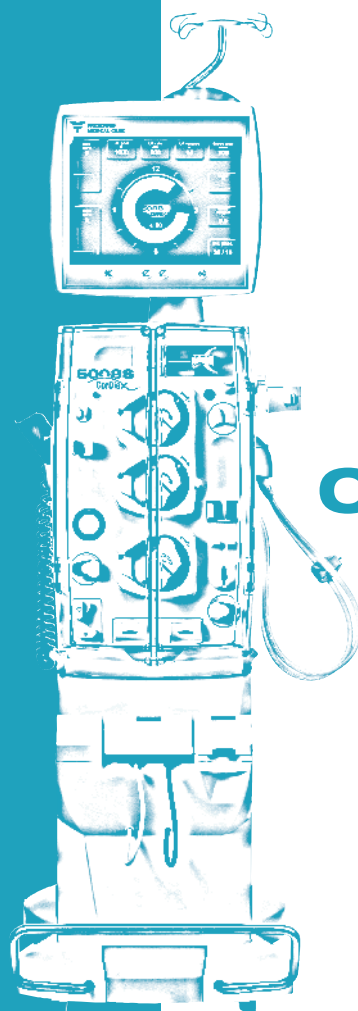


Hemodialysis

5008S

A real story of success



Volume Matters
From hemodiafiltration to
HighVolumeHDF®



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NICE 2018 guidelines recommend the consideration of in-center hemodiafiltration rather than hemodialysis

In order to provide evidence-based guidance, NICE systematically reviewed the best available renal replacement therapy studies and conducted an economic evaluation.

The assessment identified clear benefits of HDF treatment for both patients and the NHS:¹

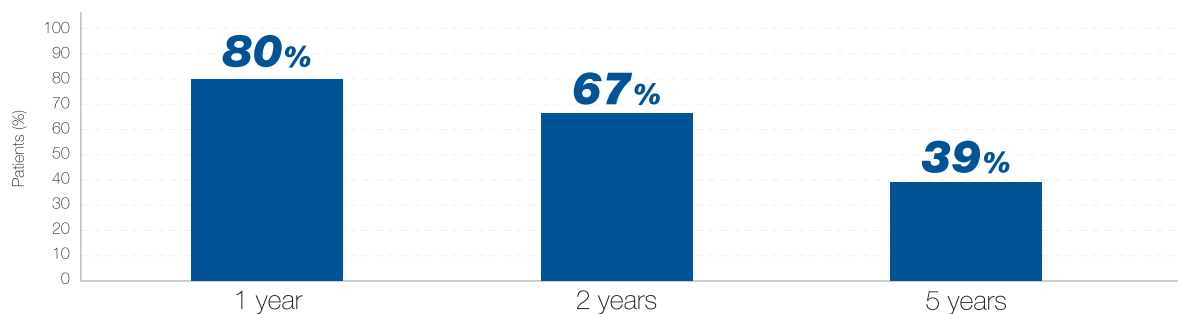
Decreased mortality rates **Cost effectiveness***

*Cost-effectiveness analyzed should always be considered in the context of relevant local healthcare system.

