

Equipment Redeployment



of the information necessary to use the system safely and effectively. Patients, partners, and providers should review and refer to the System One and PureFlow SL User Guides and Cartridge Instructions for Use for complete information including all warnings and precautions. The NxStage trademark is registered in the U.S Patent and Trademark Office and is owned by NxStage Medical, Inc. The NxStage trademark is also registered in Australia, Canada, New Zealand the European Union, and Japan. PureFlow and System One are

trademarks of NxStage Medical, Inc. CAUTION: Federal law restricts this device to sale by or on the order of a physician. TM0557 Rev. C

Objectives

- At the end of this presentation, the attendee should know:
 - Contents of the Equipment Redeployment Instructions
 - Overview of equipment redeployment steps and procedures
 - Redeployment documentation forms
 - How to obtain the redeployment instructions







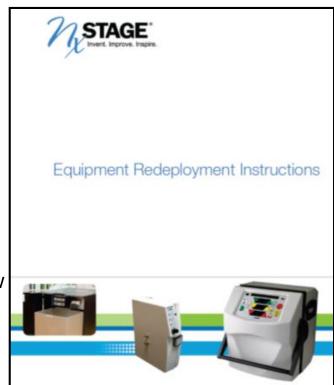


Equipment Redeployment Instructions



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 - LINX® Water Pre-Treatment System Overview
 - Express Fluid Warmer Redeployment Overview
 - Cycler Base and Fluid Detection Sensor Redeployment Overview
- Redeployment Forms
- Redeployment Instructions Availability









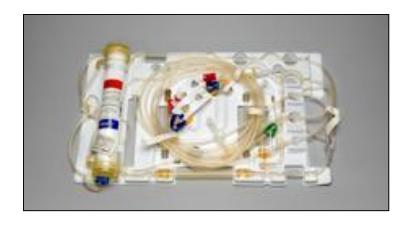


Redeployment Introduction

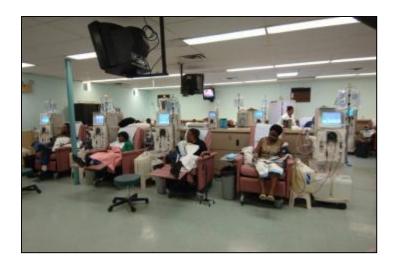


Redeploying NxStage Equipment is Safe

 Disposable fluid pathways minimize fluid contact with equipment



 Similar to in-center equipment use from one patient shift to the next



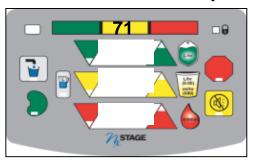


Redeploying NxStage Equipment is Safe

- NxStage equipment:
 - Has built-in self tests:
 - Power ON
 - Use of each Cartridge
 - New PAK is installed/primed
 - Use of each SAK



















Redeployment General Information



Always and as Soon as Possible

Always:

- Use universal precautions
- Call Technical Support, if needed
- Refer to:
 - Product User Guides
 - Equipment Redeployment Instruction

As soon as possible:

- Retrieve equipment from the patient's home
- Perform redeployment procedures
- Inform Customer Service of redeployed equipment serial numbers









Prior to Redeployment



Train Center Personnel

- Review the Redeployment Instructions
- Provide a demonstration of steps/procedures
- Monitor a return demonstration
- Document competency

| Procedures (refer to "Redeployment Procedures" on page 18) | Instruction provided: Trainer's initials/date | e procedures listed. Learner understands demonstrates procedures correctly. Trainer's initials/date | |
|--|---|--|--|
| Roviow Equipment Redeployment Instructions (NC3927) | | | |
| Cycler | | - | |
| Respond to Cycler Caution 71 | | | |
| Decontaminate returned equipment and accessory exterior surfaces | | - | |
| Distrifect the Interior surface of the Cycler and clean blood leak detector | | (k)2 | |
| Adjust System Settings to default values | 5 | | |
| Cycler Base, Fluid Detection Sensor, and Wa | armer | | |
| Decontaminate returned equipment and accessory exterior surfaces | | | |
| Test leak detector sensor alarm | 2 | 100 | |
| PureFlow SL | | | |
| Respond to Caution 2 and Alarm 853 | * | * 0 | |
| Check ultraviolet light preventive maintenance status | | | |
| Check conductivity sensor preventive maintenance status | | | |
| Verify conductivity and drain line check valve function | | | |
| Perform CPM-001 procedure | | | |
| Distrifect the conductivity line | | - 80. | |
| Disinfect the drain line | | | |
| Decontaminate returned equipment and accessory exterior surfaces | | | |
| Replace the air filter media | 8 | - 55 | |
| LINX System | 97. | 7-0) 40-10 | |
| Replace DI Cells | • | • • | |
| Verify self-tests begin | | | |
| NxStage Equipment Redeployment Training | Is Complete | - 1 | |
| Instructor Signature: | | hite: | |
| Learner Signature: | D | ate: | |



