NxStage's authorization. Unauthorized changes or modifications to equipment may impact performance which may lead to patient or operator injury or death.

PRECAUTION

Preventive maintenance on NxStage equipment must be performed in accordance with this User Guide or applicable Instructions for Use. When the Cycler displays a Yellow Caution 71, it is time to contact Technical Support or an authorized distributor to schedule maintenance on the Cycler.

When you turn on the cycler, it runs a self-test to check all the systems. The cycler also checks the alarms system and the priming of the cartridge before use.

These tests are designed to detect most system problems, including:

Power-up test	Internal electronics and software, control panel, and lights
Prime and Alarm Tests	Pressure sensors. Air sensors. Blood leak detector. Door sensors. Speed, direction, and occlusion for the pumps. Clamp occlusion on venous blood line and waste line. Volumetric system. Control panel and electronics. Alarms.

When the system tests fail, the cycler generates alarms. To know how to respond to these alarms, see Chapter 5, Troubleshooting.

When it is time to do preventive maintenance on your cycler, it generates a Yellow Caution 71 alarm (Preventive maintenance due). If you receive this alarm, you need to return your cycler for maintenance. Contact Technical Support to schedule the return of your cycler and to receive a new cycler.

This page intentionally left blank.

Chapter 7 Hardware specifications

The NxStage System One was designed and built with these hardware specifications.

NxStage cycler CYC-D2E (NX1000-1 and NX1000-3)

Environmental requirements

Table 7-1: Environmental requirements for NX1000-1 and NX1000-3 cycler

Room operating temperature	15°C to 32°C (59°F to 90°F)
Room operating humidify	0% to 95% non condensing
Maximum operating altitude	Not applicable
Transport and storage temperature	0°C to 50°C (32°F to 122°F) Before using, keep cycler at room temperature for one hour
Transport and storage humidity	0% to 95% noncondensing
Protection against ingress of fluids	Drip proof IPX1 (per IEC 60529)
Chemical resistance	Resistant to 0.25% sodium hypochlorite (bleach)
Input voltage	100–120/230 VAC, auto-ranging
Frequency	50/60 Hz
Input power	600 VA: 200 VA for cycler 400 VA for AC outlet

Electrical safety

The NxStage System One Cycler models CYC-D2E (NX1000-1 and NX1000-3) meet the following standards:

- UL 60601-1:2003
- CAN/CSA-C22.2 No. 601.1-M90 inc. Supplement No. 1-94 and 2-98
- IEC 60601-1:1988 inc. Am.1:1991 and Am.2:1995
- IEC 60601-1-1:2000
- IEC 60601-1-4:2000
- IEC 60601-2-16:1999
- IEC 60529:2001 for IPX1
- EN 60601-1:1990 inc. Am. A1 and Am. A2

Table 7-2: Electrical safety for NX1000-1/NX1000-3 cycler

Classification	Portable, continuous operation, Class I, Type BF Applied Part	
Maximum Earth Leakage Current	**Standard**	**Conditions of Test**
300 micro-amps	UL 60601-1 (National Difference per 19.5 DV)	With and without the loss of protective earth with the supply conductors normal and reversed.
500 micro-amps	IEC 60601-1	With the loss of protective earth with the supply conductors normal and reversed.
1000 micro-amps	IEC 606601-1 UL 60601-1	With the loss of protective earth with the supply conductors normal and reversed and with the interruption of one supply conductor at a time.

The AC power outlet on the back of the NxStage System One cycler model CYC-D2E (NX1000-1 and NX1000-3) is for use with the NxStage ComfortMate Fluid Warmer (Model FW-200), NxStage Express Fluid Warmer (FW-300), and NxStage PureFlow SL (NX2000-1). Do not use this outlet with another device without first consulting Technical Support.

Electromagnetic compatibility (EMC)

The NxStage System One Cycler model CYC-D2E (NX1000-1 and NX1000-3) meets IEC 60601-1-2:2001, 2nd edition. The cycler is suitable for use in the specified electromagnetic environment. The user of the NxStage System One Cycler should make sure that it is used in an electromagnetic environment as described in Table 7-5, page 7-5.

NxStage cycler NX1000-4

Environmental requirements

Table 7-3: Environmental requirements for NX1000-4 cycler

Room operating temperature	15°C to 37°C (59°F to 99°F)
Room operating humidify	15% to 93% non condensing
Maximum operating altitude	0 m to 3000 m (700 hPa to 1060 hPa)
Transport and storage temperature	-25°C (13°F) without relative humidity control to 70°C 158°F) at 93% relative humidity, non condensing. Before using, keep the cycler at room temperature for one hour.
Protection against ingress of fluids	Drip proof IP22 (per IEC 60529)
Chemical resistance	Resistant to 0.25% sodium hypochlorite (bleach)
Input voltage	100–120/230 VAC, auto-ranging
Frequency	50/60 Hz
Input power	600 VA: 200 VA for cycler 400 VA for AC outlet
Fuse	5x20 mm, Time-lag, 4 amp High-breaking capacity, rated for 250 V

Electrical safety

The NxStage System One Cycler NX1000-4 meets the following standards:

- ANSI/AAMI ES60601-1:2005
- IEC 60601-1:2005
- CAN/CSA-C22.2 No. 60601-1: 2008
- IEC 60601-2-16:2008 and 2012
- IEC 60601-1-11:2010

Table 7-4: Electrical safety for the NX1000-4 cycler

Classification	Portable, continuous operation, transport operable, Class II, Type BF Applied Part

The AC power outlet on the back of the NxStage System One cycler model NX1000-4 is for use with the NxStage Express Fluid Warmer (FW-301) and NxStage PureFlow SL (NX2000-10). Do not use this outlet with another device without first consulting Technical Support.

Electromagnetic compatibility (EMC)

The NxStage System One cycler modelNX1000-4 conforms to IEC 60601-1-2:2007, 3rd Edition, and is suitable for use in the specified electromagnetic environment. The user of the NxStage System One cycler should make sure that it is used in an electromagnetic environment as described in Table 7-5, page 7-5.

Electromagnetic environment

Table 7-5: Electromagnetic environment

Test	Compliance	Environment
Emissions		
Radio Frequency Emissions	Class B	Suitable for use in all establishments, including those directly connected to a public low-voltage power supply network.
Harmonic Emissions (EN 61000-3-2)	Complies	Suitable for use in all establishments, including those directly connected to a public low-voltage power supply network.
CISPR 11 (EN 55011)	Group 1	Uses RF energy only for its internal function. Therefore, the RF emission is very low and not likely to cause any interference in nearby electronic equipment.
Voltage Fluctuations/ Flicker Emissions (EN 61000-3-3)	Complies	Suitable for use in all establishments, including those directly connected to a public low-voltage power supply network.

Test	Compliance	Environment
Immunity		
Electrostatic Discharge (ESD) (EN 61000-4-2)	+/- 6 kV Contact +/- 8 kV Air (Computer: +/- 4 kV Contact)	All floors are wood, concrete, or ceramic tile, or floors are covered with a synthetic material and the relative humidity is at least 30%.
Radiated RF (EN 61000-4-3)	10 V/m 80 MHz to 2.5 GHz	Portable and mobile RF communications equipment is used no closer to any part of the system than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter. Recommended separation distances: d = .35 √P 80 MHz to 800 MHz d = .7 √P 800 MHz to 2.5 GHz where "P" is the power rating of the transmitter in watts (W) according to the transmitter manufacturer and "d" is the recommended separation distance in meters (m). Interference may occur in the vicinity of equipment marked with the following symbol: 
Electrical Fast Transient/Burst (EN 61000-4-4)	2 kV at mains plug	Mains power quality should be that of a typical domestic, commercial, or hospital environment.
Surge (EN 61000-4-5)	1 kV differential mode 2 kV common mode	Mains power quality should be that of a typical domestic, commercial, or hospital environment.

Test	Compliance	Environment
Conducted RF (EN 61000-4-6)	3 Vrms 150 MHz to 80 MHz	Portable and mobile RF communications equipment is used no closer to any part of the system than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter. Recommended separation distance: $d = 1.17 \sqrt{P}$ where "P" is the power rating of the transmitter in watts (W) according to the transmitter manufacturer and "d" is the recommended separation distance in meters (m). Interference may occur in the vicinity of equipment marked with the following symbol: 
Power Frequency Magnetic Field (EN 61000-4-8)	50 and 60 Hz 3 A/m	Power frequency magnetic fields are at levels characteristic of a typical location in a typical (EN 61000-4-8) domestic, commercial, or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines (EN 61000-4-11)	100% Dip for 0.5 cycles 60% Dip for 5 cycles 30% Dip for 25 cycles 95% Dip for 5 seconds	Mains power quality should be that of a typical domestic, commercial, or hospital environment. The system powers off during a 5 second loss of AC mains power but is recoverable using normal operator controls once power is restored. If the user of the system requires continued operation during power mains interruptions, it is recommended that the system be powered from an uninterruptible power supply.

Recommended separation distances

The NxStage System One is suitable for use in the electromagnetic environment in which radiated disturbances are controlled. You can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment and the cycler. See Table 7-6 for the recommended separation distances at the maximum output power of the communications equipment.

Table 7-6: Recommended separation distance

Max Output Power (Watts)	Separation 150kHz to 80MHz D = (1.17)(Sqrt P)	Separation 80 to 800MHz D = (0.35)(Sqrt P)	Separation 800MHz to 2.5GHz D = (0.7)(Sqrt P)
0.01	0.12 m	0.04 m	0.07 m
0.1	0.37 m	0.11 m	0.22 m
1	1.17 m	0.35 m	0.70 m
10	3.69 m	1.11 m	2.22 m
100	11.67 m	3.50 m	7.00 m

The service computer contains components that generate RF energy. It has been tested to ensure no interference with the operation of the cycler. The device complies with Part 15 of the Federal Communications Commission (FCC) Rules. Operation is subject to the following two conditions:

1. The device may not cause harmful interference.
2. The device must accept any interference received, including interference that may cause undesired operation.

   Components generating RF energy maintain minimum spacing requirements to comply with RF exposure/Specific Absorption Rate (SAR) requirements.

Operating ranges

Table 7-7: NxStage System One Operating Ranges

Parameter	Performance	Condition
Blood Flow Rate		
Device	Peristaltic pump	
Range	50 to 600 ml/min[1] 10 to 600 ml/min[2, 3]	Set by user.
Resolution	10 ml/min	
Accuracy	± 15%	@200 ml/min; inlet pressure, -50 mmHg; outlet pressure, 50 mmHg, using water at 37°C
NOTE Blood flow and thus treatment efficacy may be reduced when pre-pump arterial pressures are extremely negative		
Protective system	Effluent and venous pressures. Hall-effect speed sensor.	Tested during Alarms Test. Monitored during treatment.
Effluent Fluid Flow (and Dialysate Exchange) Rate		
Device	Peristaltic pump	
Range	NX1000-1: 0 to 12.0 L/hr NX1000-3 or higher: 0 to 18.0 L/hr	Set by user; dialysate flow dependent on effluent flows.
Resolution	0.1 L/hr	
Accuracy	Greater of ± 10% or 10 ml/min	
Volume Accuracy	**For software versions 4.7 and below:** Greater of 300 ml/12 hr or 3% of exchange volume **Note:** Combined accuracy of ultrafiltration and dialysate exchange flows. **For software version 4.8 and higher**:	
Protective System	Effluent and waste line pressures. Hall-effect speed sensor.	Tested during Alarms Test. Monitored during treatment.

Dialysate Flow Rate (L/hr)	Specification Greater Of	
> 3	± 5% of UF* or	± 100 ml/hr*
≤ 3		± 25 ml/hr*

*Representing 95/90 tolerance interval established under controlled laboratory testing conditions.

1 For software versions below 4.6
2 For software versions 4.6 and 4.7
3 For software version 4.8 and higher

Table 7-7: NxStage System One Operating Ranges

Parameter	Performance	Condition
Ultrafiltration Only		
Device	Peristaltic pump	
Range	0 to 2.4 L/hr or 0 to 999 ml/hr	Set by user
Resolution	0.01 L/hr or 1 ml/hr	
Accuracy	**For software versions 4.7 and below:** Greater of 10% or 0.06 kg/hr **For software version 4.8 and higher:** Greater of 5% of ultrafiltration rate or 30 ml/hr* *Representing 95/90 tolerance interval established under controlled laboratory testing conditions.	
Protective system	Effluent and venous pressures. Hall-effect speed sensor.	Tested during Alarms Test. Monitored during treatment.
Fluid Bolus Flow Rate (Hemofiltration only)		
Device	Peristaltic pump	
Range	2 to 200 ml/min	System Setting
Resolution	1 ml/min	
Accuracy	Greater of ±10% of bolus volume or ±30 ml	
Protective system	Effluent and venous pressures. Hall-effect speed sensor.	Monitored during treatment bolus infusion.
Fluid Bolus Volume (Hemofiltration only)		
Range	0 to 500 ml	System Setting
Resolution	5 ml	
Dialyzer Blood Volume		
Range	10 to 220 ml	System Setting
Resolution	1 ml	
Rinseback Factor		
Range	0.1 to 5	System Setting (Rinseback Volume = (Blood-side Dialyzer Volume + Blood Cartridge Volume) **x** Rinseback Factor)
Resolution	0.01	

Alarms and monitors

During the alarms test, the cycler verifies all alarms and monitoring functions. It also normalizes the blood leak detection.

Table 7-8: NxStage System One alarms and monitors

Parameter	Performance
Venous Pressure	
Device	Electronic sensor
Range	0 to 1500 mmHg
Accuracy	Greater of ±20 mmHg or ±10%
High fixed alarm point	400 mmHg sustained, 600 mmHg sustained during ramp-up and Prime and Alarm Test. 1500 mmHg instantaneous
Low fixed alarm point	20 mmHg sustained
Low adjustable alarm point	-20 to -90 mmHg (in 10 mmHg increments) from venous pressure "lock on" (default is 60 mmHg). "Lock on" occurs when the pressure has been stable for a certain time period (based on pump flow rates) after targeted pump flow rates are achieved.
Protective system	Continuous monitoring by safety subsystem.
Arterial Pressure, Prepump	
Device	Electronic sensor
Range	-50 to -500 mmHg
Accuracy	Greater of ±20 mmHg or ±10%
Arterial Pressure, Dialyzer	
Device	Electronic sensor
Range	0 to 1500 mmHg
Accuracy	Greater of ±20 mmHg or ±10%
Effluent Pressure	
Device	Electronic sensor
Range	0 to 1500 mmHg
Accuracy	Greater of ±20 mmHg or ±10%
High fixed alarm point	1500 mmHg instantaneous
Low fixed alarm point	20 mmHg sustained

Table 7-8: NxStage System One alarms and monitors

Parameter	Performance
Low adjustable alarm point	-10 to -200 mmHg (in 10 mmHg increments) from effluent pressure “lock on” (default is 100 mmHg). “Lock on” occurs when the pressure has been stable for a certain time period (based on pump flow rates) after targeted pump flow rates are achieved.
Protective system	Continuous monitoring by safety subsystem.
Transmembrane Pressure	
Computed as the difference between venous and effluent pressures.	
High fixed alarm point	500 mmHg sustained
Waste Line Pressure	
Device	Electronic sensor
Range	0 to 1500 mmHg
Accuracy	Greater of ±20 mmHg or ±10%
High fixed alarm point	900 mmHg sustained, 1500 mmHg instantaneous
High adjustable alarm point	100 to 450 mmHg sustained
Protective system	Continuous monitoring by safety subsystem.
Balance Chamber Pressure	
Device	Electronic sensor
Range	0 to 1500 mmHg
Accuracy	Greater of ±20 mmHg or ±10%
High fixed alarm point	600 mmHg sustained, 1500 mmHg instantaneous
Air Detection	
Device	Ultrasonic detector
Sensitivity	Reduction of detector signal lasting 6 ms minimum. Approximates a 60 µl bubble at 400 mmHg venous pressure and 600 ml/min blood flow.
Protective system	Continuous monitoring by safety subsystem.

Table 7-8: NxStage System One alarms and monitors

Parameter	Performance
Dialyzer Blood Leak Detector	
Device	Optical emitter and sensor.
Sensitivity	A blood leak is indicated when the 20 second average of the detector signals drops more than 15% below the normalized detector signals. Signal reduction % based on a 0.35 ml/min leak rate of 32 Hct blood.
Protective system	Continuous monitoring by safety subsystem.
Audible Alarms	
Power fail	Continuous for at least one minute.
System fail	Continuous
Others	Continuous, may be silenced for two minutes. Immediate for Red Alarm conditions, delayed for Yellow Caution conditions. Alarm resumes if conditions remain unresolved.
Output	>65 dBA at 1 m
Fluid Temperature Sensor	
Device	Thermistor
Alarm Point (High)	42°C (108°F)[1]
Alarm Point (Low)	<33.3°C (91.9°F)[2]
1 For software versions 4.6 and higher 2 Only applies to software version 4.9 and higher	

Table 7-8: NxStage System One alarms and monitors

Parameter	Performance
Alarm Delay	33.2°C (91.8°F): 304 minutes 33.1°C (91.6°F): 274 minutes 33.0°C (91.4°F): 251 minutes 32.9°C (91.2°F): 232 minutes 32.8°C (91.0°F): 217 minutes 32.7°C (90.9°F): 204 minutes 32.4 - 32.6°C (90.3 - 90.7°F): 183 minutes 32.2 - 32.3°C (90.0 - 90.1°F): 166 minutes 31.8 - 32.1°C (89.2 - 89.8°F): 141 minutes 31.3 - 31.7°C (88.3 - 89.1°F): 123 minutes 30.6 - 31.2°C (87.1 - 88.2°F): 101 minutes 29.6 - 30.5°C (85.3 - 86.9°F): 81 minutes 27.8 - 29.5°C (82.0 - 85.1°F): 60 minutes 24.5 - 27.7°C (76.1 - 81.9°F): 40 minutes 17.1 - 24.4°C (62.8 - 75.9°F): 20 minutes <17.1°C (62.8°F): 0 minutes Delay times based on temperature estimated at the dialyzer, 35.6°C (96.1°F) pre-dialysis core temperature, 34.0°C (93.2°F) dialysis core temperature, 52 kg (115 lb) body weight, 300 ml/min dialysate rate, 350 ml/min blood flow rate, 15 - 20°C (59 - 68°F) ambient temperature, and use of a NxStage chronic cartridge in a hemodialysis configuration.
Accuracy	± 2°C (± 3.6°F)[1] $\frac{+0}{-2}$ °C $\left(\frac{+0}{-3.6}\text{°F}\right)$[2] $\frac{+2.5}{-0}$ °C $\left(\frac{+4.5}{-0}\text{°F}\right)$ at low temperature caution and dialysate rates ≥ 5 L[3].
Protective system	Continuous monitoring by safety subsystem.

