



Introducing HighVolume Hemodiafiltration

(HighVolumeHDF) and the
5008X™ CAREsystem

5008X™
CAREsystem

What Is Hemodiafiltration (HDF)?

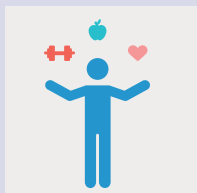
HDF is an advanced dialysis therapy that helps clean your blood when your kidneys stop working. It is similar to conventional hemodialysis (HD*) and can effectively remove a wider range of waste and toxins from your blood¹.

What Is High-Volume Hemodiafiltration (HighVolumeHDF)?

HighVolumeHDF is when 21 or more liters** of substitution fluid are used to help remove even more toxins and waste than both conventional HD and HDF. It gives your blood a more thorough cleanse.

Potential Benefits of HighVolumeHDF Compared to Conventional HD

HighVolumeHDF is a fast-growing therapy around the world. Patients on **HighVolumeHDF** therapy in Europe have experienced the following benefits:

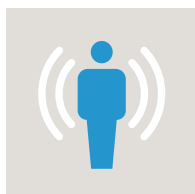


Improved
Quality of Life²

- Slower decline in cognitive and physical functions
- Extended ability for social participation
- Trend for reduced interference of daily activities due to pain



Lower Risk
of Death³
by up to 23%



Reduced
blood pressure
events during
dialysis^{4***}



Lower Risk
of Hospital
Stays^{4****}

Fresenius Medical Care is proud to bring the 5008X CAREsystem – the first in-center dialysis device designed to perform **HighVolumeHDF** – to US patients. Thanks to the 5008X CAREsystem, US patients can start to access this advanced therapy. The clinical studies showing the above potential outcomes with **HighVolumeHDF** were conducted outside of the U.S. and did not involve the 5008X CAREsystem. Patient experiences may vary when being treated with **HighVolumeHDF** therapy.

* Hemodialysis helps to clean your blood if your kidneys are failing or no longer work. It can remove waste, toxins, and extra fluids from your body. If you need hemodialysis, it can help to balance electrolytes.

** **HighVolumeHDF** uses at least 21 liters of fluid to help clean your blood during dialysis. This amount may not be reached in every session.

*** HDF patients in this study were younger and had fewer co-morbidities.

**** It depends on the prescription treatments and patient conditions to achieve **HighVolumeHDF**.

What Is the 5008X CAREsystem?

The 5008X CAREsystem allows your care team to provide advanced dialysis therapy. It is the first device in the US that can do both conventional HD and **HighVolumeHDF******. It is safe and works like other Fresenius Medical Care in-center hemodialysis machines that have helped millions of dialysis patients worldwide.



Questions to Ask Your Care Team

- How do I know if **HighVolumeHDF** is right for me?
- How will my treatment change?
- Does my clinic have the 5008X CAREsystem?
- How can I get **HighVolumeHDF**?
- How will I know the “high volume” is achieved in a treatment?
- What does the transition look like when switching from HD to **HighVolumeHDF**?
- Are there any extra risks or side effects with **HighVolumeHDF**?



Ask Your Doctor About
HighVolumeHDF Today



References

1. Morena M, Creput C, Bouzernidj M, et al. Randomised trial on clinical performances and biocompatibility of four high-flux hemodialyzers in two mode treatments: hemodialysis vs post dilution hemodiafiltration. *Sci Rep.* 2019;9(1):18265. Published 2019 Dec 4. doi:10.1038/s41598-019-54404-7
2. Rose M., et al. "The CONVINCe randomized trial found positive effects on quality of life for patients with chronic kidney disease treated with hemodiafiltration", *Kidney International*, Nov. 2024: Volume 106, Issue 5, p765-1002
3. Blankenstijn PJ et al. "Effect of Hemodiafiltration or Hemodialysis on Mortality in Kidney Failure." *N Engl J Med* 2023; 389: 700-709.
4. Maduell F. et al., High-Efficiency Postdilution Online Hemodiafiltration Reduces All-Cause Mortality in Hemodialysis Patients, *J Am Soc Nephrol* (2013); 24: 487-497.



The CONVINCe study has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 754803.

Indication for Use

The 5008X system is indicated for intermittent hemodialysis treatment for patients with acute and chronic renal failure in a healthcare facility. Therapy options for patients weighing more than 40 kg include: Hemodiafiltration (HDF), Hemodialysis (HD), Hemofiltration (HF) and Isolated Ultrafiltration (ISO-UF).

The 5008X Machine is equipped with a bibag® system, but it may also be used with liquid bicarbonate using the connector included with the machine.

The bibag system is indicated for use in patients undergoing extracorporeal bicarbonate hemodialysis for acute and chronic renal failure. The bibag system is intended to be used as one component in the preparation of dialysate according to a physician's prescription in a 3-stream proportioning hemodialysis machine equipped with the bibag module.

The 5008X Machine is available equipped with a Crit-Line® Clip (CLiC™) Monitor System.

The optional CLiC system is used to non-invasively measure hematocrit, oxygen saturation and percent change in blood volume in real time for application in the treatment of dialysis patients with the intended purpose of providing a more effective treatment for both the dialysis patient and the dialysis technician. Based on the data that the monitor provides, the clinician/nurse, under physician direction, intervenes (i.e. increases or decreases the rate at which fluid is removed from the blood) in order to remove the maximum amount of fluid from the dialysis patient without the patient experiencing the common symptoms of dialysis which include nausea, cramping and vomiting.

Caution: Federal law restricts this device to sale by or on the order of a physician.

© 2025 Fresenius Medical Care. All Rights Reserved. Fresenius Medical Care, the triangle logo, 5008X, bibag, Crit-Line, and CLiC are trademarks for which Fresenius Medical Care AG holds rights. All other trademarks are the property of their respective owners. D/N US-5008X-000002 Rev B 10/2025