Obtain Patient Redeployment Kit and Gather Supplies







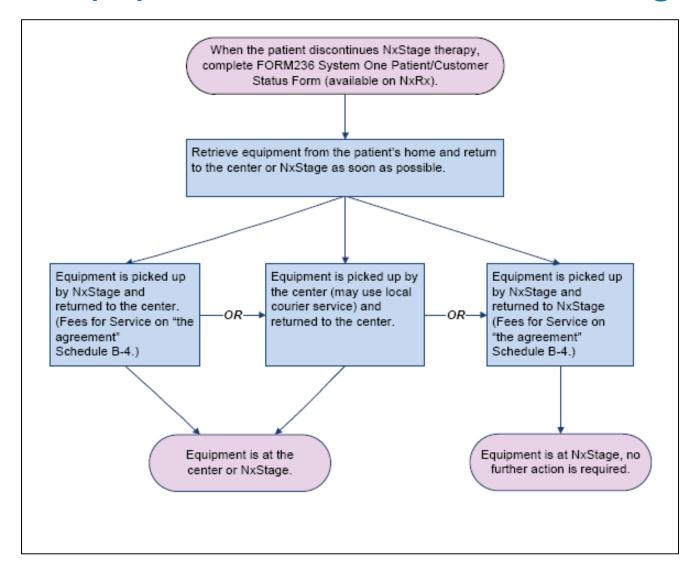




Equipment Redeployment Steps



Return Equipment to Center or NxStage





Inspect Equipment and Accessories

Fauipment and Accessories Form

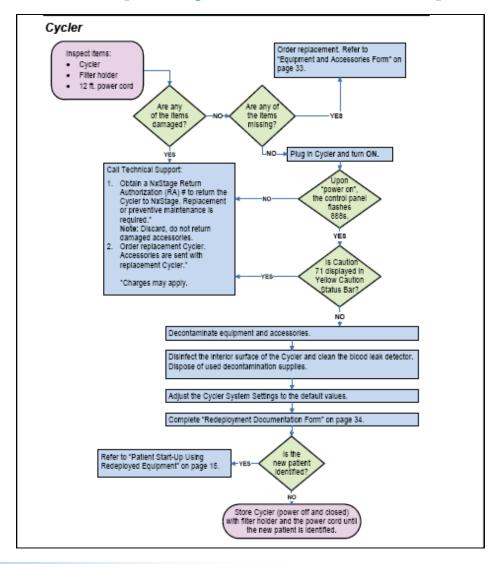
Call Technical Support if...

Call CustomerSupport if ...

| Order replacement accessories from Customer Service as | • | |
|--|------------------|-------------------|
| Note: Based upon your center contract, there may be a charge fo | r accessories. | |
| Equipment / Accessories | Check If Present | Reorder Number |
| System One Cycler with Computer (Jewel Box or ConNx Box attached) | | NX1000-1 |
| Filter holder | | NX0593-P |
| 12' power cord | | NC1176 |
| Cycler Base, including: | | NX0642 |
| Fluid Detection Sensor * | | NX0664 |
| PureFlow SL cabinet | | NX2000-2 |
| PureFlow SL wheeled base | | NX2000-3 |
| PureFlow SL control unit | | NX2000-1 |
| Interconnect power cord | | 86557300 |
| 12' power cord | | NC1176 |
| Saline hook | | NX0429-P |
| Air filter fan cover | | NC3823 |
| USB cable | | NX0509 |
| ComfortMate Fluid Warmer | | FW-200 |
| IV pole used with table top stand | | NX0248-02 |
| Table top stand, including: | | NX0248-01 |
| 4-hanger top for IV pole* | | 228 |
| Screw (spade head) to attach hanger to pole* | | NC0384 |
| Screw (2") to attach pole to stand * | | NC1292 |
| Screw (thumb screw) to attach table top stand to Cycler* | | NC0426 |
| 0.5 meter interconnect power cord for FW-200* | | 86557030 |
| Express Fluid Warmer | | FW-300 |
| Express Fluid Warmer Accessory Kit, including: | | FW-300-1 |
| Bag cover* | | NX0599 |
| IV pole* | | NX0485 |
| Interconnect power cord* | | 86557030 |
| Top mount* | _ | NX0484 |
| Bottom mount* | _ | NX0600 |
| Screw (thumb screw) to attach Bottom Mount to Cycler* | _ | NC0426 |