1 For software versions below 4.6
2 For software versions 4.6 and higher
3 For software versions 4.9 and higher

Fluid temperature

Parameter	Performance
Input fluid temperature range	33.3 to 41.9°C
Output fluid temperature range	33.3 to 41.9°C

Energy consumption

For a typical three-hour long hemodialysis treatment, with a blood flow rate of 500 ml/min, a dialysate flow rate of 9 L/hr, and an ultrafiltration rate of 0.5 L/hr, the cycler uses approximately 0.2 kWh. Approximately 20% of the energy used is released into the environment as heat.

Contact materials

A list of generic materials that come into contact with blood and fluids is available upon request.

Chapter 8 Glossary

This section defines terms and abbreviations used throughout this user guide.

Terms

Air detectors
Sensors in the cycler that monitor the blood circuit for air. The air detectors can detect bubbles of air in the blood and fluid circuit. The air detectors start an alarm and stop the movement of fluids when there is air in the blood circuit.

Air vent
Small tube found on the ComfortMate fluid warmer to release air out of the warmer.

Ancillaries
Accessories and disposables used with the NxStage System One.

Anticoagulant
Type of medication used to prevent blood from clotting. Heparin is an anticoagulant.

Anticoagulation
Anticoagulation is the use of an anticoagulant to prevent blood from clotting.

Arterial access pressure
Pressure measured in the arterial bloodline before the blood pump. The arterial pressure measures the resistance to flow that must be overcome to pull blood from the patient access. A pressure pod placed on the arterial line measures this pressure. If there is no pressure pod on the arterial bloodline, patients cannot measure their arterial pressure.

Aseptic technique
Aseptic technique is a set of steps to follow before and during treatment to reduce the risk of germs from entering the body. Germs include bacteria, virus, and fungi. Practices include washing hands regularly and thoroughly, wearing gowns, gloves, face and shield masks, and not touching any connections on the blood and fluid lines. See also **Bacteria**.

Bacteria
Very small organisms that may be found in the air, soil, water, and inside the body and on the skin. Bacteria can cause infection, disease, and even death.

Blood-borne pathogens
Organisms too small to see with the naked eyed that may be present in human blood and transferred among humans. Blood-borne pathogens can cause disease.

Blood flow rate
Blood flow rate is the amount of blood flowing through the bloodlines and dialyzer during treatment. It is measured in milliliters per minute.

Blood leak
A blood leak is the escape of blood from the blood circuit into the dialysate. It is generally due to a small break or a tear in the dialyzer fibers or membrane.

Blood line
A general term applied to the part of a tubing set that fills with blood, also called a patient line. There are two blood lines: the arterial line between the arterial access of the patient and the dialyzer, and the venous line between the dialyzer and the venous access of the patient.

Bolus
A bolus is a single delivery of a specific amount of intravenous fluid. During treatment, a bolus of saline is generally used to treat low blood pressure.

Cartridge
A cartridge is a single use disposable used in hemodialysis. It has a blood circuit for carrying the blood to and from the patient into the dialyzer. It has a fluid circuit, isolated from the blood circuit, to deliver a flow of dialysate through the dialyzer. It drains away the waste fluid.

Catheter
A catheter is a soft tube that is inserted into a large vein in the neck, chest, or leg to access blood. See also **Vascular Access**.

Check valve
A check valve is a small valve that allows fluid to flow in one direction only.

Clamp
Any devices used to stop the flow of blood or fluid through the cartridge.

Convection
The process by which the waste products are carried across the membrane of the dialyzer by the movement of plasma, fluid, and ultrafiltrate.

Creatinine
A waste product released from the muscles of the body. Creatinine is normally removed from the blood by the kidneys. Creatinine is removed from blood of patients during hemodialysis.

Cycler
The cycler is the dialysis machine. The cycler controls the pumps; balances the fluids; and calculates the treatment time. It controls the dialysate, ultrafiltration, and blood flow rate. It controls the dialysate and ultrafiltration volume. It monitors the pressure in the arterial and venous bloodlines. It also detects bubbles of air in the blood and fluid circuit.

Dialysate
Dialysate is a solution of pure water, electrolytes, and salts used to clean the blood of patients during dialysis. See **Electrolytes**.

Dialysate line inlet
The tube opening that lets the dialysate enter the cartridge.

Dialysate line outlet
The tube opening that lets the dialysate out of the balancing system into the dialyzer.

Dialysate rate
The amount of dialysate flow measured in liters per hour.

Dialysis
Dialysis is the process of using a dialyzer to remove waste and excess fluid from the blood of patients whose kidney are no longer working well.

Dialyzer
The filter used in hemodialysis to clean the blood of accumulated waste and excess fluid. The dialyzer is a canister containing fibers with microscopic holes. During hemodialysis, the blood flows through the filter and the dialysate fills the canister around the fibers. Water and waste pass from the blood into the dialysate solution.

Diffusion
Diffusion is a process that moves waste products out of the blood through the dialyzer into the dialysate.

Disinfection
The cleaning process used to kill or prevent the growth of bacteria that could lead to infection.

Dry weight
Dry weight is the weight of the patient after removing excess fluid. Dry weight is the weight when the blood pressure is normal and there is no swelling. See also **Fluid balance.**

Effluent
Effluent is the used dialysate and excess fluid collected in a waste fluid bag or drained into a sink or toilet. This effluent contains the waste and excess fluid removed from the blood of patients.

Effluent line
The section of tubing that carries the used dialysate to the waste line.

Electrolytes
Salts dissolved in the body fluids, including sodium, potassium, magnesium, and chloride. The kidneys control the amount of electrolytes in the body. When kidneys fail, electrolytes get out of balance, causing potentially serious health problems.

Endotoxin
Endotoxins are substances found in the outer covering of some bacteria. Endotoxins can cause serious illness and infection. See also **Bacteria**.

Endotoxin filter
Endotoxin filter is a filter that removes endotoxins from water or other fluids.

Extracorporeal circuit
Extracorporeal circuit is the path of blood circulating outside the body of the patient during hemodialysis.

Female-female connector
A female-to-female connector is a plastic connector with luer fittings on both ends.

Flow fraction
The ratio of effluent to blood flow, expressed as a percentage. See also **Effluent**.

Fistula

Fistula is a direct connection of an artery to a vein. A surgeon creates the fistula to make the vein grow bigger and stronger. Once the fistula has matured, the needle can be inserted in the same fistula many times over. The National Kidney Foundation agrees that fistulas are the best type of vascular access. The fistula has a lower risk of infection and it stays functional for longer than other access types. See also **Vascular Access.**

Fluid balance

Fluid balance is the amount of fluid in the body. The kidneys maintain normal fluid balance by removing excess fluid from the body. When kidneys fail, fluid balance must be controlled during treatment to remove excess fluid from the body of patients. See also **Dry weight.**

Fluid balancing system

The fluid-balancing system is a mechanical system that controls the volume of fluid entering and leaving the cartridge on the cycler.

Fluid warmer

A fluid warmer is a device that warms the dialysate to a comfortable temperature.

Graft

A man made tubing that connects an artery to a vein under the skin. It is surgically created to access blood. A graft does not need time to enlarge and can be used soon after it is created. A graft is used when a fistula is not possible. A graft is easier to use than a catheter. It has a lower risk of infection and it stays functional for longer than a catheter. See also **Catheter**.

Grounded electrical outlet

An electrical outlet that is wired to reduce the risk of electrical shock.

Hemodialysis

Hemodialysis is a dialysis treatment option. It uses a dialyzer to clean wastes and excess fluid from the blood when the kidneys have failed. The blood is removed from the body and filtered through the dialyzer, and then returned to the body. The dialyzer has many fibers. Each fiber has a membrane that separates the blood from the dialysate. The membrane allows water and waste to pass through, but does not allow the blood cells to pass through. See also **Dialyzer**.

Hemofiltration

Hemofiltration is the process that removes waste and excess fluid from the blood through a filter using convection. See also **Convection**.

Hypotension
Hypotension means low blood pressure.

Kidney failure
Kidney failure is the loss of kidney function. Kidney failure means that the kidneys have failed to work well enough to sustain life without dialysis or kidney transplant. See also **Hemodialysis** and **Hemofiltration**.

Luer caps
Screw-on, protective caps placed on luer connectors. The caps protect the tubing ends from contamination.

Luer connector
A standard connector designed for leak tight connection. Syringes, dialyzers, and blood tubing commonly have luer connectors.

Multi-line adapter
Tubing set that allows several bags of fluids to connect and drain into a common inlet.

Nephrologist
A nephrologist is a doctor who specializes in kidney function and disorders.

Pathogen
Pathogen is any microorganisms that cause disease, for example bacteria.

Patient lines
See **Blood line**.

Power cord
Power cord is the cable that connects a device to the wall outlet. It supplies electricity to the device.

Power input
Power input is the socket for the plug that connects the power cord to the device.

Premixed dialysate
Premixed fluid containing electrolytes and specific chemicals dissolved in purified water. The dialysate removes wastes and excess fluid from the blood of patients. It also balances blood chemistry during hemodialysis. See also **Electrolytes** and **Dialysate**.

Prescription
Written instructions from the doctor directing the use of therapy based on the individual needs of patients. The dialysis prescription may include dialysate composition, volume and rate, length of treatment, frequency of treatment, blood flow rate, anticoagulants, and target dry weight.

Pressure sensor
A pressure sensor is a device inside the cycler that measures the pressure of fluid through the circuit.

Prime
Prime is a process that uses saline to remove bubbles of air from the tubing and dialyzer before treatment.

Pyrogenic
Pyrogenic means causing fever.

Pyrogens
Pyrogens are bacterial toxins that cause fever. See **Toxins**, **Endotoxin**.

Red alarm
Red alarm is an audible and visual indication of a major condition on the cycler. The cycler indicates the red alarm number in the red alarm window. A red alarm stops the pumps until the user responds to the alarm.

Replacement fluid
Replacement fluid is a solution of sterile water and electrolytes used in hemofiltration. It is used in replacement of plasma water during hemofiltration.

Rinseback
Rinseback is a process that uses sterile saline to flush the blood of patients back into the body at the end of treatment.

Saline
Saline is a sterile solution of salt in water having the same salt concentration as blood. Saline is used to remove bubbles of air in the dialyzer and bloodlines at the start of treatment. Saline is also used to deliver a bolus during treatment and to rinseback the blood at the end of treatment.

Toxins
Poisonous substances produced by living cells. In hemodialysis, toxins refer to waste that build up in the blood. Healthy kidneys normally remove toxins from blood. During hemodialysis, the dialyzer removes toxins from blood. See **Creatinine**.

Transmembrane pressure
Transmembrane pressure is the difference between venous and effluent pressure inside the dialyzer.

Ultrafiltration
Ultrafiltration is a process that removes fluid from blood. Ultrafiltration takes place in the dialyzer. Ultrafiltration removes the excess fluid from the blood of patients during treatment to reach dry weight. See also **Dry weight**.

Ultrafiltration rate
The amount of fluid removed from blood, measured in milliliters per hour or liters per hour. See also **Ultrafiltration**.

Universal Precautions
Refers to the practice, in medicine, of avoiding contact with bodily fluids of patients that may be infected with microorganisms that cause disease. See also **Aseptic technique**.

Use-by-Date
The date by which supplies must be used. Discard any supplies for which the Use-by-Date has passed.

Vascular Access
The site where the venous blood is accessed for treatment and where the filtered blood is then returned to the patient. The three basic kinds of vascular access are fistula, graft, and catheter. See also **Fistula**, **Graft**, **Catheter**.

Warmer Disposable Set
A single use disposable tubing set that fits inside the ComfortMate fluid warmer. It lets the dialysate flow from the warmer to the cartridge.

Warning
A warning alerts the user to the possibility of serious injury, other adverse reactions, or death associated with the use or misuse of the device.

Waste
Waste is any toxins removed from the blood of patients during hemodialysis, for example creatinine. See also **Effluent**.

Waste Line Extension
Waste line extension is the waste line from the cartridge to the drain.

Yellow Caution

Yellow caution is an audible and visual indication of a condition on the cycler. The cycler indicates the number in the yellow caution window. A yellow caution gives information about the condition. Some yellow cautions need a user response to the alarm; others do not.

Abbreviations

Table 8-1 lists common abbreviations used throughout this user guide.

Table 8-1: Abbreviations

Abbreviation	Descriptions
°C	degrees Centigrade
°F	degrees Fahrenheit
ACS	Arterial Connection Sensor
BFR	blood flow rate
FF	filtration fraction/flow fraction
FXR	fluid exchange rate
Ga	gauge
Hct	hematocrit
hr	hour
Hz	Hertz (frequency)
ID	inside diameter
IEC	International Electrotechnical Commission
IV	intravenous
kg	kilogram
Kuf	coefficient of ultrafiltration
L	liter
LED	light-emitting diode
m	meter
mm	millimeter
min	minute
ml	milliliter
MLA	Multi-Line Adapter
mmHg	millimeters of mercury
NA	not applicable
RF	radio frequency
RA	return authorization
TMP	transmembrane pressure
Tx	treatment
UF	ultrafiltration; ultrafiltrate

Table 8-1: Abbreviations (continued)

Abbreviation	Descriptions
UFR	ultrafiltration rate
Un	drop in main voltage
V	Volts
Vac	Volts (alternating current)
Vdc	Volts (direct current)
vol	volume

Chapter 9 System Settings

To change the System Settings on the cycler, follow the instructions in this chapter. The System Settings table lists all of System Setting parameters for the cycler.

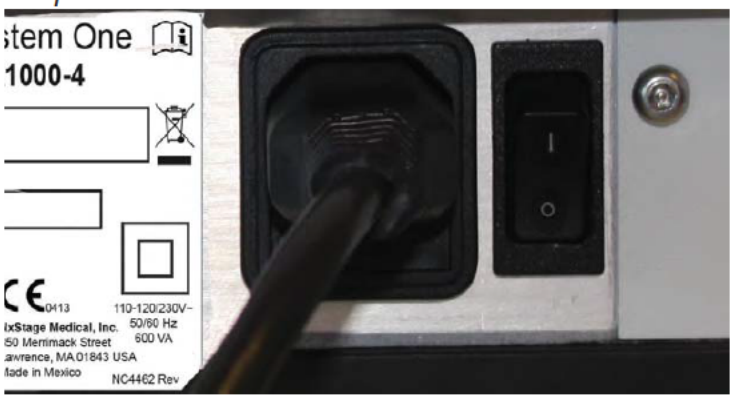
Changing system settings

The following example explains how to change the system setting to the treatment parameters that the doctor or center has prescribed for the patient. Refer to the NxStage cartridge *Instructions for Use* for suggested settings to aid priming. All System Settings are listed after the example.

In this example, System Setting 2 (Initial fluid pump (FP) rate) will be changed from 0.1 to 6.0.

1. Turn on the cycler.

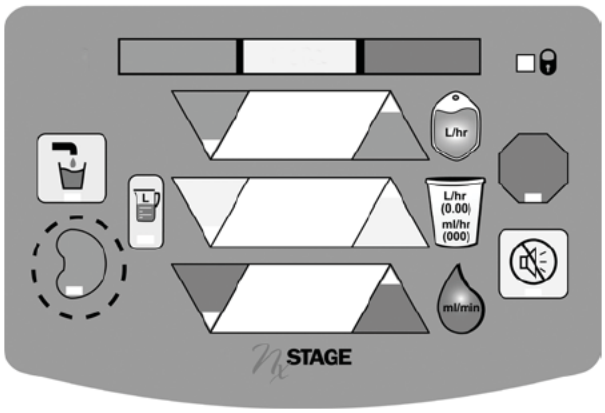
Figure 9-1: Cycler power switch



- The power switch is on the back of the cycler.
- The front panel will flash **8** multiple times in quick succession, go blank, and then flash multiple times again.

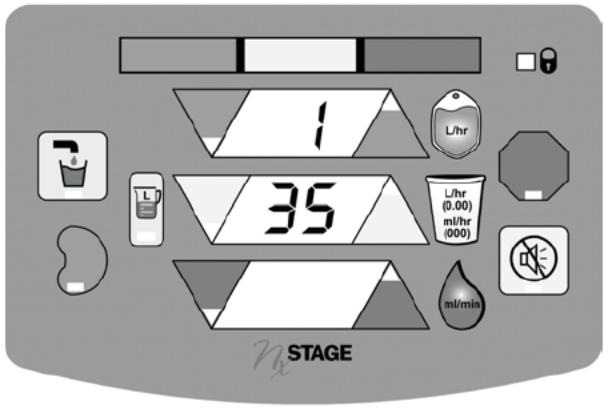
2. Listen closely for the beep and quickly press the **TREATMENT** key. You are now in the System Setting Mode.

Figure 9-2: The TREATMENT key



3. Watch for the number **0** or **1** in the top window.

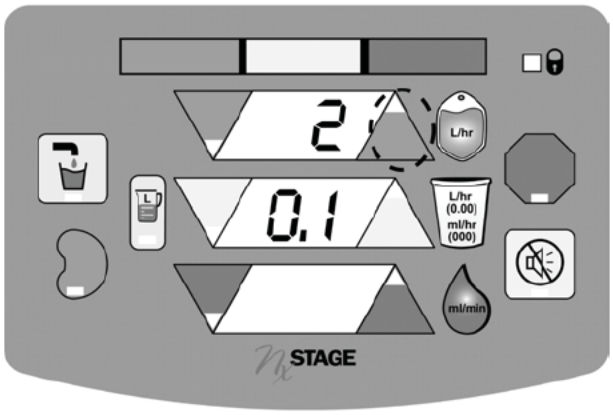
Figure 9-3: System Setting Mode



- You can now change the system settings. If the numbers do not appear, repeat Steps 1 and 2.
- The top window shows the parameter setting number. The middle window shows the current value.

4. Press the **ADJUSTMENT ARROWS** keys in the top window until you see the parameter setting you want to change.

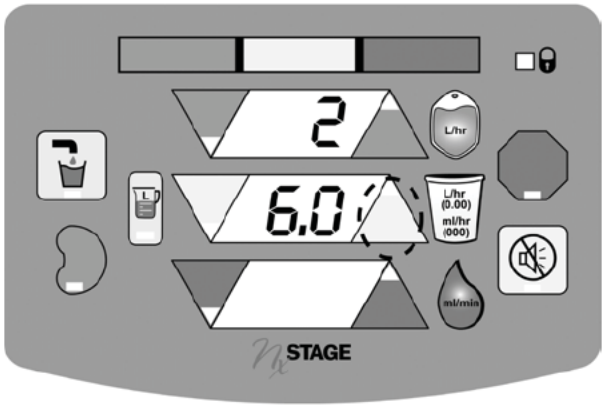
Figure 9-4: Top Adjustment Arrows keys



- See Table 9-1 for all settings options.
- For this example, System Setting 2 is selected (Initial Fluid Pump rate).

