

NxStage® System One™ Fact Sheet

About NxStage System One

- The NxStage System One is the only truly portable hemodialysis system cleared for home use during the day or overnight. The System One received clearance for home hemodialysis treatments in June 2005 and clearance for nocturnal therapy in December 2014.
- The System One was designed to deliver more frequent home hemodialysis with simplicity, flexibility, portability and without compromising safety.
- Comprised of a small control unit (the “cyclor”), a disposable cartridge and filter (the “cartridge”) and high-purity fluid (“dialysate”), the System One is just over a foot tall and weighs approximately 75 pounds.
- The NxStage System One requires no special plumbing or electrical infrastructure, fitting easily into a patient’s home.
- The NxStage PureFlow™ SL is an accessory to the NxStage System One that prepares dialysate for use during hemodialysis. It eliminates the need for specialized water purification and minimizes maintenance and disinfection needs by using disposable materials. PureFlow SL is a compact integrated, self-contained system designed to produce ultra-pure water from ordinary tap water, which is then precisely mixed with sterile-filtered concentrate to produce high-purity dialysate for use in treatment.

Using NxStage® System One™

- The simple interface of the NxStage System One is easy to learn and use, allowing therapy to be delivered by a trained patient and their care partner. NxStage provides in-depth training and offers 24/7 support for both the patient and their care partner, even if the patient is “trained and qualified,” they should not dialyze alone.
- For most patients, therapy typically lasts two and a half to three hours and is conducted five to six days a week. With the portable convenience of NxStage System One, this can be done at a time that is convenient for the patient.
- For patients performing nocturnal therapy using the System One, treatments are done overnight while patients and their care partners are sleeping. For patients on nocturnal therapy certain ancillary devices are recommended or required.
- Patients can do treatments in the comfort of their home or while traveling. The System One can be taken in a car, recreational vehicle, on a plane and even on cruises.
- The more frequent hemodialysis schedule enabled by the NxStage System One better mimics the continuous functioning of healthy kidneys, providing many patients health and quality of life benefits.^{1,2}
- In a clinical study, a significant percentage of patients performing more frequent hemodialysis experienced a reduction in post-dialysis recovery time to less than one hour, helping patients to return to their daily routines.¹
- Clinical data also indicates that more frequent home hemodialysis with the NxStage System One is associated with a 13% lower risk for all-cause mortality than in-center hemodialysis.³



Despite the health benefits that more frequent home hemodialysis may provide to those with chronic kidney disease, this form of therapy is not for everyone. Home hemodialysis with the NxStage System One requires a patient and partner who are committed to being trained on and following the guidelines for proper system operation.

The reported benefits of home hemodialysis may not be experienced by all patients.

The NxStage System One is a prescription device and, like all medical devices, involves some risks. The risks associated with hemodialysis treatments in any environment include, but are not limited to, high blood pressure, fluid overload, low blood pressure, heart-related issues, and vascular access complications. The medical devices used in hemodialysis therapies may add additional risks including air entering the bloodstream, and blood loss due to clotting or accidental disconnection of the blood tubing set. Patients should consult with their doctor to understand the risks and responsibilities of home and/or more frequent hemodialysis using the NxStage System One.

Certain risks are unique to the home. Treatments at home are done without the presence of medical personnel and on-site technical support. Patients and their partners must be trained on what to do and how to get medical or technical help if needed.

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. Patients should consult with their physician to understand the risks and responsibilities associated with home nocturnal hemodialysis using the NxStage System One.

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