Perform Redeployment Steps





Perform Redeployment Procedures

F. Disinfect the PureFlow SL Drain Line

 Attach a recirculation connector (female-female adapter) to a 30 ml syringe to create a recirculation adapter (RA).



- Fill the RA with 30 ml of the prepared 1:10 bleach solution.
- 3. Connect the RA to the control unit waste line connector (yellow connector).
- Push the bleach solution into the waste line connector. A drain line must be connected to the control unit and positioned in the drain.



- Let the solution stay in the drain line for ten minutes.
- Disconnect the RA from the waste line connector and repeat Steps 2 through 5. A total of 60 ml of the bleach solution is used to flush the drain line.
- Disconnect the RA. Thoroughly rinse with tap water. Refill with 30 ml of tap water.
- Connect the RA to the control unit waste line connector.
- 9. Push the tap water into the waste line connector on the control unit.
- 10.Repeat Steps 7 through 9 two more times. This ensures that the bleach solution is outside of the PureFlow SL and into the drain line.

Note: Residual chlorine testing of the drain line is not required because patient contact is impossible: 1) Multiple check valves contained in the lines; 2) uni-directional pump flow prevents reverse flow during use; and 3) connection is upstream to a single-use disposable.









Cycler Redeployment Overview



Cycler Redeployment





Jewel Box connections shown



Cycler Redeployment

















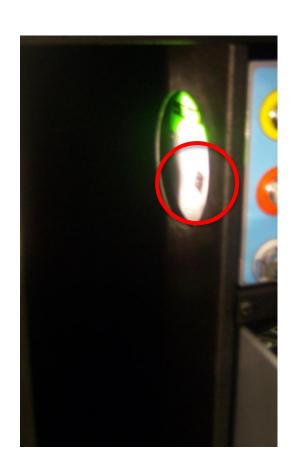
PureFlow SL Redeployment Overview







Control Unit rear connections



PAK electrical cable connection





Your software version may differ from this display.



- Check Control Unit Ultraviolet
 Light preventive maintenance
 - If time is less than 156
 batches, replace Control
 Unit

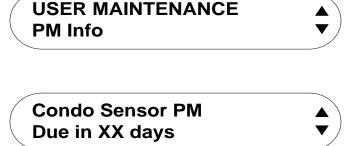
USER MAINTENANCE
Settings

▼

UV Light PM
Due in XX batches

▼

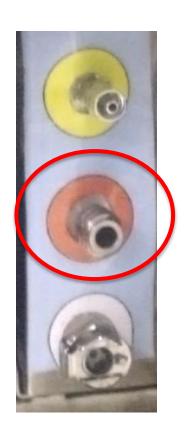
 Check Control Unit Conductivity Sensor preventive maintenance





Verify Conductivity Line check valve function







 If the Conductivity Sensor preventive maintenance time is less than 300 days, perform the CPM-001 procedure