5. Press the **ADJUSTMENT ARROW** in the center window until you see the setting value that you want to use.

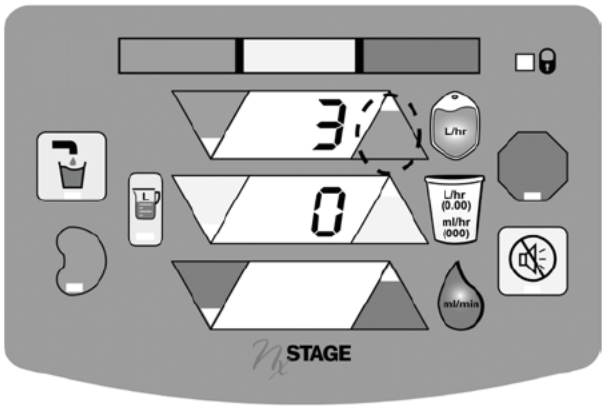
Figure 9-5: Center Adjustment Arrows keys



- In this example, **0.1** is changed to **6.0**.

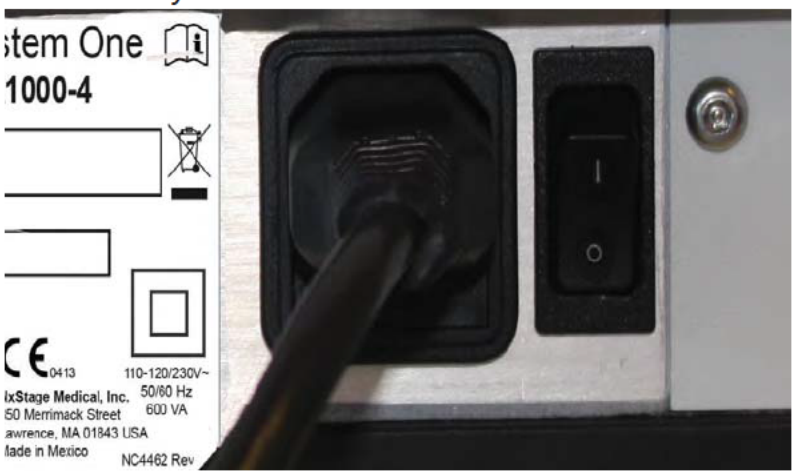
6. Repeat the steps to change other settings as needed.

Figure 9-6: Changing the System Settings



7. After changing all system settings, turn off the cycler.

Figure 9-7: Turn off the cycler



- The power switch is on the back of the cycler.
- When you turn off the cycler, the new settings are saved.

System Settings

Table 9-1: System Setting Parameters

Parameter: No.	Name	Description	Units	Resolution	Range: Low	High	Default Value
0	Cartridge Type	Cartridge type	selector	N/A[1] 1[2,3,4]	N/A[1] 0[2,3,4]	N/A[1] 11[2] 12[3] 13[4]	N/A[1] 0[2,3,4]
1	Maximum FF	Maximum filtration fraction/flow fraction (FF).	%	1	5	480	35%[5]
2	Initial FP	Initial fluid pump (FP) rate.	L/hr	0.1	0	12.0 18.0 [6]	0 L/hr
3	Initial UFP	Initial ultrafiltration pump (UFP) rate.	L/hr	0.01	0	2.40	0 L/hr
4	Initial BP	Initial blood pump (BP) rate.	ml/min	10	50[1] 10[2,3,4]	600	200 ml/min
5	Initial Fluid Volume	Initial fluid volume to process.	L	0.1	0	90.0	15.0 L
6	Initial Weight to Remove	Default setting for weight to remove.	L	0.1	0	99.9	0 L
7	Venous Pressure Decreasing Alarm Offset	Sets a low pressure limit below the stabilized pressure following a pump rate change. Indicates the amount pressure can drop before alarm.	mmHg	10	20	90	60 mmHg

1 For software versions below 4.6
2 For software version 4.6
3 For software version 4.7
4 For software version 4.8 and higher
5 For NX1000-3 with dialysate rates higher than 12 L/hr, adjust FF to prescribed value
6 For NX1000-3 and higher with Cartridge Type set to 13

Table 9-1: System Setting Parameters

Parameter: No.	Name	Description	Units	Resolution	Range: Low	High	Default Value
8	Effluent Pressure Decreasing Alarm Offset	Sets a low pressure limit below the stabilized pressure following a pump rate change. Indicates the amount pressure can drop before alarm.	mmHg	10	10	200	100 mmHg
9	Bolus Volume	Volume of fluid to be given during automatic bolus.	ml	10[1] 5[2,3]	0	500	0 ml
10	Bolus Rate	The flow rate for bolus fluid.	ml/min	10[1] 1[2,3]	10[1] 2[2,3]	200	100 ml/min
11	Net Positive Bolus	**0** = Bolus counted in the cycler's fluid balance. **1** = Bolus not counted in cycler's fluid balance.	selector	1	0	1	0 selector
12	Blood-side Dialyzer Volume	The blood volume of the dialyzer.	ml	1	10	220	91 ml
13	Rinseback Factor	System Setting Rinseback Volume = (Blood-side Dialyzer Volume + Blood Cartridge Volume) **x** Rinseback Factor	multiplier	0.01	0.1	3[1,2] 5[3]	1.45 multiplier
14	Rinseback Limit	Number of full rinseback cycles permitted.	selector	1	1	5	2 selector

1 For software versions below 4.6
2 For software version 4.6
3 For software versions 4.7 and higher

Table 9-1: System Setting Parameters

Parameter: No.	Name	Description	Units	Resolution	Range: Low	High	Default Value
15	Rinseback Rate Limit	Maximum blood pump rate during rinseback is the lower of this value or the last commanded blood pump (BP) rate during treatment.	ml/min	10	50[1] 10[2]	600	200 ml/min
16	Power Failure Recovery Timeout	Time limit to recover from power failure. When setting this parameter, allow one minute for cycler initialization in addition to the desired time for operator to recover from power failure.	min	1	1	15	2 min
17	Green Window Scroll Delay	Sets the time duration during the green window scroll.	sec	1	1	10	5 sec
18	Arterial Air Override Duration	Upon start of blood pump (after Alarm 11), time before arterial air sensor activates.	sec	1	10	60	10 sec
19	Preprime FP	Fluid pump (FP) rate before Prime Step 2.1.	ml/min	1	20	200	200 ml/min
20	Preprime WBP	Target waste bag pressure (WBP) before Prime Step 2.1.	mmHg	10	200	600	450 mmHg

1 For software versions below 4.6
2 For software versions 4.6 and higher

Table 9-1: System Setting Parameters

Parameter: No.	Name	Description	Units	Resolution	Range: Low	High	Default Value
21	Flush Volume	Volume of priming solution needed to flush a wet dialyzer.	L	0.1	1	5	1.5 L
22	Dialyzer Flush FP	Fluid pump (FP) rate during dialyzer flush.	ml/min	1	0	200	100 ml/min
23	Dialyzer Flush UFP	Ultrafiltration pump (UFP) rate during dialyzer flush.	ml/min	1	0	200	40 ml/min
24	Dialyzer Flush BP	Blood pump (BP) rate during dialyzer flush.	ml/min	10	50	600	600 ml/min
25	Reconfigure Cartridge Line	**0** = Skips this step. **1** = Prompts operator to move the cartridge line.	selector	1	0	1	0 selector
26	Prime Timer	Length of time of Prime Step 3.2.	sec	1	0	600	0 sec
27	Prime FP	Fluid pump (FP) rate during Prime.	ml/min	1	40	200	200 ml/min
28	Prime UFP	Ultrafiltration pump (UFP) rate during Prime.	ml/min	1	40	200	40 ml/min
29	Prime BP	Blood pump (BP) rate during Prime.	ml/min	1	50	600	360 ml/min
30	Recirculation FP	Fluid pump (FP) rate during recirculation.	ml/min†	10†	0†	200†	40 ml/min†
31	Recirculation BP	Blood pump (BP) rate during recirculation.	ml/min	10	0	600	320 ml/min

† In recirculation, this pump does not run unless the Recirculation BP (System Setting 31) is also greater than zero.

Table 9-1: System Setting Parameters

Parameter: No.	Name	Description	Units	Resolution	Range: Low	High	Default Value
32	WBP Alarm Limit	Waste bag pressure (WBP) alarm limit.	mmHg	1	100	450	250 mmHg
33	Cartridge Life Timeout	Cartridge life maximum in hours.	hrs	1	1	72	72 hrs
34	Cartridge Max. Volume	Cartridge life maximum in volume.	L	4	100	864	864 L
35	Dimming Timer	Delay before display is dimmed. (If set to **0**, dimming feature is disabled.)	min	1	0	60	0 min
36	Dimmed Caution Intensity	Sets display intensity during caution condition, if dimming feature is enabled and timer exceeded.	selector	1	0	15	15 selector
37	Dimmed Intensity	Sets display intensity during normal condition, if dimming feature is enabled and timer exceeded.	selector	1	0	15	15 selector
38	Remove Rinseback Volume	**0** = Rinseback volume not removed prior to weight to remove decrementing **1** = Rinseback volume removed prior to weight to remove decrementing.	selector	1	0	1	1 selector

Table 9-1: System Setting Parameters

Parameter: No.	Name	Description	Units	Resolution	Range: Low	High	Default Value
39	Venous Pressure Decreasing/ Low Alarm Delay	Time delay for low venous pressure to alarm.	sec	0.1	0.1	8.0	5.0 sec
40	Effluent Pressure Decreasing Alarm Delay	Time delay for low effluent pressure to alarm.	sec	0.1	0.1	8.0	5.0 sec
41	TMP and VP High Alarm Delay	Time delay for high venous pressure (VP) or transmembrane pressure (TMP) to alarm.	sec	0.1	0.1	3.0	2.0 sec
42	Therapy Target Met	Notifies user that target volume has been achieved.	selector	1	0	1	1 selector
43	Volumetric Fluid Management System Check Interval	Time between VFMS checks.	min	1	15	60	30 min

NOTE

The first VFMS check of a treatment is performed at an interval defined by System Setting 63. Timing of subsequent VFMS checks is determined by this System Setting.

Table 9-1: System Setting Parameters

Parameter: No.	Name	Description	Units	Resolution	Range: Low	High	Default Value
44	Alternate UF Units	**0** = Ultrafiltration (UF) units expressed as L/hr; weight to remove expressed as 0.1 L. **1** = Ultrafiltration (UF) units expressed as ml/hr; weight to remove expressed as 0.01 L.	selector	1	0	1	0 selector
45	Effluent Pressure Decreasing Caution Offset	Sets a low pressure limit below the stabilized pressure following a pump rate change. Indicates the amount pressure can drop before an effluent pressure decreasing caution becomes active.	mmHg	10	10	200	80 mmHg
46	Effluent Pressure Decreasing Caution Delay	Time delay for the effluent pressure decreasing caution.	sec	0.1	0.1	8.0	5.0 sec
47	Access Pressure Decreasing Caution Limit	Sets the access pressure decreasing caution point.	mmHg	10	100[1] 50[2]	400	220 mmHg
48	Access Pressure Decreasing Caution Delay	Time delay for the access pressure decreasing caution.	sec	0.1	0.1	8.0	5.0 sec

1 For software versions below 4.6
2 For software versions 4.6 and higher

Table 9-1: System Setting Parameters

Parameter: No.	Name	Description	Units	Resolution	Range: Low	High	Default Value
49	Dialyzer Pressure Drop Increasing Caution Offset	Sets a pressure limit above the stabilized dialyzer pressure following a pump rate change. Indicates the amount of increase of dialyzer pressure before a caution occurs.	mmHg	10	50	500	150 mmHg
50	Dialyzer Pressure Drop Increasing Caution Delay	Time delay for the dialyzer pressure drop increasing caution.	sec	0.1	0.1	8.0	5.0 sec
51	Dialyzer Clotting Detection Pressure High Alarm Limit	Sets the dialyzer pressure high alarm point.	mmHg	10	400	900	800 mmHg[1] 600 mmHg[2]
52	Dialyzer Clotting Detection Pressure High Alarm Delay	Time delay for the dialyzer pressure high alarm.	sec	0.1	0.1	5.0	3.0 sec
53	Access Pressure in Use	**0** = Do not use access pressure sensor, even if equipped. **1** = Use access pressure sensor (must be equipped).	selector	1	0	1	1 selector

1 For software versions below 4.6
2 For software versions 4.6 and higher

Table 9-1: System Setting Parameters

Parameter: No.	Name	Description	Units	Resolution	Range: Low	High	Default Value
54	Dialyzer Pressure in Use	**0** = Do not use dialyzer pressure sensor, even if equipped. **1** = Use dialyzer pressure sensor (must be equipped).	selector	1	0	1	0 selector
55	Pump Status Indication	**0** = Do not indicate pump on/off status. **1** = After Alarms Test, right most decimal point of corresponding display is lit when pump is on.	selector	1	0	1	1 selector
56	Access Pressure Decreasing Alarm in Use	Enables access pressure alarm functionality if set to **1**.	selector	1	0	1	1 selector
57	Access Pressure Decreasing Alarm Limit	Access pressure exceeded alarm threshold. Alarm will sound if access pressure is less than -1 times this threshold.	mmHg	10	100[1] 50[2]	400	300 mmHg
58	Access Pressure Decreasing Alarm Delay	Time delay for access pressure decreasing alarm.	sec	0.1	0.1	8.0	3.0 sec

1 For software versions below 4.6
2 For software versions 4.6 and higher

Table 9-1: System Setting Parameters

Parameter: No.	Name	Description	Units	Resolution	Range: Low	High	Default Value
59	Venous Pressure Approaching High Alarm Limit Caution Offset	Venous pressure approaching high caution becomes active if the VP rises to within this offset from the venous pressure high alarm limit.	mmHg	10	0	90	0 mmHg
60	Venous Pressure Approaching High Alarm Limit Caution Delay	Time delay for the venous pressure approaching high caution.	sec	1	0.0	10.0	3.0 sec
61	Venous Pressure Decreasing Caution Offset	Sets a low pressure limit below the stabilized pressure following a pump rate change. Indicates the amount the pressure can drop before a VP decreasing caution becomes active.	mmHg	10	10	100	40 mmHg
62	Venous Pressure Decreasing Caution Delay	Time delay for the venous pressure decreasing caution.	sec	0.1	0.1	8.0	5.0 sec
63	First Volumetric Fluid Management System (VFMS) Check Interval	Time into treatment to perform the first VFMS check. Timing of subsequent VFMS Checks is determined by System Setting 43.	min	5	5	60	15 min

Table 9-1: System Setting Parameters

Parameter: No.	Name	Description	Units	Resolution	Range: Low	High	Default Value
64	Air Removal Required	**1** = Prompts user to remove air from dialyzer. **0** = No additional user prompt is displayed.	selector	1	0	1	0 selector
65	Recirculation Ultrafiltration Rate	Ultrafiltration pump (UFP) rate during recirculation.	ml/min	10†	0†	200†	40 ml/min†
66	Venous Pressure Increasing Caution Offset	Sets a high pressure limit above the stabilized pressure following a pump rate change. Indicates the amount pressure can increase before a VP increasing caution becomes active.	mmHg	10	20	380	60 mmHg
67	Venous Pressure Increasing Caution Delay	Time delay for the venous pressure increasing caution.	sec	0.1	0.1	8.0	5.0 sec
68	Prime Venous Line BP	Blood pump (BP) rate when priming the venous line (Alarms Tests only).	ml/min	10	200[1,2] 10[3]	600	360 ml/min

1 For software versions below 4.6
2 For software versions 4.6
3 For software versions 4.7 and higher
† In recirculation, this pump does not run unless the Recirculation BP (System Setting 31) is also greater than zero (**0**).

Table 9-1: System Setting Parameters

Parameter: No.	Name	Description	Units	Resolution	Range: Low	High	Default Value
69	Venous Pressure High Test BP	Blood pump (BP) rate when conducting the venous pressure test (Alarms Tests only).	ml/min	10	200	600	600 ml/min
70	Max Fluid Volume for End of Treatment	Allowable variation of dialysate to reach end of treatment.	L	0.1	0	1.5	1.0 L
71	Minimum BP for Enabling the Access Pod Caution	Minimum blood pump (BP) rate at which the access pressure pod caution will be enabled.	ml/min	10	50[1] 10[2]	200	100 ml/min
72	Blood Set Volume[2]	The blood volume of the cartridge without the dialyzer (see System Setting 12 for dialyzer volume).	ml	1[2]	40[2]	200[2]	100 ml[2]
73	TMPa Alarm[2]	Enables TMPa pressure alarm functionality if set to **1**.	selector	1[2]	0[2]	1[2]	0[2] selector
74	Blood Pump (BP) Rate for BLD Normalization[2]	Blood pump (BP) rate in Step 19 of Prime.	ml/min	10[2]	10[2]	300[2]	20 ml/min[2]

1 For software versions below 4.6
2 For software versions 4.6 and higher

Table 9-1: System Setting Parameters

Parameter: No.	Name	Description	Units	Resolution	Range: Low	High	Default Value
75	FP Rate Maximum[1]	Fluid pump (FP) rate maximum.	L/hr	6.0	12.0	12.0 18.0[2]	12.0 L/hr
76	Target Volume Mute Span[1]	**0**: Caution 5 is a one-time message, pressing the **MUTE** key after Caution 5 is issued will permanently mute it. **1-15**: The number of minutes of mute duration for Caution 5. When Caution 5 has been issued, if the **MUTE** key is pressed, and if after this specified number of minutes the condition is still not corrected, Caution 5 will be re-issued.	selector	N/A	0	15	0 selector

1 For software version 4.8 and higher
2 For NX1000-3 or NX1000-4 with Cartridge Type set to 13

Table 9-1: System Setting Parameters

Parameter: No.	Name	Description	Units	Resolution	Range: Low	High	Default Value
77	Volume Display Timeout[1]	Volume toggle timeout duration is specified by this in unit of seconds. Volume display replaces rate display for this duration after **VOLUME** key is pressed.	sec	10	10	180	60 sec
78	Enable BP Occlusion Alarm[1]	**0** = Suppress BP Occlusion Alarm 62. **1**= Enable BP Occlusion Alarm 62.	selector	1	0	1	1 selector
79	Enable RF Low Temperature Warning[1]	**0** = Disable RF low temperature monitoring. Will not issue Caution 53, but will issue Caution 54 (Low Temp Warning Disabled) on power up. **1** = Enable RF low temperature monitoring and issuing Caution 53 depending on RF low temperature monitoring results.	selector	1	0	1	1 selector
1 Only applies to software version 4.9 and higher							

This page intentionally left blank.