Survival of end-stage renal disease patients in selected countries

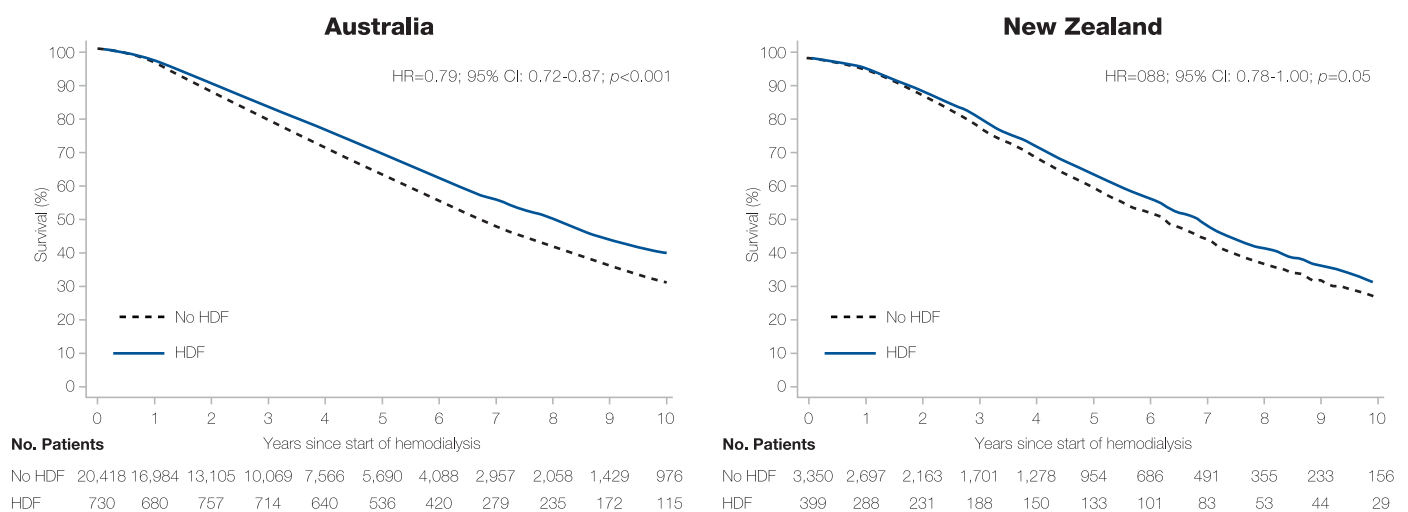
Increasing the dose or urea clearance with standard HD has not been shown to improve survival nor reduce the rate of hospitalization.³ In patients with lower residual kidney function, higher B2-microglobulin (B2-M) clearance is associated with higher survival, highlighting the importance of middle molecules clearance.⁴

Survival probability of ESRD in selected European countries²



Real-world data shows HighVolumeHDF® is associated with improved survival

Real-world data from the Australia and New Zealand Dialysis and Transplant Registry shows that HDF patients are associated with improved survival versus HD patients.⁵



Volume Matters

Peters et al. have shown that increased convection volume is associated with increased survival rate⁶

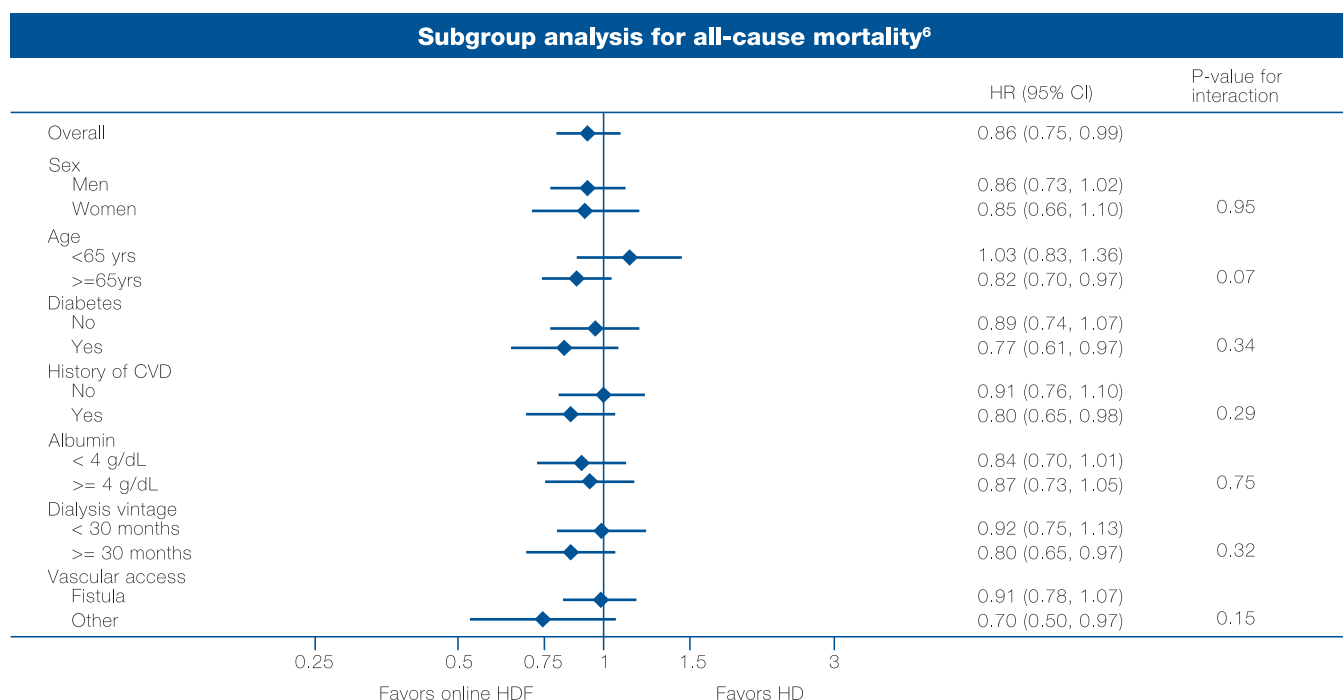
Convection Volume, L/1.73m ² per Session	HR (95% CI)	
	HD (n=1,369)	HDF (n=1,367)
All-cause mortality		
All	1.0	0.86 (0.75-0.99)
<19	1.0	0.83 (0.66-1.03)
19-23	1.0	0.93 (0.75-1.16)
>23	1.0	0.78 (0.62-0.98)
Cardiovascular mortality		
All	1.0	0.77 (0.61-0.97)
<19	1.0	0.92 (0.65-1.30)
19-23	1.0	0.71 (0.49-1.03)
>23	1.0	0.69 (0.47-1.00)