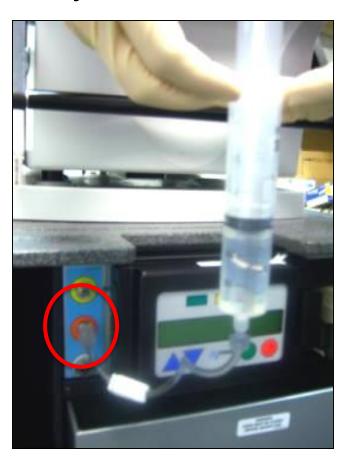






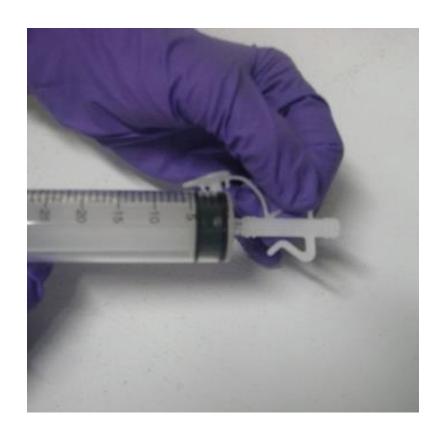
Disinfect the Conductivity Line

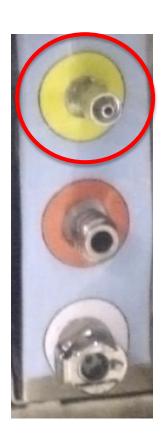






Verify Drain Line check valve function







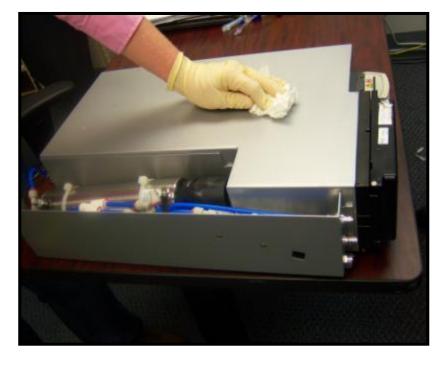
Disinfect the Drain Line





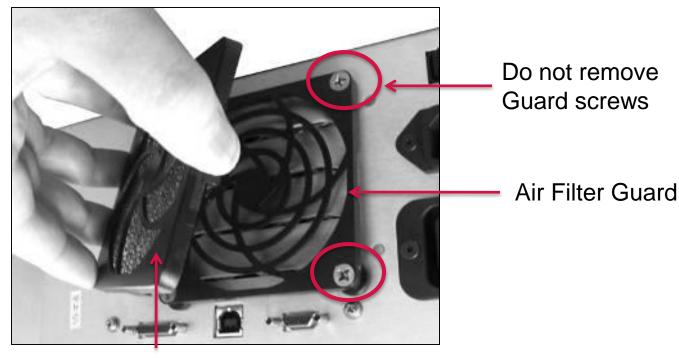








- Replace the PureFlow SL Air Filter media
 - Note: Leave the Guard attached to PureFlow SL.



Air Filter cover with media









LINX Water Pre-Treatment System Overview



LINX Redeployment









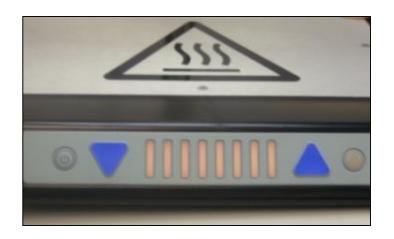




Express Fluid Warmer Redeployment Overview



Express Warmer Redeployment















Cycler Base and Fluid Detection Sensor Redeployment Overview



Cycler Base and Fluid Detection Sensor













Redeployment Forms



Redeployment: Training Documentation

| (refer to "Redeployment Procedures" on page 18) | Instruction provided: Trainer's initials/date | Learner understands / demonstrates procedures correctly: Trainer's initials/date | |
|--|---|---|--|
| Roviow Equipment Redeployment Instructions (NC3927) | | | |
| Cycler | | 3/10 | |
| Respond to Cycler Caution 71 | | | |
| Decontaminate returned equipment and accessory exterior surfaces | | ** | |
| Disinfect the interior surface of the Cycler and clean blood leak detector | <u> </u> | 50 D | |
| Adjust System Settings to default values | | | |
| Cycler Base, Fluid Detection Sensor, and Wi | armer | - | |
| Decontaminate returned equipment and accessory exterior surfaces | | | |
| Test leak detector sensor alarm | | | |
| PureFlow SL | | | |
| Respond to Caution 2 and Alarm 853 | • | * * | |
| Check ultraviolet light preventive mainlenance status | | | |
| Check conductivity sensor preventive mainlenance status | * | -20 | |
| Verify conductivity and drain line check valve function | | | |
| Perform CPM-001 procedure | | - 2 | |
| Disinfect the conductivity line | | - | |
| Distrifect the drain line | 0. | 32 S | |
| Decontaminate returned equipment and accessory exterior surfaces | | | |
| Replace the air filter media | 2 | | |
| LINX System | 3. - | 700 200 | |
| Replace DI Cells | * | • • | |
| Verify self-tests begin | | - | |
| NxStage Equipment Redeployment Training | Is Complete | *** | |
| Instructor Signature: | | late: | |