Chapter 10 Conversion Tables and Formulas

The conversion tables are tables that help you understand the conversion of one measurement to another, for example, from degree Fahrenheit (°F) to degree centigrade (°C). Endotoxin and dosing formulas are formulas that help the nurse practitioner to determine the level of exposure to endotoxins an if the dialysis dose for daily treatment is sufficient.

Volume and Rates for Water

1 milliliter (ml)	=	1 cubic centimeter (cc)
1 cubic centimeter (cc)	=	1 gram (g)
1000 milliliters (ml)	=	1 liter (L)
1000 grams (g)	=	1 kilogram (kg)
1 liter (L)	=	1 kilogram (kg)
1000 cubic centimeters/hour (cc/hr)	=	17 milliliters/minute (ml/min)
1 liter/hour (L/hr)	=	17 milliliters/minute (ml/min)
1 kilogram	=	2.2 pounds (lb)

Temperature

°F . . . . . (9/5 * °C) + 32
°C . . . . . 5/9 * (°F - 32)
Example . . . . . .37°C = 98.6° F

Weight, Molarity, and Valency

Substance	Milligrams	mmol	mEq
Na^+	23	1	1
K^+	39	1	1
Ca^{2+}	40	1	2
Mg^{2+}	24	1	2
Cl^-	35	1	1
HCO_3^- (bicarbonate)	61	1	1
$C_3H_5O_3^-$ (lactate)	89	1	1
$C_6H_5O_7^{3-}$ (citrate)	189	1	3

Endotoxin

Toxins are released by microorganisms (specifically gram-negative bacteria) when they break down or die. These toxins can cause serious illness and pyrogenic reactions upon patient exposure. Always calculate the maximum potential patient endotoxin exposure for prescribed sterile intravenous (IV) prescription fluids at the prescribed prescription fluid flow rates.

- Potential exposure/hr =
  Prescribed prescription fluid flow rate (ml/min) * endotoxin specification of prescription fluid (EU/ml) * 60 min/hr
- USP exposure threshold/hr = 5 EU * patient body weight (kg)

If potential endotoxin exposure exceeds the US Pharmacopoeia (USP) exposure threshold or is unknown, use endotoxin-reducing IV filters. Commercially available IV fluids (such as Lactated Ringers or 0.9% Saline) labeled as “nonpyrogenic” may contain endotoxins up to a USP specification level. Contact your pharmacist for additional information.

Dosing (Kt/V)

Daugirdas formula (K-DOQI recommended):

spKt/V = -Ln (R-0.008 * t) + (4-3.5*R) * UF/W

where:

R = post-BUN/pre-BUN

t = time in minutes

UF = excess fluid volume removed during the treatment

W = post dialysis weight

Chapter 11 Clinical study summary

A clinical study was done to support the daily use of hemodialysis in the home. This is the summary of the clinical study.

Introduction

From February 2004 through November 2004, a study was conducted to determine whether or not delivery of hemodialysis with the NxStage System One in the home and in-center environments is equivalent on a per treatment basis. This study was performed to support an explicit home indication for hemodialysis with or without ultrafiltration. The NxStage System One has not been clinically evaluated for isolated ultrafiltration in the home setting.

This was a prospective, multi-center, two-treatment, two-period, open-label, cross-over study conducted at 6 centers, using daily hemodialysis. For the purpose of this study, daily hemodialysis was defined by a frequency of six dialysis treatments per week lasting under 3.5 hours each. The first phase (In-Center) consisted of 48 treatments (six per week, in an eight week period) performed in the dialysis center. The second phase (Home) consisted of the same number of treatments, also performed over an eight-week period at the same frequency in the subject's home setting. Between the two phases, a two-week wash-out/run-in period (Transition Phase) occurred primarily in the home. Subjects had physical examinations at enrollment, the end of the In-Center Treatment phase and at the end of the Home phase. Subjects were evaluated on a routine basis via clinical laboratory testing and adverse event monitoring.

Thirty-two patients were enrolled and 25 patients completed the study. The reasons for study discontinuation were investigator judgment (2), patient request (4), and transplant (1). No subjects discontinued therapy due to death or adverse event. At the end of the formal clinical trial, most patients continued to use the NxStage System One at home on a simplified protocol (the "Extension Study").

Overall, the mean subject age was 51 years and ranged from 18 to 71 years. Sixty-three percent of the subjects were male. Seventy-five percent of the subjects were white, and nineteen percent were black/African-American. The primary etiology for renal disease was well distributed within the following classifications: diabetes, hypertension, glomerulonephritis, polycystic disease, and other.

During the formal clinical trial, approximately 2,200 treatments were administered, of which over 1,000 were at home. As of February 2005, after formal study completion, there had been over 4,600 dialysis treatments with patients who participated in the study, of which nearly 3,200 were done at home.

Criteria for Evaluation

The primary efficacy endpoint was the ability to deliver the clinically prescribed amount of therapy. The total effluent (spent dialysate plus net ultrafiltrate) volume produced during each treatment was electronically recorded and compared to the prescribed fluid volume, the latter of which was based on a clinically accepted urea kinetic modeling approach. Successful therapy delivery was defined by attainment of a delivered volume that was at least 90% of the prescribed volume.

The primary safety endpoint was the composite of intradialytic and interdialytic adverse event profiles.

The following secondary endpoints were also evaluated:

- Delivered single-pool urea Kt/V per treatment
- Kidney Disease Quality of Life (KDQoL) Short Form
- Successful completion of the training program by the subject and the subject's partner
- Clinical utility (defined as usability) of the NxStage System One
- Ultrafiltration: ability to achieve target net ultrafiltration volume per treatment

Results

Primary efficacy endpoint

Successful therapy delivery was 98.5% In-Center and 97.3% In-Home (p=0.0678). Neither the effect of the treatment period (center vs. home) nor study week was determined to be significant.

Primary safety endpoint

Adverse events were categorized during analysis as anticipated treatment observations (ATO), adverse events (AE), and unanticipated adverse device effects (UADE), and device issues. Event rates are summarized in the following table. (Event rate is per 100 hemodialysis treatments.)

Category	In Center (n=32)	Transition (n=27)	Home (n=27)
All anticipated treatment observations (ATO)			
Number of subjects (%) with at least one ATO	30 (93.75)	14 (51.85)	19 (70.37)
Number of reports	379	66	202
Event rate	26.45	20.89	16.93
All AEs			
Number of subjects (%) with at least one AE	24 (75)	4 (14.8)	13 (48.1)
Number of reports	76	6	25
Event rate	5.30	1.90	2.10
All unanticipated adverse device effects (UADE)			
Number of subjects (%) with at least one UADE	1 (3)	0 (0)	0 (0)
Number of reports	1	0	0
Event rate	0.07	0	0
Device issues (any problem)			
Number of subjects (%) with at least one device issue	27 (85)	12 (44)	21 (78)
Number of reports	109	24	68
Event rate	7.61	7.59	5.70

More ATOs were reported In-Center compared to in the Home. The ATO event rate in the In-Center environment was 35% higher than that in the home, although this difference was not statistically significant. The difference in event rates (In-Center minus Home, per 100 treatments) was 7.06 (95% CI: -1.32 to 15.43). The most common ATOs experienced by subjects during both the In-Center and Home treatment phases were muscle cramping and hypotension. ATOs with event rates greater than 1.0 per 100 hemodialysis treatments occurring during the In-Center treatment phase were blood under-heating, muscle cramping, hypotension, headache, dizziness, and fatigue and during the Home treatment phase were muscle cramping, hypotension, blood under-heating, and fatigue.

The AE event rate during the In-Center treatment phase (5.31) was statistically significantly higher than the AE event rate during the Home treatment phase (2.14) (p=0.0070). The most common AEs occurring in greater than 5% of subjects during In-Center treatment were dysgeusia, back pain, dizziness, sinusitis, arthralgia, night cramps, neck pain, and tremor; and the most common adverse events during In-Home treatment were arthralgia, night cramps and nausea. A statistically significantly higher rate of infections and infestations was observed for the In-Center treatment phase compared to the Home treatment phase.

One UADE, a plastic taste in mouth, was reported during the study. This was later independently adjudicated as dysgeusia and did not meet the definition of a UADE. This event was further classified as mild in severity, therapy-related, seemed to be quite transient and not associated with any serious or lasting consequences. The full analysis was provided to the FDA during the study.

The rate of device issues were not statistically different between the In-Center and Home treatment phases. The most common device issues were repeated unresolved alarms and operator error.

There were no clinically meaningful findings or patterns in clinical laboratory data, vital signs, physical examinations, or concomitant medications.

Secondary endpoints

The delivered single pool Kt/V per treatment was not different between the In-Center and Home treatment phases. The estimated mean In-Center Kt/V value was 0.5365 and the estimated mean Home Kt/V value was 0.5413 (p=0.6251).

There were no significant differences noted between the two treatment environments on the KDQoL Short Form for any of the items surveyed.

With respect to the training program, the mean number of days required to complete training for the study subjects was 14.5 (+9.21) and the mean number of days required to complete training for the subject's partners was 11.6 (+9.15). The mean number of times the examination was taken by study subjects was 1.1 (+0.38) and 1.1 (+0.27) for the partners.

Clinical utility was measured by the number and frequency of device alarms, the time taken to respond to the alarms, and the duration of treatment. The number of device alarms per treatment was 2.19 in-center vs. 2.10 in the home (difference was not significant). The time taken to respond to each alarm was not statistically different between the two environments. Treatment time, at 2.8 + 0.58 hours in center vs 2.8 + 0.61 at home, was also not significantly different between the two environments.

The planned analysis of UF volumes was not considered meaningful for multiple reasons. UF volumes were, however, included in the calculation of the primary efficacy endpoint.

Conclusions

Overall, hemodialysis with the NxStage System One in the Home and In-Center were found to be equivalent on a per treatment basis as demonstrated by the ability of the NxStage System One to deliver at least 90% of the prescribed volume. The mean single-pool urea Kt/V values were also similar across the eight weeks of study treatment in each environment. Additionally, there were no significant differences noted in the parameters surveyed on the KDQoL Short Form between the two environments.

The AE profiles were similar between hemodialysis treatment in the two environments. The nature and types of AEs reported are commonly seen with hemodialysis treatment. The incidence rate of anticipated treatment observations and device issues was also similar between the environments.

This page intentionally left blank.

Chapter 12 Warnings and Precautions

Read all the warnings and precautions before beginning your treatment with the NxStage System One. Do not use the NxStage System One without reading and understanding all warnings and precautions in the user guide.

Warnings

A warning is a statement that alerts you to the possibility of serious injury, other adverse reactions, or death associated with the use or misuse of the device.

WARNINGS

1. All NxStage equipment and disposables must be used as described in the applicable User Guides and Instructions for Use, and in accordance with a physician's prescription. Make sure that all User Guides are carefully read and understood, and are always available to the operator at the treatment location. Improper use may cause injury or death.
2. Treatment with the NxStage System One should only be done under the responsibility of a physician and performed by a trained and qualified person. A trained and qualified person must observe all treatments so that alarms and harmful conditions can be responded to promptly. Possible harmful conditions include, but are not limited to venous disconnects, inadvertent fluid administration, or excessive ultrafiltration. A patient should not dialyze alone, even if they are trained and qualified.
3. Always follow universal precautions when operating the NxStage System One, cleaning or disinfecting equipment, or observing patient treatment, to avoid infection.

4. Weigh the patient before treatment to make sure that the appropriate ultrafiltration volume is calculated. Follow the physician's prescription for maximum volume and rate of fluid to be removed. Removing too much or too little fluid, or removing fluid too quickly, may cause patient injury. In addition, prescribing physicians should be aware that certain patients, such as low weight patients and patients at or near their dry weight, may be unable to tolerate fluid balance variations in amounts less than the total fluid accuracy tolerances of the NxStage System One Cycler and other ancillary fluid delivery devices. These patients must be closely monitored for signs and symptoms of excessive ultrafiltration or fluid overload. Refer to the System One User Guide for additional information on ultrafiltration during dialysis.
5. Hemodialysis may result in significant changes in the blood concentration of electrolytes and glucose and in the patient's volume status. Appropriate monitoring of the patient's hemodynamic, fluid, electrolyte, and acid-base balance should be performed regularly, per physician orders, to ensure appropriate response to therapy. Failure to do so could result in inappropriate therapy for the patient.
6. The Dialyzer may remove medications given into the Arterial Patient Line (red clamp). Refer to the medication manufacturer's labeling for clearance characteristics of any medications given into the Arterial Patient Line (red clamp). Follow the policies and procedures of your center for infusing fluid or medications into the blood circuit. Infusing fluids or medication incorrectly may reduce the dose given to the patient or cause harm to the patient.
7. When a heart rate monitor is used during treatment, the NxStage System One Cycler's pumps may produce electrostatic discharges that may appear as artifacts on the monitor's screen. The electrostatic discharges produced by the Cycler will not harm the patient. Look at the monitor's screen when the Cycler's pumps are running and when they are stopped to confirm it is the Cycler that is producing these artifacts.
8. Observe the patient for allergic reactions, especially if the patient has a history of allergies. If the patient has an adverse reaction, stop the treatment and follow your center's instructions.
9. If you are using a Cartridge without a pre-attached Dialyzer, make sure that the Dialyzer you select has a maximum transmembrane pressure (TMP) of at least 500 mmHg or higher. Use of a Dialyzer with a lesser TMP rating increases the risk of a blood leak. NxStage defines TMP as the difference between venous pressure and effluent pressure. Follow the Dialyzer manufacturer's instructions for use for TMP rating.

10. Do not use any supplies after their expiration date or Use-by Date, or the supplies may not perform as intended.
11. Manual fluid boluses and fluid consumed during treatment are not included in the System One fluid balance calculations. Excessive fluid boluses, whether intentional or unintentional, or failure to account for consumed fluid during treatment, may cause patient injury. Include fluid boluses and the volume of fluid consumed in manual fluid balance calculations. Make sure that the administration lines used for manual bolus or rinseback are clamped after use.
12. Extreme high or low fluid temperatures may cause injury or death. The NxStage System One Cycler checks for high and low dialysate temperature during normal operation. The temperature of rinseback and manual bolus fluids is not monitored at all. At dialysate rates lower than 5 L/hr, low fluid temperatures are more likely to occur. If System Setting #79 is set to 0 or the Cycler software version is less than 4.9, low temperature monitoring is disabled at all times. In instances of low fluid temperatures, the patient may feel discomfort, which may include but is not limited to shivering. Sedated or comatose patients should be watched carefully when fluid temperature is not monitored.
13. The NxStage System One disposables are for single use only unless otherwise indicated. Do not reuse or resterilize. Materials used to make the disposables may not withstand reprocessing or reuse or both. Reuse or resterilization of the disposables may result in, but is not limited to, the following problems:
    - risk of cross contamination
    - material degradation
    - biocompatibility issues
    - endotoxin reactions
    - failure of the disposable to perform as intended.

14. The NxStage System One Cycler will automatically remove the rinseback volume when both the System Setting #38 is set to 1 and the Ultrafiltration pump rate (UFR) is greater than 0. Automatic removal of the rinseback volume is not displayed to the operator. Therefore it is important to account for the rinseback volume when calculating the ultrafiltration rate and volume for the treatment. Do not add the rinseback volume to the targeted ultrafiltration volume when the Cycler is set to automatically remove the rinseback volume or excess ultrafiltration will result. For patients that may be unable to tolerate even small fluid balance changes, such as low weight patients and patients at or near their dry weight, the excess ultrafiltration may result in hypotension or hypovolemia which may cause patient injury or death. When automatic removal of the rinseback volume is not desired, System Setting #38 should be set to 0.
15. In order to avoid electric shock, patients with a central venous catheter must not touch or be in contact with any AC powered electric devices during their treatment. Examples include but are not limited to, electric blankets or heating pads, electric lamps or lights, computers that are plugged into an electrical outlet, and electric powered chairs.
16. Physicians must ensure that central venous catheters are not placed in the right atrium. The risk of microshock to the patient resulting in fibrillation is increased when the tip of a central venous catheter placed in the right atrium touches the atrium wall during use of the NxStage System One.
17. Caution should be taken with babies and young children around the System One and PureFlow SL. The disposable lines or bags pose a strangulation hazard. The disposables also contain small parts that pose a choking hazard if swallowed.
18. The NxStage System One contains alarms that may be configured by the operator. The operator should check that the current alarm settings are correct for the patient. Incorrect settings may cause injury or death.
19. Use only physiologic fluids prescribed by a physician with the NxStage System One. Fluids must meet the requirements of local regulations, standards, or laws. Refer to fluid labeling for complete instructions. Fluids for hemofiltration, priming, bolus, and rinseback must be indicated for infusion. Dialysate fluids must be used for hemodialysis. The use of incorrect fluids may cause patient injury or death.

20. Do not use any fluid delivery devices that have a post-pump drip chamber or a maximum output pressure of less than 600 mmHg. Using these devices may cause blood loss, undesired fluid delivery, inaccurate flows, leaks, and other failure of the fluid delivery device to perform its intended function.
21. Do not connect to the accessory electrical outlet on the back of the Cycler any electrical items that are not specified as part of, or approved for use with, the NxStage System One Cycler. Unapproved or incompatible electrical items can create an electrical hazard.
22. Make sure only compatible devices are used with the NxStage equipment. Non-compatible devices may not perform as intended.
23. When using pharmacy-compounded fluids, the physician should make sure that the potential exposure to endotoxins does not exceed the USP/EP guideline levels for the prescribed therapy. If you are not sure, consult a pharmacist. If the potential exposure exceeds the guideline levels, use endotoxin-reducing IV filters with a working pressure higher than 15 psi. Using an IV filter with a working pressure lower than 15 psi may increase the risk of IV filter failure and may lead to a pyrogenic reaction. Refer to the *NxStage System One User Guid*e for tables and conversions for endotoxins.
24. Physicians should take extra care when prescribing dialysate for patients with an increased level or an impaired metabolism of lactate ions, as in severe hepatic insufficiency.
25. A trained person must install and test the NxStage System One. Improper installation and testing could lead to malfunction or damage, which may cause patient injury or death.
26. Unless specifically recommended by NxStage, non-medical electrical equipment should not be used within 1.8 meters (6 feet) of the System One. Use of such equipment may affect patient safety.
27. Do not use NxStage equipment in the presence of a Flammable Anesthetic Mixture with Air, a Flammable Anesthetic Mixture with Oxygen, or a Flammable Anesthetic Mixture with Nitrous Oxide or in an oxygen-enriched or explosive atmosphere.
28. To avoid injury, the NxStage System One Cycler must be plugged into a properly grounded outlet, except for Cyclers with the model number NX1000-4. Ask a qualified electrician to check your outlet if you are not sure that it is properly grounded. Cyclers with the model number NX1000-4 do not require a grounded outlet for their safe operation; the model number is located at the rear of the Cycler.