As shown in a pooled individual participant analysis of four clinical trials, online (OL)-HDF reduced the risk of:⁶

- All-cause mortality by **14%** compared with HD (HR=0.86; 95% CI: 0.75-0.99).
- Cardiovascular mortality by **23%** compared with HD (HR=0.77; 95% CI: 0.61-0.97).

The NICE guideline suggested that patients who achieved **higher convection volumes would get a greater benefit from HDF**⁷

Most patients are suitable for HighVolumeHDF®



Adapted from Peters et al.⁶

Several clinical benefits and cost effectiveness* have been associated with HighVolumeHDF®

o Improved intradialytic hemodynamic stability

May reduce intradialytic symptomatic hypotension with long-term use⁸

o Decreased inflammatory response

May be associated with decreased inflammation, with significantly lower plasma CRP levels observed⁹

o Lower serum β 2-microglobulin

Lesser increase in β 2 microglobulin with Online HDF after 36 months when compared to the HD, as shown by the **ESHOL trial**¹⁰

o Better anemia control

Can contribute to better control of anemia, with lower erythropoietin doses being used with HDF than HD, as shown by the **Turkish OL-HDF** study¹¹

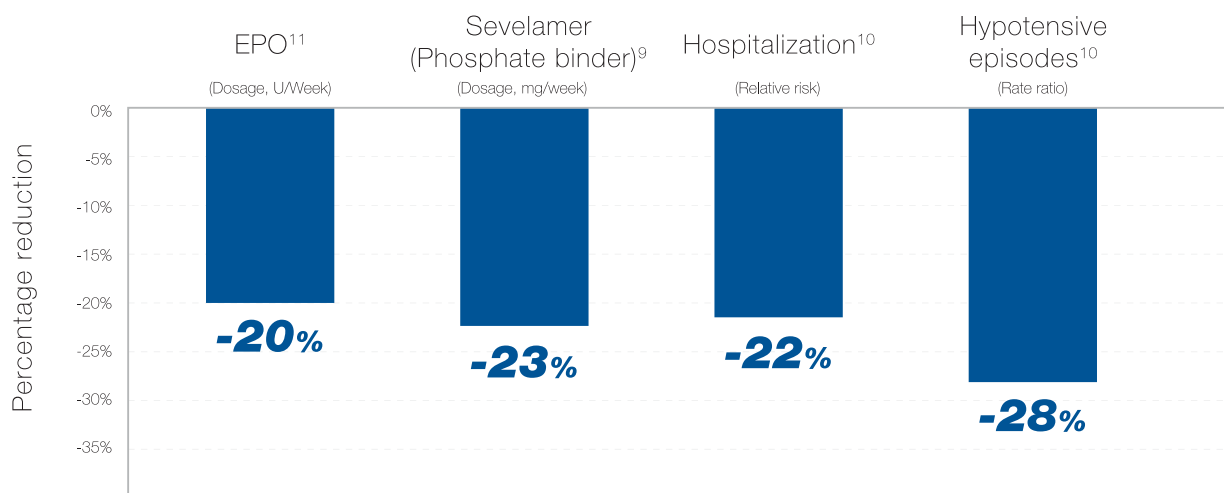
*Cost-effectiveness analyzed should always be considered in the context of relevant local healthcare system.