Redeployment: Equipment Documentation

| Cycler Serial # | ☐ Replace DI Cells | | | | |
|---|--|--|--|--|--|
| Confirm the following: | Completed by | | | | |
| Equipment and accessories inspected. | Signature: Date | | | | |
| ☐ Upon Power On: the Control Panel Flashes 888s. | ComfortMate Serial #: | | | | |
| □ Upon Power On: Yellow Caution #71 not displayed. | Table Top Stand Serial #: N/A Confirm the following: | | | | |
| ☐ Equipment exterior surfaces and accessories | Equipment and accessories inspected. | | | | |
| decontaminated. Cycler interior surface disinfected, and blood leak detector and mirror cleaned. | Upon Power On, the warmer's control panel lights flash, an alarm sounds and the green light on the front of the warmer remains lit. | | | | |
| ☐ System Settings set to CAR-170 default values. | Equipment exterior surfaces and accessories deconsaminated. | | | | |
| Completed by Signature: Date | Compleied by Signature: Date | | | | |
| Cycler Base and Fluid Detection Sensor Serial #: N/A | PureFlow SL Control Unit Serial #: | | | | |
| Confirm the following: | Confirm the following: | | | | |
| ☐ Inspect equipment and accessories. | Equipment and accessories inspected. | | | | |
| Sensor alarms appropriately when basery inserted and when the sensor's metal bars are contacted with moist cloth. | Upon Power On: the control panel LEDs flash red green, yellow and the panel displays NxStage Medical Inc. and software version. | | | | |
| Equipment exterior surfaces and accessories decontaminated. | Upon Power On: Caution 2 or Alarm 853 are not displayed. | | | | |
| Completed by Signature: Date | Preventive Maintenance (PM) status for the Ultraviolet (UV) light is greater than 156 batches. | | | | |
| Express Fluid Warmer Serial #: | Conductivity check valve and drain line check valve function verified. | | | | |
| Confirm the following: | And the second s | | | | |
| Equipment and accessories inspected. | Conductivity sensor PM is due in greater than 30 days or CPM-001 is completed. | | | | |
| ☐ Upon power cord connection, the Express Fluid | Conductivity line disinfected. | | | | |
| Warmer's Comfort status lights flash rod, yellow then green and the standby and hot surface | ☐ Drain line disinfected. | | | | |
| indicators come on then go off. An alarm sounds, all lights go out and the standby light remains lit. | Equipment and accessories exterior surfaces decontaminated. | | | | |
| Equipment and accessories exterior surfaces decontaminated. | Air filter media replaced. | | | | |
| Completed by | Completed by Signature: Date | | | | |
| Signature:Date | PureFlow St. Cabinet Scrial #: | | | | |
| LINX Water Pre-Treatment System Sorial #- | Confirm the following: | | | | |
| Confirm the following: | Equipment and accessories inspected. | | | | |
| ☐ Equipment and accessories inspected | Equipment exterior surfaces and accessories decontaminated. | | | | |
| Upon power on - the LINX status lights go on and off and there is NO audible alarm. | Completed by Signature Date | | | | |



Patient Equipment Log

| Patient Eq | quipmei | nt Log | Form | | | |
|------------------------------|------------------|-----------|-------------|---------------------------------------|--------------------|----------------------------|
| Use this form | to maintai | n a recor | d of patier | nt equipment by serial | number | |
| Patient Name | | | | | | _ |
| Therapy Start | Date: | | | Therapy End Date: | | _ |
| Equipment Serial # | Date Received | | nxStage | Date Redeploy Procedures Completed | Date Redeployed | Redeployed to (Patient) |
| Cycler | | | | | | |
| | | | | | | |
| PureFlow SI. Control Unit | | | | | | |
| | | | | | | |
| PureFlow SL Cabinet | | | | | | |
| | | | | | | |
| ComfortMate Warmer | | | | | | |
| | | | | | | |
| Express Fluid Warmer | | | | | | |
| | | | | | | |
| LINX System | | | | | | |
| | | | | | | |
| Other | | | | | | |
| | | | | | | |