29. Use only routers, switches, or other data networking equipment that comply with IEC 60950 if they are used to connect the computer on the back of the NxStage System One Cycler to a wired-data network. The use of equipment that does not comply with IEC 60950 may result in electric shock to the patient or operator.
30. Do not connect printers or other equipment to the computer on the back of the NxStage System One Cycler to reduce the risk of electrical shock to the patient or operator. USB thumb drives or USB connections from the PureFlow SL are the only devices than can be connected to the computer on the back of the Cycler.
31. The NxStage System One Cycler weighs approximately 34 kilograms (75 pounds). To avoid injury, two people must lift and carry the Cycler. Close and lock the door of the Cycler before lifting and carrying it. Do not lift and carry the Cycler by the door handle. Use the grip points under the Cycler or the handles included on some models.
32. Make sure that the NxStage System One Cycler and its ancillaries are attached securely to its mobile stand or placed on a table sturdy enough to hold the weight of the Cycler, its ancillaries, and fluid bags. Check the bolts on the mobile stand regularly to make sure that they are fastened securely, especially before moving the Cycler. If the bolts are not fastened securely, the Cycler, its ancillaries, or the fluid bags may fall and cause injury.
33. Use only the power cords supplied by NxStage or its authorized distributors. Do not connect portable multiple-socket outlets or extension cords to any NxStage equipment. Non-authorized or incompatible electrical power cords and outlets can create an electrical hazard.
34. Always visually inspect the package and product before use. Do not use any disposables if the package is open, damaged, or if any of the connector's protective caps are loose, disconnected, or missing. These disposables may no longer be sterile and may cause patient infection.
35. Do not touch surfaces of any disposable covered by protective caps. This includes connectors and needleless access sites. Always use aseptic technique when handling connections. Touching these surfaces may make them non-sterile, which may cause patient infection.

36. Do not use excessively cold dialysate. Under certain conditions, including but not limited to patient weight, dialysate flow rates and treatment durations, some patients may develop hypothermia when exposed to excessively cold dialysate.
37. Do not use a knife or other sharp instrument to open any shipping carton or case containing disposables because it may cut or damage the contents. Do not use any disposables from a shipping carton or case that has been opened with a knife or other sharp instrument. Damage to disposables may cause blood or air leaks, causing patient injury or death.
38. Do not use ultrasound gel, or any gel-like substances around the air detectors. These substances may prevent the detection of air in the blood lines. If air cannot be detected it may cause an air embolism in the patient.
39. The maximum fluid volume for transporting the NxStage System One Cycler using the mobile base with the ComfortMate Fluid Warmer is 10 liters of fluid. Do not transport the Cycler with fluid using the mobile base if using the Express Fluid Warmer. The maximum fluid volume for stationary use of the Cycler with an IV pole is 29 liters of fluid when using the ComfortMate Fluid Warmer or 21 liters of fluid when using the Express Fluid Warmer. Fluid volume must not be exceeded and fluid must be evenly distributed on the IV pole to prevent accidental tipping of the Cycler.
40. Do not attach ancillary devices that can restrict blood flow, such as stopcocks, to the patient lines. Restrictions in the blood circuit can cause hemolysis.
41. Do not use a Cartridge with kinked blood lines. Always inspect the blood lines for kinks before and during use, particularly around Dialyzer connections. Kinked blood lines may cause hemolysis.

42. The risk of blood clotting in the Cartridge and Dialyzer is higher during long treatments, when no anticoagulation is used, in certain patients who are more prone to excess clotting, or any time when the blood flow stops, including when the NxStage System One Cycler loses power or during an unrecoverable alarm. The risk of blood clotting increases the longer treatment continues and the longer blood flow is stopped. To reduce the risk of blood clotting and identify the early signs of clotting:
    - Follow your center's instructions to give and monitor anticoagulant.
    - During treatment, regularly check the Cartridge and Dialyzer for clotting by looking closely at the Cartridge and Dialyzer, and periodically flushing the Dialyzer with a manual fluid bolus.

    Failure to respond to blood clotting in the Cartridge and Dialyzer may result in a blood clot being released into the patient's bloodstream and causing a blockage (thromboembolism). Failure to respond to clotting may also lead to sustained high pressures in the blood circuit and cause a dialyzer blood leak or hemolysis. These conditions may cause serious injury or death if not responded to promptly and appropriately. Regularly check the Dialyzer for any evidence of a leak. Do not return the blood if the blood flow is stopped for a long time. Discard the Cartridge and Dialyzer if they are clotted.
43. To avoid injury when closing the Cycler door, make sure to keep fingers and other body parts away from the door opening.
44. Only spike the saline bag after loading the Cartridge and closing the door of the NxStage System One Cycler. Failure to do so may cause Cartridge leaks or a misalignment of the Cartridge, resulting in compromised treatment, injury, or death.
45. Never connect the patient to the Cartridge before you see the treatment parameters in the NxStage System One Cycler's window, which indicates that the Prime and Alarms Test is completed. Some safety systems are not active during the Prime and Alarms Test. Connecting the patient at any time before completion of the Prime and Alarms Test may cause serious injury or death.
46. Do not tap the Dialyzer against a hard surface, such as the NxStage System One Cycler. This may damage the Dialyzer and may cause a blood or fluid leak, causing patient injury or death.
47. The Cartridge has multiple connection points. Failure to make the proper connections may cause compromised treatment, blood loss, injury or death. Make sure mated luer-connectors are secure but do not over-tighten, especially when connections are wet.

48. Manually prime any administration “T”s and ports, if present, even if they are not used, to prevent air from entering the patient blood lines. Secure caps and close clamps after priming, and after each use to prevent blood loss or air entering the patient blood lines.
49. Do not adjust the vascular access while the Blood Pump is running. Adjusting the vascular access while the Blood Pump is running increases the likelihood of needle dislodgement, which may result in a significant blood loss.
50. Never try to open the door of the NxStage System One Cycler when the door lock symbol is on. If the door is opened by force, all safety systems will no longer be active, which may cause patient injury or death. If the door must be opened while the patient is connected, press the STOP key, immediately clamp all fluid and blood lines, turn the power switch OFF on the Cycler, and then open the door of the Cycler.
51. When a Yellow Caution is displayed, some safety systems may not be active. Monitor the system and the patient until the Green Safe Operating condition returns. Failure to do so may cause patient injury or death.
52. Before starting treatment, check the patient blood lines for air. Check again before and during rinseback. Follow the instructions to remove air before starting treatment or rinseback. Failure to remove air from the patient blood lines may cause an infusion of air, which may lead to an embolism.
53. Do not disconnect and reverse patient blood lines during treatment. This may cause an infusion of air into the patient blood lines, which may lead to an embolism.

54. The NxStage System One Cycler may not detect slow fluid or blood leaks from loose connections, faulty components, venous access disconnection, vascular needle dislodgement, or other potential causes. Leaking fluids may cause blood loss, injury, or death. Leaking fluids on the floor may also cause a person to slip or fall.

    To reduce the risk of fluid or blood leaks, or accidental disconnections:

    - Keep vascular access sites and all Cartridge connections visible throughout the treatment. Do not cover sites or connections with a blanket, or clothing, or any objects that block the view of the site and connections.
    - Before starting treatment, make sure all manual connections are secure and fluid-tight, but not over-tight.
    - A trained and qualified observer must check the system for blood and fluid leaks during treatment and pay close attention to the blood line and access connections, especially when the patient is connected and disconnected. If any leaks are found and cannot be stopped, end the treatment and rinse back the patient's blood, unless the center gives instructions not to rinse back. Do not rinse back the patient’s blood if there are clots or air in the blood circuit or in the patient blood lines. Do not rinse back if the blood is hemolyzed.
    - Before connecting the patient, make sure that there is no blood or other lubricious fluid on the Cartridge connectors and mating connectors, such as on vascular access devices. Lubricious fluids, including but not limited to blood, silicone oil, and povidone iodine-based disinfectants on mated luer-connections may significantly increase the chance of accidental disconnections.
    - Strictly follow the center’s procedure for taping the blood lines and access device connections to the patient. Check all connections and secure taping again, if necessary, when the patient changes position, when changing the dressing of the catheter, or if there is stress on the Cartridge tubing or blood access device.
    - Use only Dialyzers, catheters or AVF needles, and other devices that have locking connectors in compliance with ISO 594 parts 1 and 2 and ISO 8638 when connected to the Cartridge. With repeated patient treatments, a temporary or permanent catheter’s connectors may change shape and no longer comply with ISO 594 parts 1 and 2 and become incompatible with the Cartridge. Using incompatible connectors with the Cartridge may cause blood loss, patient injury, or death. Contact the device manufacturer for all compliance questions.

55. Follow your center's instructions for rinsing back blood at the end of treatment. Blood that is left in the blood lines after rinseback will result in blood loss.
56. During a manual rinseback, do not apply excessive pressure or use devices that apply pressure on the saline bag (for example, blood pressure cuffs). The use of excessive pressure or a device that applies pressure to the saline bag may cause an infusion of air into the patient blood lines, which may lead to an embolism.
57. When performing manual rinseback, the NxStage System One Cycler door is open, which deactivates all safety systems. The operator must visually monitor for air in the patient blood lines, to prevent an infusion of air, which may lead to an embolism.
58. There are no operator or customer technician serviceable parts in any NxStage equipment. Unless otherwise instructed or authorized, NxStage or its agent must perform all maintenance and repair. No changes or modifications to any NxStage equipment are allowed without NxStage's authorization. Unauthorized changes or modifications to equipment may impact performance which may lead to patient or operator injury or death.
59. Clean and disinfect NxStage equipment in a well-ventilated environment in accordance with instructions included in this User Guide. Failure to follow these instructions increases the risk of exposure to infectious diseases and may also cause damage to the equipment.

Precautions

A precaution or caution is a statement that alerts you to the possibility of a problem with the device associated with its use or misuse. Such problems include device malfunction, device failure, damage to the device, or damage to other property.

⚠ PRECAUTIONS

1. Federal law (USA) restricts this device to sale by or on the order of a physician or properly licensed practitioner.
2. The maximum dialysate flow rate for the NxStage System One is 300 ml/min. Consider this when prescribing dialysis.
3. Do not use the Cartridge for more than 72 hours or 864 liters of blood processed.
4. The NxStage System One has only been studied for up to 4 hours of hemodialysis therapy in the home setting.
5. Do not alter any NxStage disposables. Performance of altered disposables cannot be guaranteed.
6. Store and transport NxStage disposables and equipment in accordance with applicable Instructions for Use or labeling. Failure to do so may affect performance.
7. Follow your center's instructions for steps to take in case of emergency. Each home patient should develop a personal disaster plan with their center to address the actions that they should take in the event of a natural or other disaster affecting their home such as a fire, flood or loss of electrical power.
8. In a low humidity environment, static electricity can build up and you will produce an Electrostatic Discharge (ESD) to any conductive surface, resulting in a small electric shock. The NxStage System One Cycler and its accessories have conductive surfaces. Static electricity can especially build up when removing the plastic outer wrap from the dialysate bags, therefore it is recommended that you grasp the IV Pole or saline hook to discharge any built up static electricity before hanging the bags.

9. Preventive maintenance on NxStage equipment must be performed in accordance with this User Guide or applicable Instructions for Use. When the Cycler displays a Yellow Caution 71, it is time to contact Technical Support or an authorized distributor to schedule maintenance on the Cycler.
10. After use, discard all disposables in accordance with local, national and federal regulations as instructed by your center. Use universal precautions when disposing of Cartridges.
11. The clamps included on disposables are intended to be used to allow flow when opened and stop flow when closed. They are not intended to be used to control the rate of flow.
12. It is the responsibility of the healthcare provider to make sure that the procedures to return the product are followed.
13. Make sure that premixed Dialysate is at room temperature before using. If it is not at room temperature, outgassing of air may occur as the fluid is warmed, which may cause NxStage System One Cycler air alarms.
14. When an IV filter is used during treatment, a check valve is required. Failure to put the check valve between the blood path and IV filter may damage the IV filter.
15. If too many devices are plugged into the same electrical circuit, the circuit may become overloaded. The NxStage System One Cycler does not require a dedicated electrical outlet, however, to avoid overloading the circuit, plug the Cycler into a circuit separate from other devices.
16. Inspect all NxStage System One Cycler components for damage before use. If product is damaged, follow the procedures to return the product included in this User Guide.
17. Do not alter the factory-set height of the IV pole. The height of the IV pole is important to maintain adequate fluid flow. Altering the height of the IV pole may negatively impact system performance and result in nuisance alarms.
18. Refer to Electromagnetic Compatibility (EMC) specifications in this User Guide to make sure that the equipment is being operated within these specifications.
19. Keep all equipment out of direct sunlight to prevent the device from overheating.
20. Keep children and pets away from all equipment to prevent damage that may lead to poor system performance.

21. Allow the Cycler to adjust to a room temperature between 15°C and 37°C (59°F and 99°F) for at least one hour before use.
22. Allow the Cartridge to adjust to a room temperature between 15°C and 37°C (59°F and 99°F) for at least one hour before use.
23. Use caution when handling any Disposable Set to avoid tearing and puncturing.
24. The default value for System Setting #9 is zero (0) for hemodialysis which disables the automatic bolus feature. In certain geographic areas outside of the US, additional labeling provides more information on using the NxStage System One to deliver an automatic fluid bolus.
25. If you do not pass the NxStage System One Cycler's Prime and Alarms Test, repeat the test. If you do not pass again or you do not pass the Display Tests, do not connect the patient to the Cartridge. Call Technical Support.
26. Remove accumulated air as instructed prior to making patient connections to minimize the chance of NxStage System One Cycler air alarms after making patient connections.
27. Do not disconnect any Cartridge pressure pod monitoring line from the NxStage System One Cycler after priming the Cartridge, unless directed to do so in the Troubleshooting section of this guide. Doing so may result in inaccurate pressure readings and may lead to false cautions and alarms or failure of appropriate cautions and alarms to occur.
28. Do not allow fluid or blood to contact the NxStage System One Cycler's pressure sensor connection points. If this happens, return the Cycler for service. This is a preventive measure to make sure that the pressure readings are accurate. It also eliminates the potential for cross contamination.
29. Do not reprime a Cartridge that has been used on a patient. Failure to follow the instructions for repriming a Cartridge may cause damage to the Cartridge or misloading, and may impact system performance.
30. Keep all equipment free of dust by regularly cleaning around and under the equipment. Excessive dust on equipment can lead to poor system performance.

This page intentionally left blank.

NxStage Customer Service Center (United States only)
Tel: 1-866-NXSTAGE (1-866-697-8243)
Fax: 1-978-687-4809
Email: customerservice@nxstage.com

Outside the United States, contact your healthcare provider or distributor.

CE 0413

EC REP

MEDISYSTEMS EUROPE, S.P.A.
Via G. Galilei, 20
Sorbara Di Bomporto (MO)
Italy 41030

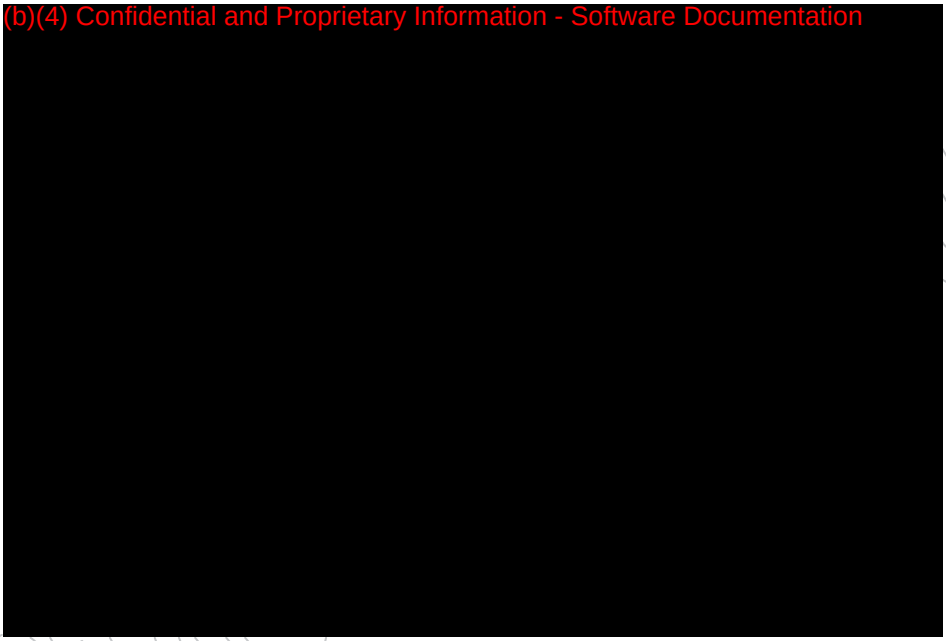
NxSTAGE® Invent. Improve. Inspire.