Cost-effectiveness* of HighVolumeHDF®

HighVolumeHDF® is associated with cost-saving potential.

In addition to direct procedure costs, hospitalization, erythropoietin (EPO) and phosphate-binder use are the main drivers for dialysis-related treatment costs. Multiple studies have shown that HighVolumeHDF is associated with a reduction of the amount of EPO and phosphate binders administered to dialysis patients⁹⁻¹¹



*Cost-effectiveness analyzed should always be considered in the context of relevant local healthcare system.

Provide a higher quality of care with a lower burden



General data

Dimensions 5008S	1,680 x 350 x 780 mm (H x W x D) at bed/dialysis chair level (width at base: 520 mm, depth with canister holder: 900 mm)
Weight	approx. 100 kg
Monitor/Screen	15" high-resolution TFT LCD with touch screen user interface. Monitor rotatable around the 3 axes
Card reader	Smart card (ICC) for Patient, User and ServiceCard
Water supply	
Water inlet pressure	1.5 – 6.0 bar
Water inlet temperature	5 – 30 °C; for "integrated hot rinse" 85 – 95 °C
Max. drain height	1 m
Flush	Rinse of water supply area (option)
Concentrate supply	
Supply pressure	0 to 100 mbar; 1 m suction height with Central Delivery System: 0.05 to 2.0 bar
Central supply	1 central acid concentrate (option)
Electrical data	
Power supply	100 to 240 V AC $\pm$ 10 %, 47 – 63 Hz
Current consumption	Approx. 6 A (at 230 V) at a water inlet temperature of 17 °C, Dialysate temperature 37 °C Dialysate flow: 500 mL/min
External connections	Alarm output: potential free alarm outlet (alternating contact max. 24 V/24 W). LAN (RJ 45) port for data exchange with Therapy Data Management System/Finesse®

Extracorporeal circuit

Arterial pressure monitoring	
Display range	- 300 mmHg to + 300 mmHg
Accuracy	$\pm$ 7 mmHg
Resolution	5 mmHg
Venous pressure monitoring	
Display range	- 100 mmHg to + 500 mmHg
Accuracy	$\pm$ 7 mmHg
Resolution	5 mmHg
Transmembrane pressure monitoring	
Display range	- 100 mmHg to + 400 mmHg
Resolution	5 mmHg
Arterial blood pump	
Blood flow range (effective)	30 to 600 mL/min
Accuracy	$\pm$ 10 %
Single-Needle system (Option)	2 blood pumps. Internal pressure/pressure control with variable stroke volume (max. 50 mL)
Air bubble detector	Ultrasound transmission measurement on blood line, additional capacitive level and optical monitoring
Heparin pump	Delivery range: 0.5 to 10 mL/h Bolus function: 1.0 up to 20.0 mL Syringe size: 20/30 mL

Dialysis fluid circuit

Dialysis fluid flow range	
Selectable	0 – 1,000 mL/min (steps of 100 mL/min)
AutoFlow (selectable)	Automatic adaptation of the dialysate flow to the effective blood flow (factors adjustable)

Abbreviations: CI=confidence interval; CRP=C-reactive protein; EPO=erythropoietin; ESRD=end-stage renal disease; HD= hemodialysis; HDF=hemo-diafiltration; HF=hemo-filtration; HR=hazard ratio; NHS=National Health Service; NICE=National Institute for Health and Care Excellence; OL-HDF=online hemodiafiltration