NxRx Center Inventory Report

| show 25 ventries | | Se | earch: | |
|--------------------|---|------------|-------------|------------|
| Equipment Location | Part | Serial No. | Ship Date 🔷 | Status |
| 1:-4-4 | NX2000-2 (PureFlow SL Chassis) | 1190 | 10/12/2006 | Unemployed |
| List of | FW-200 (Comfortmate Warmer) | C8911 | 02/27/2009 | Unemployed |
| Patient's | NX1000-1 (NxStage System One - Chronic) | 7403 | 11/03/2008 | Unemployed |
| i aliciil s | FW-200 (Comfortmate Warmer) | C12378 | 01/05/2009 | Unemployed |
| Name | NX1000-1 (NxStage System One - Chronic) | 5117 | 01/05/2009 | Unemployee |
| | NX2000-1 (NxStage PureFlow SL Control Unit) | 4176 | 01/22/2009 | Unemployed |
| | NX2000-2 (PureFlow SL Chassis) | 4798 | 01/15/2009 | Unemployee |
| | NX2000-2 (PureFlow SL Chassis) | 2454 | 06/27/2007 | Unemployed |
| | NX2000-2 (PureFlow SL Chassis) | 2926 | 10/04/2007 | Unemployed |
| | FW-200 (Comfortmate Warmer) | C8997 | 10/09/2008 | Deployed |
| | NX1000-1 (NxStage System One - Chronic) | 7470 | 09/22/2008 | Deployed |
| | NX1000-1 (NxStage System One - Chronic) | 7385 | 06/09/2008 | Deployed |
| | FW-200 (Comfortmate Warmer) | C9050 | 07/10/2006 | Unemployee |
| | FW-200 (Comfortmate Warmer) | C12629 | 02/14/2009 | Deployed |
| | NX1000-1 (NxStage System One - Chronic) | 9519 | 10/10/2008 | Deployed |
| | NX2000-1 (NxStage PureFlow SL Control Unit) | 4013 | 10/10/2008 | Deployed |
| | NX2000-2 (PureFlow SL Chassis) | 4504 | 10/10/2008 | Deployed |
| | FW-200 (Comfortmate Warmer) | C8337 | 08/02/2007 | Deployed |
| | NX1000-1 (NxStage System One - Chronic) | 5780 | 05/16/2008 | Deployed |
| | NX2000-1 (NxStage PureFlow SL Control Unit) | 2201 | 01/07/2009 | Deployed |
| | NX2000-2 (PureFlow SL Chassis) | 1062 | 08/21/2006 | Deployed |
| | NX1000-1 (NxStage System One - Chronic) | 7433 | 05/19/2008 | Unemployed |
| | NX2000-2 (PureFlow SL Chassis) | 2848 | 09/21/2007 | Unemployed |
| | FW-200 (Comfortmate Warmer) | C9963 | 04/10/2007 | Deployed |
| reisen, seraia | NX1000-1 (NxStage System One - Chronic) | 7014 | 03/24/2008 | Deployed |







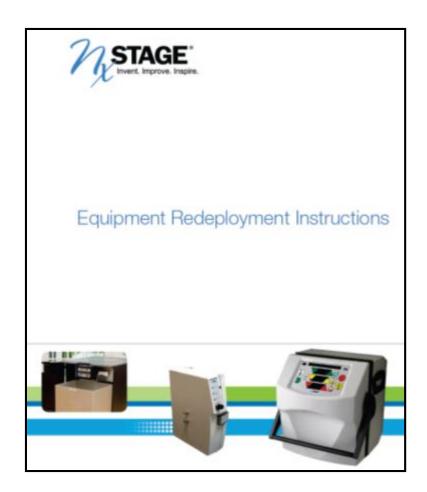


Redeployment Instructions Availability



Available Electronically

- NxDocuments
- NxStage Web Site





thank you