NxStage Medical, Inc.
350 Merrimack Street
Lawrence, MA 01843 USA

Appendix 2 – Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation



(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

(b)(4) Confidential and Proprietary Information - Software Documentation

Appendix 3 – Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

(b)(4) Confidential and Proprietary Information - Risk Management

Traditional 510(k) Premarket Notification

Appendix 4 – Clinical Study Report and Appendices

NxStage® Medical, Inc.
NxStage® System One™

NxStage Medical, Inc
350 Merrimack Street
Lawrence, MA 01843

Confidential

Appendix 4 – Clinical Study Report

(b)(4) Confidential and Proprietary Information - Clinical Study

(b)(4) Confidential and Proprietary Information - Clinical Study

(b)(4) Confidential and Proprietary Information - Clinical Study

(b)(4) Confidential and Proprietary Information - Clinical Study

(b)(4) Confidential and Proprietary Information - Clinical Study

(b)(4) Confidential and Proprietary Information - Clinical Study

(b)(4) Confidential and Proprietary Information - Clinical Study

(b)(4) Confidential and Proprietary Information - Clinical Study

(b)(4) Confidential and Proprietary Information - Clinical Study

(b)(4) Confidential and Proprietary Information - Clinical Study

(b)(4) Confidential and Proprietary Information - Clinical Study

(b)(4) Confidential and Proprietary Information - Clinical Study

(b)(4) Confidential and Proprietary Information - Clinical Study

(b)(4) Confidential and Proprietary Information - Clinical Study

(b)(4) Confidential and Proprietary Information - Clinical Study

(b)(4) Confidential and Proprietary Information - Clinical Study

(b)(4) Confidential and Proprietary Information - Clinical Study

(b)(4) Confidential and Proprietary Information - Clinical Study

(b)(4) Confidential and Proprietary Information - Clinical Study

(b)(4) Confidential and Proprietary Information - Clinical Study

(b)(4) Confidential and Proprietary Information - Clinical Study

(b)(4) Confidential and Proprietary Information - Clinical Study

(b)(4) Confidential and Proprietary Information - Clinical Study

(b)(4) Confidential and Proprietary Information - Clinical Study

(b)(4) Confidential and Proprietary Information - Clinical Study

(b)(4) Confidential and Proprietary Information - Clinical Study

(b)(4) Confidential and Proprietary Information - Clinical Study

(b)(4) Confidential and Proprietary Information - Clinical Study

(b)(4) Confidential and Proprietary Information - Clinical Study

(b)(4) Confidential and Proprietary Information - Clinical Study

(b)(4) Confidential and Proprietary Information - Clinical Study

(b)(4) Confidential and Proprietary Information - Clinical Study

(b)(4) Confidential and Proprietary Information - Clinical Study

(b)(4) Confidential and Proprietary Information - Clinical Study

(b)(4) Confidential and Proprietary Information - Clinical Study

(b)(4) Confidential and Proprietary Information - Clinical Study

(b)(4) Confidential and Proprietary Information - Clinical Study

(b)(4) Confidential and Proprietary Information - Clinical Study

(b)(4) Confidential and Proprietary Information - Clinical Study

(b)(4) Confidential and Proprietary Information - Clinical Study

(b)(4) Confidential and Proprietary Information - Clinical Study

(b)(4) Confidential and Proprietary Information - Clinical Study

(b)(4) Confidential and Proprietary Information - Clinical Study

(b)(4) Confidential and Proprietary Information - Clinical Study

(b)(4) Confidential and Proprietary Information - Clinical Study

(b)(4) Confidential and Proprietary Information - Clinical Study

(b)(4) Confidential and Proprietary Information - Clinical Study

(b)(4) Confidential and Proprietary Information - Clinical Study

(b)(4) Confidential and Proprietary Information - Clinical Study

(b)(4) Confidential and Proprietary Information - Clinical Study

(b)(4) Confidential and Proprietary Information - Clinical Study

(b)(4) Confidential and Proprietary Information - Clinical Study

(b)(4) Confidential and Proprietary Information - Clinical Study

(b)(4) Confidential and Proprietary Information - Clinical Study

(b)(4) Confidential and Proprietary Information - Clinical Study

(b)(4) Confidential and Proprietary Information - Clinical Study

(b)(4) Confidential and Proprietary Information - Clinical Study

(b)(4) Confidential and Proprietary Information - Clinical Study

(b)(4) Confidential and Proprietary Information - Clinical Study

(b)(4) Confidential and Proprietary Information - Clinical Study

(b)(4) Confidential and Proprietary Information - Clinical Study

(b)(4) Confidential and Proprietary Information - Clinical Study

(b)(4) Confidential and Proprietary Information - Clinical Study

(b)(4) Confidential and Proprietary Information - Clinical Study

(b)(4) Confidential and Proprietary Information - Clinical Study

(b)(4) Confidential and Proprietary Information - Clinical Study

(b)(4) Confidential and Proprietary Information - Clinical Study

(b)(4) Confidential and Proprietary Information - Clinical Study

(b)(4) Confidential and Proprietary Information - Clinical Study

(b)(4) Confidential and Proprietary Information - Clinical Study

Appendix A – Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

(b)(4) Confidential and Proprietary Information - Protocol

NxSTAGE

K141752 | S001

July 24, 2014

US Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center – WO66-G609
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Re: Replacement eCopy for NxStage System One RTA Hold Response for K141752

Dear Document Control Center:

The enclosed replacement eCopy is an exact duplicate of the paper copy. This PDF file contains NxStage Medical's response to address the refuse to accept (RTA) hold for the NxStage System One, 510(k) number K141752.

Thank you. If you have any questions regarding this information, please contact me directly at (978) 687-4872 or via e-mail at mstroumbos@nxstage.com.

Sincerely,

Mary Lou Stroumbos

Mary Lou Stroumbos
Director, Regulatory Affairs

31

NxSTAGE

K141752/S001

July 23, 2014

US Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center – WO66-G609
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Re: eCopy for NxStage System One RTA Hold Response for K141752

Dear Document Control Center:

The enclosed eCopy is an exact duplicate of the paper copy. This PDF file contains NxStage Medical's response to address the refuse to accept (RTA) hold for the NxStage System One, 510(k) number K141752.

Thank you. If you have any questions regarding this information, please contact me directly at (978) 687-4872 or via e-mail at mstroumbos@nxstage.com.

Sincerely,

Mary Lou Stroumbos
Director, Regulatory Affairs

22

NxSTAGE

July 23, 2014

Mr. David Pudwill
Biomedical Engineer
U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: K141752 NxStage System One– RTA Hold Response

Dear Mr. Pudwill,

This letter is in response to your RTA Hold email dated July 11, 2014. Enclosed please find the following to address your RTA Hold:

- A Revised Section 7 - 510k Summary
- A Revised Section 11 - Device Description
- A new Appendix 5 to address the deficiency questions received from the Agency for K100535.

Thank you. If you have any questions regarding this response, please contact me directly at (978) 687-4872 or via e-mail at mstroumbos@nxstage.com.

Sincerely,

Mary Lou Stroumbos

Mary Lou Stroumbos
Director, Regulatory Affairs

RTA Hold Response for K141752

NxStage® Medical, Inc.
NxStage® System One™

NxStage Medical, Inc
350 Merrimack Street
Lawrence, MA 01843

Confidential

Table of Contents

July 23, 2014

Mr. David Pudwill
Biomedical Engineer
U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: K141752 NxStage System One– RTA Hold Response

Dear Mr. Pudwill,

This letter is in response to your RTA Hold email dated July 11, 2014. Enclosed please find the following to address your RTA Hold:

- A Revised Section 7 - 510k Summary
- A Revised Section 11 - Device Description
- A new Appendix 5 to address the deficiency questions received from the Agency for K100535.

Thank you. If you have any questions regarding this response, please contact me directly at (978) 687-4872 or via e-mail at mstroumbos@nxstage.com.

Sincerely,

Mary Lou Stroumbos
Director, Regulatory Affairs

Section 7 – 510(k) Summary

This 510(k) Summary is being submitted in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990. The content contained in this 510(k) summary has been provided in conformance with 21 CFR §807.92

A. Date Prepared: June 27, 2014

B. Submitter's Information:

Name:	NxStage Medical, Inc.
Address:	350 Merrimack Street Lawrence, MA 01843
FDA Establishment Owner/Operator Number:	9045797
Contact Person:	Mary Lou Stroumbos Director, Regulatory Affairs
Phone:	(978) 687-4872
Fax:	(978) 687-4750
Manufacturer:	NxStage Medical, Inc. 350 Merrimack Street Lawrence, MA 01843
FDA Establishment Registration Number:	3003464075
Sterilization Site:	Steris Isomedix (NxStage Cartridge Express) 1000 S. Sarah Place Ontario, CA 91761

C. Device Name:

Trade/Proprietary Name:	NxStage System One
Common/Usual Name:	Hemodialysis System
Classification Name:	High Permeability Hemodialysis System
Regulation Number:	876.5860
Product Code:	ODN
Device Classification:	Class II
Device Panel:	Gastroenterology/Urology

D. Substantial Equivalence:

The NxStage System One has the same intended use and utilizes the same fundamental technology as the predicate NxStage System One. The NxStage System One has been compared to the legally marketed predicate device as cleared through K140526 (May 19, 2014) and was found to be substantially equivalent.

E. Device Description/Indications for Use:

The NxStage System One is comprised of the NxStage Cycler, an electromechanical control unit; the NxStage Cartridge, a sterile, single-use extracorporeal blood and fluid management circuit (with or without a pre-attached high permeability filter) that mounts integrally within the NxStage Cycler. The combined system is designed to deliver hemofiltration, hemodialysis and/or ultrafiltration in an acute or chronic care facility. The NxStage System One is also indicated for home hemodialysis, including home nocturnal hemodialysis.

Indications for use:

The NxStage System One is indicated for the treatment of acute and chronic renal failure or fluid overload using hemofiltration, hemodialysis, and/or ultrafiltration, in an acute or chronic care facility.

The NxStage System One is also indicated for home hemodialysis, including home nocturnal hemodialysis.

All treatments must be administered under physician's prescription, and must be performed by a trained and qualified person, considered to be competent in the use of this device by the prescribing physician.

F. Technological Characteristics:

The proposed device has the same technological characteristics and is similar in design and configuration as compared to the predicate device. The proposed device is designed with similar software, components and features also used in the predicate device.

Table 1
Device Technological Characteristics Comparison Table

Parameter	**Proposed Device NxStage System One**	**Predicate Device NxStage System One (K140526)**
Intended Use		
Hemodialysis	Yes	Yes
Hemofiltration	Yes	Yes
Ultrafiltration	Yes	Yes
Technology / Components:		
Pumps	Same	4 peristaltic pumps
Valves (clamps)	Same	2 solenoid actuated pinch clamps
	Same	8 cam driven pinch clamps
Air / fluid detectors	Same	3 ultrasonic air/ fluid detectors
Blood leak detector	Same	1 optical blood leak detector
Pressure transducers	Same	5 electronic pressure transducers
Temperature sensors	Same	1 electronic temperature sensor

Table 1
Device Technological Characteristics Comparison Table

Parameter	Proposed Device NxStage System One	Predicate Device NxStage System One (K140526)
Flow Rates:		
Blood	Same	10-600 ml/min
Prescription Fluid /Dialysate Flow	Same	0-18000 ml/hr
Ultrafiltration	Same	0-2400 ml/hr
Transmembrane Pressure Monitoring Specification	Same	Yes
Venous Pressure Monitor	Same	0 to 400 mmHg
Effluent fluid Pressure Monitor	Same	0 to 500 mmHg
Air Detector	Same	Reduction of detector signal lasting 6 ms minimum (Approximates a 60 micro liter bubble at 400 mmHg venous pressure and 600 ml/min blood flow)
Blood Leak Detector	Same	15% reduction in detector signal lasting 20 seconds minimum. Signal reduction % based on a 0.35 ml/min leak rate of 32 Hct blood.
Effluent Volume Accuracy	Same	Greater of 300 ml/ 12 hr or 3% of exchange volume (For software versions 4.7 and below) For software versions 4.8 and higher: Therapy Fluid Flow Rate L/hr) / Specification greater of > 3 / + 5% UF* or ±100 ml/hr* ≤ 3 / + 5% UF* or ± 25 ml/hr* *Representing 95/90 tolerance interval established under controlled laboratory testing conditions.
IV Prescription Fluid	Same	Off-line, sterile- physician prescribed, indicated for infusion
Dialysate	Same	Dialysate available as pre-packaged pre-mixed sterile fluids or via the PureFlow SL (K043436 K060296, K090919, K111174 & K140571)
Compatible Blood Tubing Set	Same	NxStage Standard Cartridge
Software	Software version 4.10	Software version 4.9

G. Summary of Non-Clinical Test/Performance Testing – Bench and Clinical Testing

NxStage believes that the information and data provided in this submission clearly describes the proposed device and demonstrates that the device is adequately designed for the labeled indications for use. Performance, verification and validation; and clinical testing was conducted to characterize performance of the proposed device and the predetermined acceptance criteria were met.

The following non-clinical testing was conducted:

- System Verification and Software Validation
    - Software verification & validation
    - Regression testing
    - Safety systems verification
    - Labeling verification testing
    - Simulated dialysis treatments

The following clinical testing was conducted:
NxStage conducted a prospective, multi-center, two-treatment, two-phase, open-label, cross-over Investigational Device Exemption clinical study titled "Comparison of Nocturnal Hemodialysis (NHD) and Short Daily Hemodialysis (DHD) with the NxStage System One." The objective of the study was to determine whether or not NHD (6-10 hours) was equivalent to DHD (2-4 hours) on a per treatment basis, using the NxStage System One (NSO) in the home setting. A total of 58 End Stage Renal Disease (ESRD) patients >18 years of age who were currently stable on home DHD were enrolled. The primary efficacy endpoint evaluated the ability of the NSO to deliver the prescribed therapy. The primary safety endpoint evaluated the rate of adverse events experienced by the study participants. The rates of adverse events were similar in the DHD and NHD phases, and the events experienced were typical of those commonly reported for dialysis patients, including episodes of hypotension, muscle cramping, nausea/vomiting, and vascular access related problems. Non-inferiority was attained for the primary safety and efficacy endpoints, showing that NHD therapy was equivalent to DHD therapy on a per treatment basis, using the NSO in the home setting.

Conclusion: Results of the non-clinical and clinical testing have documented that the proposed NxStage System One is substantially equivalent to the predicate device and is suitable for the labeled indications for use.

Section 11 – Device Description

11.0 Device Overview

The NxStage System One is currently indicated for the treatment of acute and chronic renal failure or fluid overload using hemofiltration, hemodialysis, and/or ultrafiltration, in an acute or chronic care facility. The System is also indicated for hemodialysis with or without ultrafiltration in the home.

All treatments must be administered under physician's prescription, and must be observed by a trained and qualified person, considered to be competent in the use of this device by the prescribing physician.

The purpose of this 510(k) submission is to expand the indications for use of the NxStage System One to specifically include nocturnal hemodialysis in the home environment. NxStage performed an IDE clinical study (CP0010 and CP0010-1 under G070128) to support the specific nocturnal home hemodialysis indication. The results of this study show NHD therapy is at least equivalent to DHD therapy, on a per treatment basis, using the NxStage System One in the home setting.

The data in support of this 510(k) submission is summarized in Section 21 and in the Clinical Study Report (Appendix 4).

11.1 Device Features

As described in the previous submissions, the NxStage System One is comprised of the NxStage Cycler, an electromechanical control unit and the NxStage Cartridge, a sterile, single-use extracorporeal blood and fluid management circuit (with or without a pre-attached high permeability filter) that mounts integrally within the NxStage Cycler.

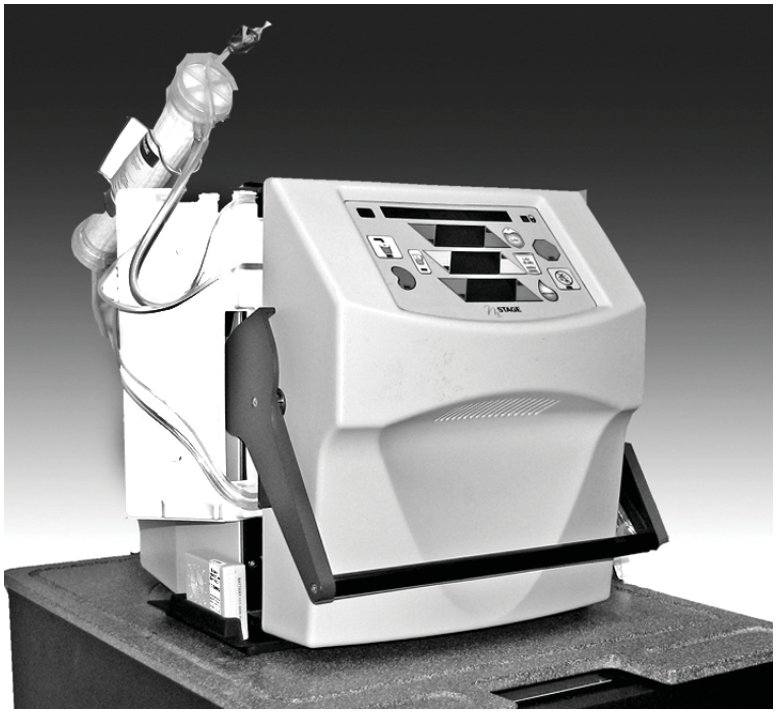


Figure 1 – NxStage System One

11.1.2 NxStage Cycler

The NxStage Cycler is an electro-mechanical device that interfaces with the disposable NxStage Cartridge. The NxStage Cycler performs the following functions:

- Loads and primes the NxStage Cartridge and filter.
- Performs pressure tests and alarms tests.
- Pumps blood from the patient, through the filter, and returns the filtered blood to the patient.
- Controls net fluid removal from the patient (ultrafiltration).
- Balances the removal of waste fluid with the infusion of sterile replacement fluid (hemofiltration).
- Balances and maintains the dialysate flow (hemodialysis).

- Monitors critical operating parameters relating to patient safety. It also monitors treatment parameters and alerts the operator for possible intervention.
- Rinses back blood to the patient at the conclusion of treatment.

The NxStage Cycler consists of the following components:

- *Control Panel*: All user inputs and informational readouts are communicated via the control panel. Each button on the panel has a specific and dedicated function.
- *Pumps*: The NxStage Cycler houses four peristaltic pumps: the blood pump, ultrafiltration pump, waste fluid pump and therapy fluid pump.
- *Balance Chambers:* Volumetric fluid management is controlled by the balance chamber subsystem, which ensures that the volume of waste fluid removed from the patient is equivalent to the volume of sterile replacement fluid infused into the patient for hemofiltration; or ensures flow rate and volume control of dialysate in hemodialysis.
- *Pressure Transducers*: Electronic pressure transducers monitor the pressures in the Cartridge blood and fluid pathways.
- *Pinch Clamp Actuators*: Solenoid and cam-driven pinch clamp actuators control the flow of blood and fluids in the Cartridge.
- *Air Detection Sensor*: An ultrasonic air detector monitors for air in the venous blood return line.
- *Blood Leak Detector:* An optical blood leak sensor monitors for blood in the waste fluid pathway.
- *Fluid Temperature Sensor*: An additional, redundant safety feature which monitors the dialysate fluid temperature.
- *Software:* There are two separate microprocessors: the Control Processor and the Safety Processor. The two processors communicate with each other via the Serial Communications Interface. The Control Processor controls the functions of the Cycler. The Safety

Processor monitors the Cycler, creates alarms, and alerts when necessary.

11.1.3 NxStage Cartridge

The NxStage Cartridge is a single use extracorporeal blood circuit and fluid management system. The Cartridge mounts integrally within the NxStage Cycler. The Cartridge consists of an outer shell structure (thermoformed tray) that properly locates the disposable components within the NxStage Cycler. The various blood and fluid pathway components are bonded together and held in place by the outer shell. The fluid management pathways contain the infusion, dialysate, ultrafiltrate and waste fluid flow paths, as well as the balance chamber liners and interfaces for the clamps and pressure monitoring. The cartridge is also available with a pre-attached high permeability filter, referred to as the NxStage Cartridge Express (NxStage Cartridge Express, subject of K014152, K032356, K050727 and K061837).

The NxStage Filter is a high flux (permeability) hollow fiber filter that is provided pre-attached to the NxStage Cartridge. During use, blood is pumped from the arterial line through the blood inlet port where it is distributed to the hollow fibers. The hollow fibers have a semipermeable membrane through which water molecules and smaller molecular weight solutes can pass, but larger molecular weight solutes (such as proteins) are rejected. Uremic toxins and waste products are removed from the patient's blood by means of diffusion through the membrane during hemodialysis.

The NxStage Cartridge includes the following components:

- Patient arterial (withdrawal) and venous (return) lines and connectors
- Filter arterial and venous lines and connectors
- Filter ultrafiltrate (effluent) line and connectors
- Waste line and connector
- Blood and fluid pathways
- Pinch clamp tubing segments
- Pressure sensor interfaces
- Balance chamber liners and membrane

- Pump header tubing
- Air detectors and blood leak detector interfaces.

11.1.4 Vascular Access Leak Detection Device

An access leak detection device is designed to help detect blood leaks during treatment. A stand alone access leak detection device with the following characteristics is required during nocturnal therapy:

- Ability to detect blood when in contact with the sensor and trigger and audible alarm loud enough to interrupt sleep;
- Ability to be positioned in a way that allows leaked blood to contact the sensor;
- Ability to be tested for functionality before use; and
- Ability to continue working properly when the patient moves.

In the NxStage clinical study "Comparison of Nocturnal Hemodialysis (NHD) and Short Daily Hemodialysis (DHD) with the NxStage System One" the following devices were used: Nytone Medical Enuretic Alarm Bedwetting device (K844866), DRI Sleeper Excel Device (510K exempt), and Redsense Alarm Unit & Sensor Patch (K092955).

11.1.5 Cycler/Cartridge Fluid Detection Device (K081043)

A fluid leak detection device is designed to help detect fluid and blood leaks from the Cycler or Cartridge during treatment. A stand alone leak detection device with the following characteristics is required during nocturnal therapy:

- Ability to detect blood or conductive fluid when in contact with the sensor and trigger an audible alarm loud enough to interrupt sleep;
- Ability to be positioned in a way that allows leaking blood or fluid to fall directly onto the sensor; and
- Ability to be tested for functionality before use.

11.2 Device Specifications/Requirements

Typical conditions and device specifications are provided in the NxStage System One User's Guide and are also provided below.

11.2.1 System One Environmental Specifications

Parameter	Performance
Ambient Operating Temperature	15° C to 37° C (59° F to 99° F)
Ambient Operating Humidity	15% to 93%, non-condensing
Maximum Operating Altitude	0 to 3000 m (700 hPa to 1060 hPa)
Transport/Storage Temperature	-25°C (13°F) without relative humidity control to 70°C (158° F) at 90% relative humidity; non condensing. Before using, keep cycler at room temperature for 1 hour.
Transport/Storage Humidity	0% to 95%,non-condensing
Protection against ingress of fluids	"Drip Proof" IP22 per IEC 60529
Chemical Resistance	Resistant to 0.25% sodium hypochlorite (bleach)
Input Voltage	100-120/230 VAC, auto-ranging
Frequency	50/60 Hz
Input Power	600VA (200 VA for cycler; 400 VA for AC outlet)
Fuse	5x20 mm, Time-lag, 4 amp high-breaking capacity, rated for 250 V.

<table>
<tr><th colspan="5">Operating Ranges</th></tr>
<tr><th>Parameter</th><th colspan="3">Performance</th><th>Condition</th></tr>
<tr><td colspan="5">Blood Flow Rate</td></tr>
<tr><td>Device</td><td colspan="3">Peristaltic pump</td><td></td></tr>
<tr><td>Range</td><td colspan="3">50 to 600 ml/min
10 to 600 ml/min</td><td>Set by user</td></tr>
<tr><td>Resolution</td><td colspan="3">10 ml/min</td><td></td></tr>
<tr><td>Accuracy</td><td colspan="3">±15%</td><td>@200 ml/min; inlet pressure, -50 mmHg; outlet pressure, 50 mmHg, using water at 37°C</td></tr>
<tr><td>Protective system</td><td colspan="3">Effluent and venous pressures. Hall Effect speed sensor</td><td>Tested during alarms test. Monitored during treatment.</td></tr>
<tr><td colspan="5">Effluent Fluid Flow (and Therapy Fluid Exchange) Rate</td></tr>
<tr><td>Device</td><td colspan="3">Peristaltic pump</td><td></td></tr>
<tr><td>Range</td><td colspan="3">NX1000-1: 0 to 12.0 L/hr
NX1000-3 and higher: 0 to 18.0 L/hr</td><td>Set by user; dialysate flow dependent on effluent flows</td></tr>
<tr><td>Resolution</td><td colspan="3">0.1 L/hr</td><td></td></tr>
<tr><td>Accuracy</td><td colspan="3">Greater of ±10% or 10 ml/min</td><td></td></tr>
<tr><td rowspan="4">Volume Accuracy</td><td colspan="3">Greater of 300 ml/12hr or 3% of exchange volume.</td><td>For software versions 4.7 and below Note: Combined accuracy of ultrafiltration and dialysate exchange flows.</td></tr>
<tr><td>Therapy Fluid Flow rate(L/hr)</td><td colspan="2">Specification Greater of</td><td rowspan="3">For software versions 4.8 and higher</td></tr>
<tr><td>>3</td><td rowspan="2">+ 5% of UF* or</td><td>±100 ml/hr*</td></tr>
<tr><td>≤3</td><td>±25 ml/hr*</td></tr>
<tr><td colspan="4">*Representing 95/90 tolerance interval established under controlled laboratory testing conditions.</td></tr>
<tr><td>Protective system</td><td colspan="3">Effluent and waste line pressures. Hall effect speed sensor</td><td>Tested during alarms test. Monitored during treatment</td></tr>
</table>

Operating Ranges		
Parameter	**Performance**	**Condition**
Ultrafiltration Only		
Device	Peristaltic pump	
Range	0 to 2.4 L/hr or 0 to 999 ml/hr	Set by user
Resolution	0.01 L/hr or 1 ml/hr	
Accuracy	Greater of 10% or 0.06 kg/hr	For software versions 4.7 and below
	Greater of 5 % of ultrafiltration rate or 30 ml/hr*	For software versions 4.8 and higher
	*Representing 95/90 tolerance interval established under controlled laboratory testing conditions.	
Protective system	Effluent and venous pressures. Hall effect speed sensor.	Tested during alarms test. Monitored during treatment.
Fluid Bolus Flow Rate (Hemofiltration Only)		
Device	Peristaltic pump	
Range	2 to 200 ml/min	System Setting
Resolution	1 ml/min	
Accuracy	Greater of ±10% of bolus volume or ±30 ml	
Protective system	Effluent and venous pressures. Hall effect speed sensor.	Monitored during treatment bolus infusion
Fluid Bolus Volume (Hemofiltration Only)		
Range	0 to 500 ml	System Setting
Resolution	5 ml	
Dialyzer Blood Volume		
Range	10 to 220 ml	System Setting
Resolution	1 ml	
Rinseback Factor		
Range	0.1 to 5	System Setting (Rinseback Volume = (Blood-side Dialyzer Volume + Blood Cartridge Volume) x Rinseback Factor)
Resolution	0.01	

11.2.2 System One Cycler Alarms and Monitors

Parameter	Performance
Venous Pressure	
Device	Electronic sensor
Range	0 to 1500 mmHg
Accuracy	Greater of ±20mmHg or ±10%
High fixed alarm point	400 mmHg sustained, 600 mmHg sustained during ramp-up and Prime and Alarm test 1500 mmHg instantaneous
Low fixed alarm point	20 mmHg sustained
Low adjustable alarm point	-20 to -90 mmHg (in 10 mmHg increments) from venous pressure "lock on" (default is 60 mmHg). "Lock on" occurs when the pressure has been stable for a certain time period (based on pump flow rates) after targeted pump flow rates are achieved.
Protective system	Continuous monitoring by safety subsystem.
Arterial Pressure, Prepump	
Device	Electronic sensor
Range	-50 to -500 mmHg
Accuracy	Greater of ±20mmHg or ±10%
Arterial Pressure, Dialyzer	
Device	Electronic sensor
Range	0 to 1500 mmHg
Accuracy	Greater of ±20mmHg or ±10%
Effluent Pressure	
Device	Electronic sensor
Range	0 to 1500 mmHg
Accuracy	Greater of ±20mmHg or ±10%
High fixed alarm point	1500 mmHg instantaneous
Low fixed alarm point	20 mmHg sustained

Parameter	Performance
Low adjustable alarm point	-10 to -200 mmHg (in 10 mmHg increments) from effluent pressure "lock on" (default is 100 mmHg). "Lock on" occurs when the pressure has been stable for a certain time period (based on pump flow rates) after targeted pump flow rates are achieved.
Protective system	Continuous monitoring by safety subsystem.
Transmembrane Pressure (TMP)	
Computed as the difference between venous and effluent pressures.	
High fixed alarm point	500 mmHg sustained
Waste Line Pressure	
Device	Electronic sensor
Range	0 to 1500 mmHg
Accuracy	Greater of ±20mmHg or ±10%
High fixed alarm point	900 mmHg sustained, 1500 mmHg instantaneous
High adjustable alarm point	100 to 450 mmHg sustained
Protective system	Continuous monitoring by safety subsystem.
Balance Chamber Pressure	
Device	Electronic sensor
Range	0 to 1500 mmHg
Accuracy	Greater of ±20mmHg or ±10%
High fixed alarm point	600 mmHg sustained, 1500 mmHg instantaneous
Air Detection	
Device	Ultrasonic detector
Sensitivity	Reduction of detector signal lasting 6 ms minimum. Approximates a 60 µl bubble at 400 mmHg venous pressure and 600 ml/min blood flow.
Protective system	Continuous monitoring by safety subsystem.

Parameter	Performance
Dialyzer Blood Leak Detector	
Device	Optical emitter and sensor
Sensitivity	A blood leak is indicated when the 20 second average of the detector signals drops more than 15% below the normalized detector signals. Signal reduction % based on a 0.35 ml/min leak rate of 32 Hct blood.
Protective System	Continuous monitoring by safety subsystem
Audible Alarms	
Power Fail	Continuous for at least one minute
System Fail	Continuous
Others	Continuous, may be silenced for two minutes. Immediate for Red Alarm Conditions, delayed for Yellow Caution conditions. Alarm resumes if conditions remain unresolved.
Output	>65 dBA at 1 m
Fluid Temperature Sensor	
Device	Thermistor
Alarm Point (High)	42° C (108° F) for SW version 4.6 and higher
Alarm Point (Low)	<33.3° C (91.9° F) for software version 4.9 and higher
Alarm Delay	33.2 °C (91.8° F):304 minutes 33.1° C (91.6° F): 274 minutes 33.0° C (91.4° F): 251 minutes 32.9° C (91.2° F): 232 minutes 32.8° C (91.0° F): 217 minutes 32.7° C (90.9° F): 204 minutes 32.4 - 32.6° C 90.3-90.7° F): 183 minutes 32.2 - 32.3° C (90.0-90.1° F): 166 minutes 31.8 - 32.1° C (89.2-89.8° F): 141 minutes 31.3 - 31.7 °C (88.3-89.1° F):123 minutes 30.6 - 31.2° C (87.1-88.2° F): 101 minutes 29.6 - 30.5° C (85.3-86.9° F): 81 minutes 27.8 - 29.5° C (82.0-85.1° F): 60 minutes 24.5 - 27.7° C (76.1-81.9° F): 40 minutes

Parameter	Performance
Alarm Delay Cont.	17.1 -24.4° C (62.8-75.9° F): 20 minutes <17.1° C (62.8° F): 0 minutes Delay times based on temperature estimated at the dialyzer, 35.6° C (96.1° F) pre-dialysis core temperature, 34.0° C (93.2° F) dialysis core temperature, 52 Kg (115 lb) body weight, 300 ml/min dialysate rate, 350 ml/min blood flow rate, 15 - 20° C (59 - 68° F) ambient temperature, and use of a NxStage Chronic Cartridge in a hemodialysis configuration.
Accuracy	±2° C (±3.6° F) for SW versions below 4.6 +0° C/ -2° C (+0° F / -3.6° F) for SW versions 4.6 and higher +2.5/-0° C (+4.5/-0° F) at low temperature caution and dialysate rates ≥ 5 L for software version 4.9 and higher.
Protective system	Continuous monitoring by safety subsystem.
Fluid Temperature	
Input fluid temperature. range	33.3 to 41.9° C
Output fluid temperature range	33.3 to 41.9° C

There are no changes to the NxStage System One system specifications as a result of this 510(k). For more detailed specifications, please refer to the NxStage System One User Guide provided in section 14.

11.3 Discussion of the Proposed Modifications

There are no hardware modifications to the NxStage System One as a result of this 510(k) submission. There are minor software modifications made to the NxStage System One for continuous improvement as detailed below:

Table 3 - NxStage System One Software 4.10 Modifications

IT	Description	Rationale for Change
IT003955	Add functionality in cycler software debug mode to allow commands through the CP serial port to change runtime settings through simulated keypad key presses.	Manufacturing Support Debug mode is available to trained service technicians only. End user is not exposed to this change; it is to improve manufacturing efficiency.
IT003922	Change default values for VFMS Comp parameters.	Manufacturing Support These parameters are established during the manufacturing process. User is not exposed to this change; it is to improve manufacturing efficiency.
IT003834	Create new parameter for Max UFR and Max FPR (System Settings 80 and 81).	Usability Enhancement Created two new parameters RX_MAX_UFR and RX_MAX_FPR (System Settings 80 and 81) to enhance set up for the user.
IT003786	Cycler high flow functionality cartridge set-up enhancement.	Usability Enhancement Cartridge type profile added to cartridge type parameter for high flow cartridges. Enhancement to make it easier for the user to set-up their cartridge for high flow.

Table 3 - NxStage System One Software 4.10 Modifications		
IT	**Description**	**Rationale for Change**
IT004066	JEM changes to support Cycler SW 4.10.	Validation Tool Update JEM is an internal validation tool. No new risks were identified. These internal changes have no impact to the user interaction with the system.

All testing has been completed following NxStage Design Controls Procedures and is summarized in Sections 17 and 19.

Appendix 5 – Discussion to Address December 9, 2010 Deficiency Letter Comments from K100535

(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information

[redacted]

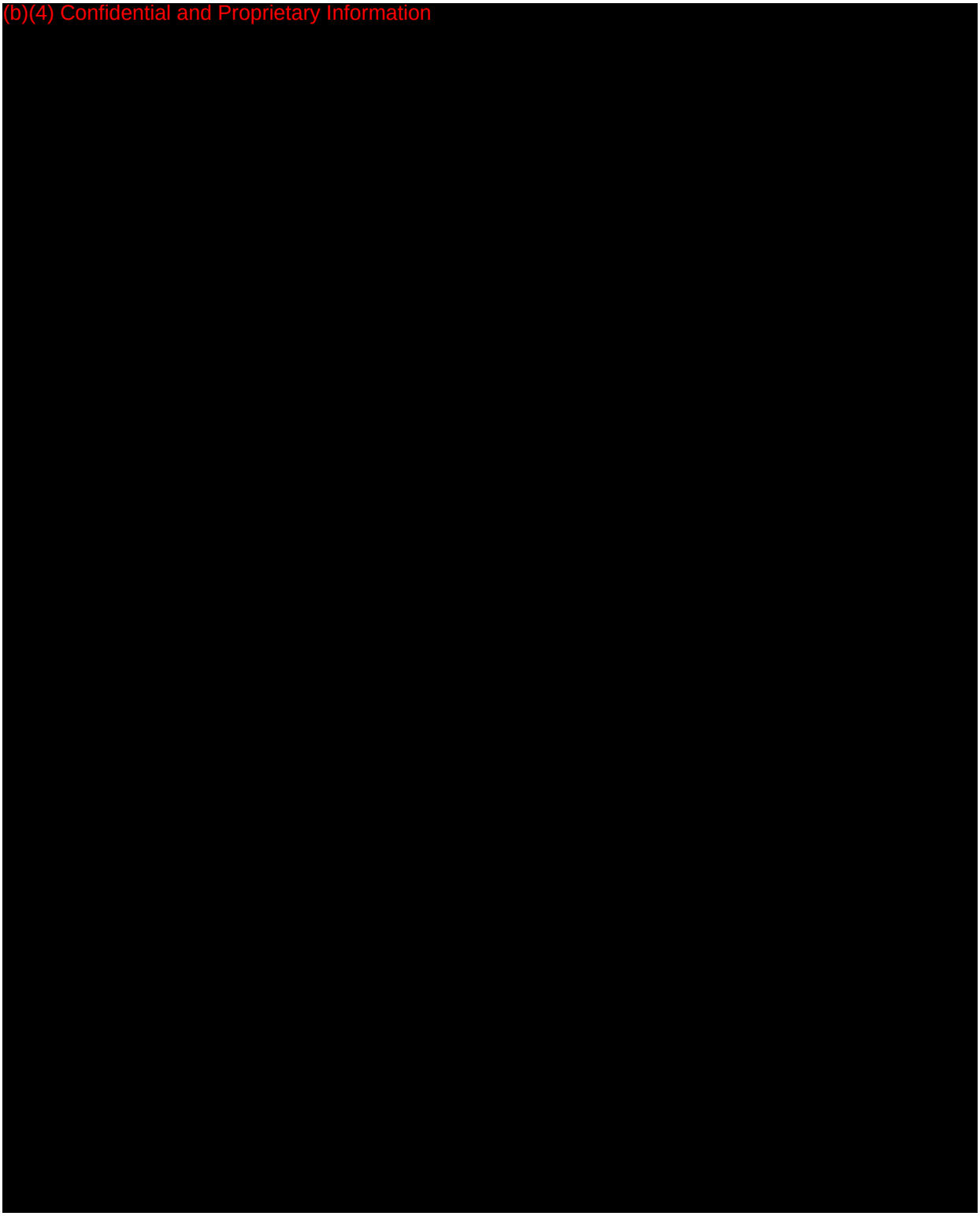
(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information



K141752/S002

November 20, 2014

US Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center – WO66-G609
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Re: eCopy for NxStage System One Additional Information Response for K141752

Dear Document Control Center:

The enclosed eCopy is an exact duplicate of the paper copy. This PDF file contains NxStage Medical's additional information response for the NxStage System One, 510(k) number K141752.

Thank you. If you have any questions regarding this information, please contact me directly at (978) 687-4872 or via e-mail at mstroumbos@nxstage.com.

Sincerely,

Mary Lou Stroumbos

Mary Lou Stroumbos
Director, Regulatory Affairs

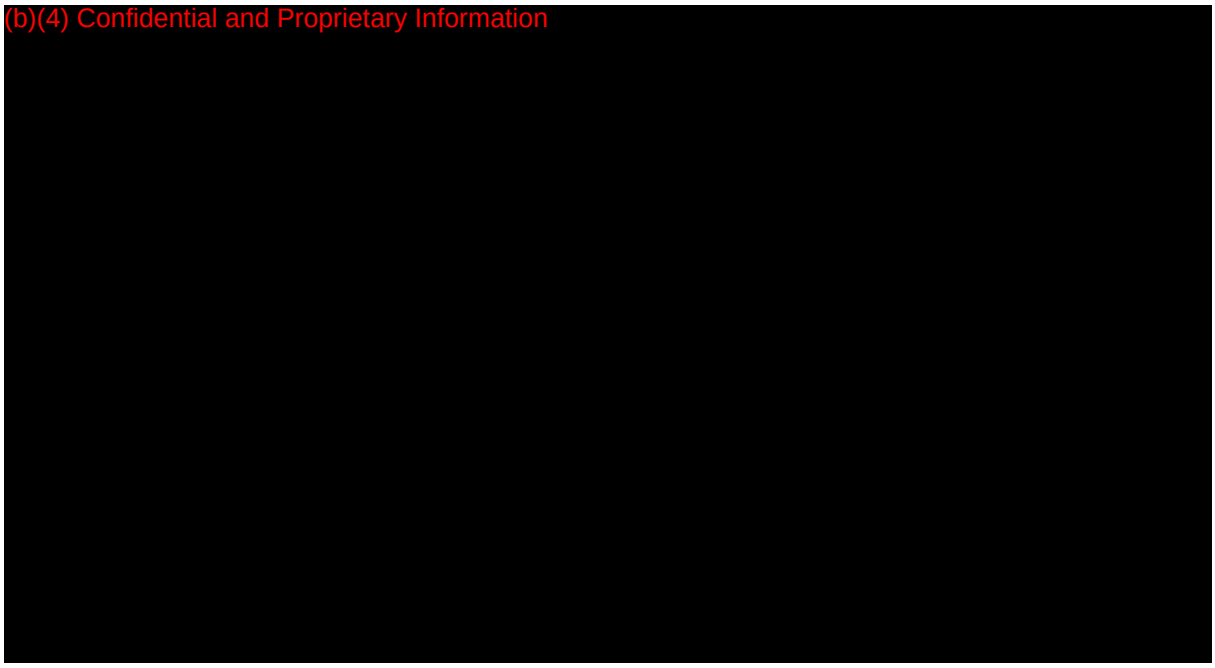
Additional Information Response for K141752

NxStage® Medical, Inc.
NxStage® System One™

NxStage Medical, Inc
350 Merrimack Street
Lawrence, MA 01843

Confidential

(b)(4) Confidential and Proprietary Information



November 20, 2014

Mr. David Pudwill
Biomedical Engineer
U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: K141752 NxStage System One–AI Response

Dear Mr. Pudwill,

This letter is in response to your email request dated September 23, 2014 for additional information relative to our 510(k) premarket notification (K141752) to market the device referenced above. All of your requests and questions are noted in bold below, followed by our corresponding response.

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

Appendix A – Revised Indications for Use and 510k Summary

INDICATIONS FOR USE

510(k) Number (if known):

Device Name: NxStage® System One™

Indications for Use: The NxStage System One is indicated for the treatment of acute and chronic renal failure, or fluid overload using hemofiltration, hemodialysis, and/or ultrafiltration, in an acute or chronic care facility.

The System is also indicated for home hemodialysis, including home nocturnal hemodialysis.

All treatments must be administered under physician's prescription, and must be performed by a trained and qualified person, considered to be competent in the use of this device by the prescribing physician.

Prescription Use ___X_____ **AND/OR** **Over-The-Counter Use_____**
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

This 510(k) Summary is being submitted in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990. The content contained in this 510(k) summary has been provided in conformance with 21 CFR §807.92

A. Date Prepared: June 27, 2014

B. Submitter's Information:

Name:	NxStage Medical, Inc.
Address:	350 Merrimack Street Lawrence, MA 01843
FDA Establishment Owner/Operator Number:	9045797
Contact Person:	Mary Lou Stroumbos Director, Regulatory Affairs
Phone:	(978) 687-4872
Fax:	(978) 687-4750
Manufacturer:	NxStage Medical, Inc. 350 Merrimack Street Lawrence, MA 01843
FDA Establishment Registration Number:	3003464075
Sterilization Site:	Steris Isomedix (NxStage Cartridge Express) 1000 S. Sarah Place Ontario, CA 91761

C. Device Name:

Trade/Proprietary Name:	NxStage System One
Common/Usual Name:	Hemodialysis System
Classification Name:	High Permeability Hemodialysis System
Regulation Number:	876.5860
Product Code:	ODN
Device Classification:	Class II
Device Panel:	Gastroenterology/Urology

D. Substantial Equivalence:

The NxStage System One has the same intended use and utilizes the same fundamental technology as the predicate NxStage System One. The NxStage System One has been compared to the legally marketed predicate device as cleared through K140526 (May 19, 2014) and was found to be substantially equivalent.

E. Device Description/Indications for Use:

The NxStage System One is comprised of the NxStage Cycler, an electromechanical control unit; the NxStage Cartridge, a sterile, single-use extracorporeal blood and fluid management circuit (with or without a pre-attached high permeability filter) that mounts integrally within the NxStage Cycler. The combined system is designed to deliver hemofiltration, hemodialysis and/or ultrafiltration in an acute or chronic care facility. The NxStage System One is also indicated for home hemodialysis, including home nocturnal hemodialysis.

Indications for use:

The NxStage System One is indicated for the treatment of acute and chronic renal failure or fluid overload using hemofiltration, hemodialysis, and/or ultrafiltration, in an acute or chronic care facility.

The System is also indicated for home hemodialysis, including home nocturnal hemodialysis.

All treatments must be administered under physician's prescription, and must be performed by a trained and qualified person, considered to be competent in the use of this device by the prescribing physician.

F. Technological Characteristics:

The proposed device has the same technological characteristics and is similar in design and configuration as compared to the predicate device. The proposed device is designed with similar software, components and features also used in the predicate device.

Table 1
Device Technological Characteristics Comparison Table

Parameter	**Proposed Device NxStage System One**	**Predicate Device NxStage System One (K140526)**
Intended Use		
Hemodialysis	Yes	Yes
Hemofiltration	Yes	Yes
Ultrafiltration	Yes	Yes
Technology / Components:		
Pumps	Same	4 peristaltic pumps
Valves (clamps)	Same	2 solenoid actuated pinch clamps
	Same	8 cam driven pinch clamps
Air / fluid detectors	Same	3 ultrasonic air/ fluid detectors
Blood leak detector	Same	1 optical blood leak detector
Pressure transducers	Same	5 electronic pressure transducers
Temperature sensors	Same	1 electronic temperature sensor

Table 1
Device Technological Characteristics Comparison Table

Parameter	**Proposed Device NxStage System One**	**Predicate Device NxStage System One (K140526)**
Flow Rates:		
Blood	Same	10-600 ml/min
Prescription Fluid /Dialysate Flow	Same	0-18000 ml/hr
Ultrafiltration	Same	0-2400 ml/hr
Transmembrane Pressure Monitoring Specification	Same	Yes
Venous Pressure Monitor	Same	0 to 400 mmHg
Effluent fluid Pressure Monitor	Same	0 to 500 mmHg
Air Detector	Same	Reduction of detector signal lasting 6 ms minimum (Approximates a 60 micro liter bubble at 400 mmHg venous pressure and 600 ml/min blood flow)
Blood Leak Detector	Same	15% reduction in detector signal lasting 20 seconds minimum. Signal reduction % based on a 0.35 ml/min leak rate of 32 Hct blood.
Effluent Volume Accuracy	Same	Greater of 300 ml/ 12 hr or 3% of exchange volume (For software versions 4.7 and below) For software versions 4.8 and higher: Therapy Fluid Flow Rate L/hr) / Specification greater of > 3 / + 5% UF* or ±100 ml/hr* ≤ 3 / + 5% UF* or ± 25 ml/hr* *Representing 95/90 tolerance interval established under controlled laboratory testing conditions.
IV Prescription Fluid	Same	Off-line, sterile- physician prescribed, indicated for infusion
Dialysate	Same	Dialysate available as pre-packaged pre-mixed sterile fluids or via the PureFlow SL (K043436 K060296, K090919, K111174 & K140571)
Compatible Blood Tubing Set	Same	NxStage Standard Cartridge
Software	Software version 4.10	Software version 4.9

G. Summary of Non-Clinical Test/Performance Testing – Bench and Clinical Testing

NxStage believes that the information and data provided in this submission clearly describes the proposed device and demonstrates that the device is adequately designed for the labeled indications for use. Performance, verification and validation; and clinical testing was conducted to characterize performance of the proposed device and the predetermined acceptance criteria were met.

The following non-clinical testing was conducted:

- System Verification and Software Validation
  - Software verification & validation
  - Regression testing
  - Safety systems verification
  - Labeling verification testing
  - Simulated dialysis treatments

The following clinical testing was conducted:

Clinical testing included 2 crossover studies with a total of 58 patients. There were 38 in the first study and 20 in the second study. Results were provided separately and pooled together to show substantial equivalence of nocturnal hemodialysis to daily hemodialysis in the home setting.

Pivotal Studies:

NxStage conducted a US prospective, multi-center, two-treatment, two-phase, open-label, cross-over Investigational Device Exemption clinical study titled "Comparison of Nocturnal Hemodialysis (NHD) and Short Daily Hemodialysis (DHD) with the NxStage System One." The objective of the study was to determine whether or not NHD (6-10 hours) was substantially equivalent to DHD (2-4 hours) on a per treatment basis, using the NxStage System One (NSO) in the home setting. The first phase (DHD) consisted of 2 to 4 hour treatments, and the second phase (NHD) consisted of 6 to 10 hour treatments. Both phases consisted of either 5 or 6 treatments per week over an 8 week period (40 or 48 treatments in total) using the NSO in the home environment. A 4 week training/transition period took place between the two phases. A total of 58 End Stage Renal Disease (ESRD)

patients >18 years of age who were currently stable on home DHD were enrolled, of which 39 completed the study period and 19 discontinued.

Primary effectiveness endpoint:
The primary efficacy endpoint for the study was the ability to deliver the clinically prescribed amount of therapy, defined by attainment of a delivered volume that was at least 90% of the prescribed volume (10% difference in success rate is the upper boundary of the 95% confidence interval).

Primary safety endpoint:
The primary safety endpoint was the composite intradialytic and interdialytic adverse event (AE) profile.

Effectiveness:
The primary endpoint for the study focused on the ability to deliver the clinically prescribed amount of therapy (success or failure). For the ITT population, the probability of a successful treatment was 90.9% in the DHD phase versus 91.7% in the NHD phase. The upper limit of the confidence interval (2.9%) was less than the protocol-specified limit (10%). Hence, the treatment success rates were similar and the protocol specified non-inferiority criterion was attained.

Safety:
For the ITT population, the composite AE rate per 100 treatments was 8.3 in the DHD phase versus 6.9 in the NHD phase. The event profiles were similar for both phases. Results were similar for the PP population.

The study reported one death not related to study participation or the study device and no unanticipated adverse device effects. In the DHD phase there were 21 severe AEs reported, and in the NHD phase there were 6 severe AEs reported. Device relatedness was recorded as cannot be ruled out for one of the severe AEs: patient was unable to self-cannulate due to a non-dialysis related surgery. The remaining 26 severe AEs were considered not related to the device. The rate of severe AEs per 100 treatments was 0.9 for DHD vs. 0.3 for NHD.

The most commonly occurring AEs were OTH-other, hypotension, and muscle cramping. OTH-other included non-dialysis related injuries and surgeries (e.g. broken ankle, knee surgery, toe infection, etc.), out of range blood laboratory values, access related events, episodes of depression, infection, kidney stone, and other isolated events. OTH-other occurred at a rate of 1.3 vs. 1.6 per 100 treatments in DHD vs. NHD, respectively. Hypotension occurred at a rate of 1.9 vs. 0.2 per 100 treatments. The rate of muscle cramping was 1.1 per 100 treatments for both study phases.

The rates of adverse events were similar in the DHD and NHD phases, and the events experienced were typical of those commonly reported for dialysis patients, including episodes of hypotension and muscle cramping.

Summary

Based on the clinical performance as documented in the pivotal clinical studies, the NxStage System One in the home setting delivers NHD therapy that is substantially equivalent to DHD therapy on a per treatment basis.

Conclusion: Results of the non-clinical testing and clinical data have documented that the proposed NxStage System One is substantially equivalent to the predicate device and is suitable for the labeled indications for use.

Appendix B – NxStage System One User Guide Page 5-21

3 - Parameter Limit Exceeded (Yellow Caution)

Priority

- Yellow Caution - Low

Alarm Event

A setting is too low or too high.

Probable Cause	Action Required
The user has attempted to input a setting (for example, flow rate) that is too low or high.	Confirm the system settings. See **Manufacturer's Default Settings**, page 9-6 for allowable settings.

4 - Blood Pump Off Caution (Yellow Caution)

Priority

- Yellow Caution - Medium

Alarm Event

The blood pump is stopped.

Probable Cause	Action Required
The user pressed the **STOP** key during Treatment Mode and the blood pump is stopped. Blood flow rate equals zero (**0**).	1. If you are using an external infusion pump, turn it off. 2. Press the **TREATMENT** key to continue Treatment Mode. 3. If you are using an external infusion pump, turn it back on again. OR, Press the **ADD FLUID** key to continue Rinseback Mode. Clotting risk increases if the blood pump is stopped for a long time.

Appendix C – Nocturnal Supplement Page 7

Vascular Access Leaks and Disconnections

WARNINGS

- Follow manufacturer's Instructions for Use to ensure correct operation of the leak detection device.
- Before each patient treatment, the Fluid Detection Sensor alarm must be tested. Failure to do so could result in a vascular access leak or disconnection or a fluid leak that goes undetected and may lead to significant blood loss, patient injury or death.
- Leak detection devices are separate from the NxStage System One Cycler and do not control the Cycler. When the leak detection device sounds an alarm, the user must press the STOP key on the Cycler to stop all pumps and close the clamps on the venous and waste lines. Failure to do so may result in significant blood loss, patient injury or death.

The vascular access and the blood lines should be correctly positioned and secure to avoid accidental dislodgement.

The use of an access leak detection device helps to detect blood leaks during treatment. The sensors of the access leak detection device should be positioned correctly so that the leak detection device alarms immediately if blood leaks from the vascular access. A stand-alone access leak detection device is required during nocturnal therapy. Test the access leak detection device following the manufacturer's Instructions for Use before each use.

When choosing an access leak detection device, make sure it can:

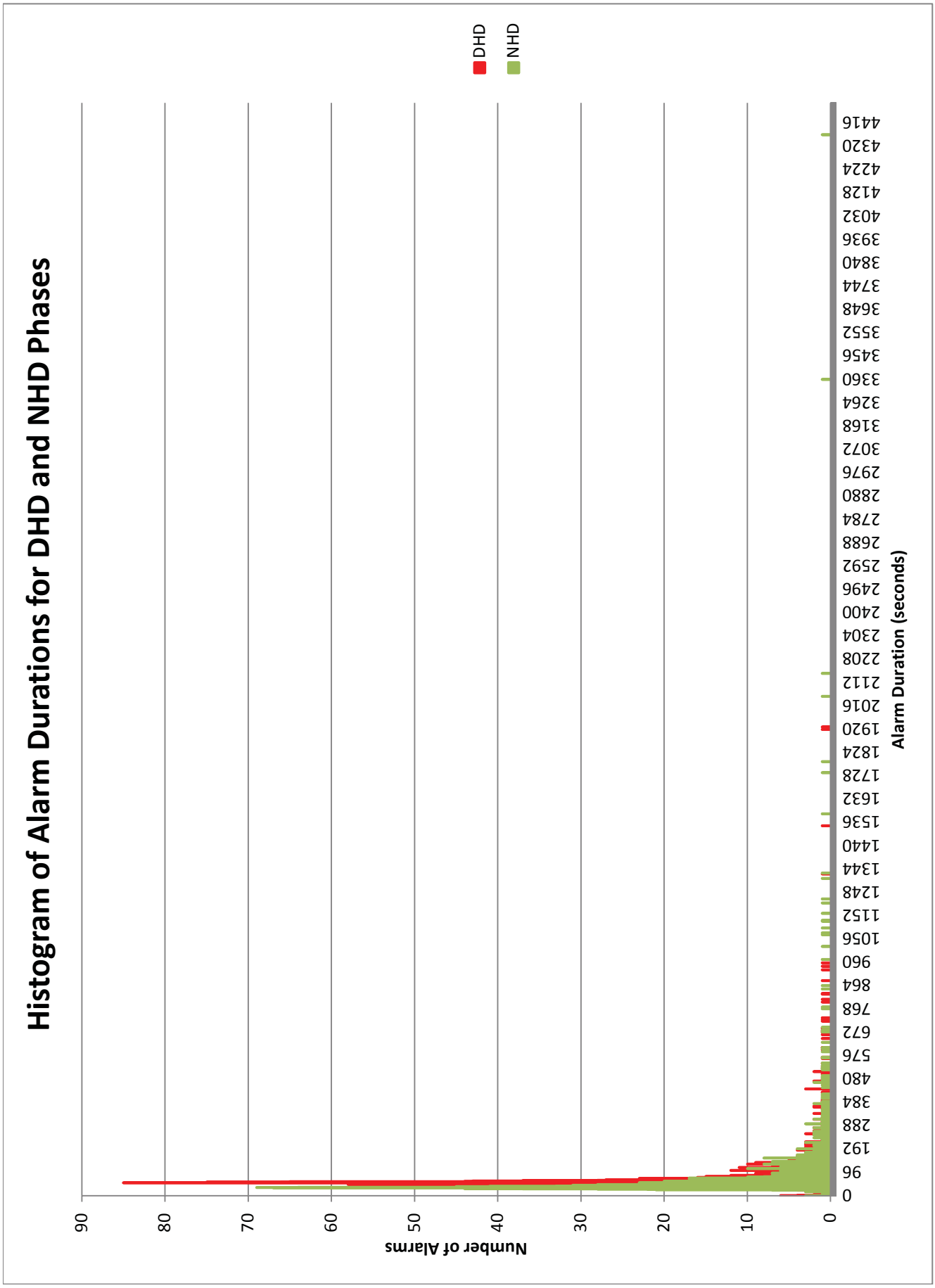
- detect blood when in contact with the sensor and trigger an audible alarm of 65 decibels or greater (loud enough to interrupt sleep);
- be positioned in a way that allows leaked blood to contact the sensor;
- be tested for functionality before use; and
- continue working properly when the patient moves.

The following access leak detection device has been validated for use with the NxStage System One to detect access leaks:

- Redsense Medical Blood Loss Detection Device (Alarm Unit and Sensor).

Other devices that meet the requirements above may be available.

Appendix D – Histogram



Appendix E – Prescription Information for Individual Medications

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information