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1. National Institute for Health and Clinical Excellence (NICE). NICE guideline. Renal replacement therapy and conservative management. 3 October 2018. Available at: <https://www.nice.org.uk/guidance/ng107>. (Accessed: 8 November 2019). 2. ERA-EDTA-Registry. ERA-EDTA Registry Annual Report 2012. Amsterdam, The Netherlands: Academic Medical Center, Department of Medical Informatics, 2014. 3. Eknoyan, G. et al. Effect of Dialysis Dose and Membrane Flux in Maintenance Hemodialysis. *NEJM* 347, 2010–2019 (2002). 4. Cheung, A. K. et al. Serum B-2 Microglobulin Levels Predict Mortality in Dialysis Patients: Results of the HEMO Study. *JASN* 17, 546–555 (2006). 5. See, E. J. et al. Patient survival on haemodialysis and haemodiafiltration: a cohort study using the Australia and New Zealand Dialysis and Transplant Registry. *Nephrol Dial Transplant* 34, 326–338 (2019). 6. Peters, S. A. E. et al. Haemodialysis and mortality in end-stage kidney disease patients: a pooled individual participant data analysis from four randomized controlled trials. *Nephrol Dial Transplant* 31, 978–984 (2016). 7. RRT and Conservative Management Cost-effectiveness analysis: HDF versus high flux HD. National Institute for Healthcare and Excellence (2018). Available at: <https://www.nice.org.uk/guidance/ng107/evidence/costeffectiveness-analysis-hdf-versus-high-flux-hd-report-pdf-6543882397>. (Accessed: 3rd April 2020). 8. Morena, M. et al. Treatment tolerance and patient-reported outcomes favor online hemodiafiltration compared to high flux hemodialysis in the elderly. *Kidney Int* 91, 1495–1509 (2017). 9. Pedrini, L. A. et al. Long-term effects of high-efficiency on-line haemodiafiltration on uraemic toxicity. A multicentre prospective randomized study. *Nephrol Dial Transplant* 26, 2617–2624 (2011). 10. Maduell, F. et al. High-Efficiency Postdilution Online Hemodiafiltration Reduces All-Cause Mortality in Hemodialysis Patients. *Am Soc Nephrol* 24, 487–497 (2013). 11. Ok, E. et al. Mortality and cardiovascular events in online haemodiafiltration (OL-HDF) compared with high-flux dialysis: results from the Turkish OL-HDF Study. *Nephrol Dial Trans* 28, 192–202 (2013).

For additional information about the product please reach out to FME India Representative or reach us at www.freseniusmedicalcare.asia or e-mail us at CEMarketing.India@freseniusmedicalcare.com



**FRESENIUS
MEDICAL CARE**

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EcoFlow	Stand-by flow of 100/150 mL/min (HD/HDF) during preparation and reinfusion
Dialysis fluid temperature	34 – 39 °C
Dialysis fluid conductivity	
Range	12.8 – 15.7 mS/cm
Accuracy	$\pm$ 0.1 mS/cm
Sodium concentration dialysis fluid	
Mixing ratio	Freely adjustable e.g. 1 + 44, 1 + 34
Adjustment range	125 to 151 mmol/L, depending on the concentrate used $\pm$ 10 % of the base value
Bicarbonate concentration dialysis fluid	
Default mixing ratio	1 + 27.6 (others possible)
Adjustment range	24.0 – 40.0 mmol/L (steps of 0.5 mmol/L)
Bicarbonate dry concentrate	bibag®
Balancing accuracy	$\pm$ 0.1 % related to the total dialysate volume
Pressure holding test	Event controlled
Ultrafiltration	
UF rate	0 – 4,000 mL/h (in steps of 10 mL)
Pump volume accuracy	$\pm$ 1 %
Parameters displayed	UF goal, UF time, UF rate, UF volume
Blood leak detector	
Sensitivity	$\leq$ 0.5 mL blood/min (Hct = 25 %) flow rate 100 mL/min – 1,000 mL/min
Dialysis fluid filter system	DIASAFE®plus
ONLINEplus	
Substitution rate	25 – 600 mL/min
Accuracy	$\pm$ 10 %
AutoSub	Substitution ideally matched to effective blood flow
OCM®	
Accuracy Clearance K	Online Clearance Monitoring $\pm$ 6 %
BPM (Option)	
Display range	Systole: 30 mmHg – 280 mmHg Diastole: 10 mmHg – 240 mmHg MAP: 20 mmHg – 255 mmHg $\pm$ 3 mmHg
Accuracy	
BTM (Option)	
Temperature measurement	Accuracy $\pm$ 0.2 °C
Body temperature control	Allowed change rate $\pm$ 0.5 °C/h
Recirculation measurement	Accuracy $\pm$ 2 %
Disinfection and cleaning programmes*	
Rinse	
Temperature/flow	37 °C/600 – 800 mL/min (adjustable)
Hot rinse (recirculation)	
Temperature/flow	85 °C/600 – 800 mL/min (adjustable)
Cleaning Sporotal® 100 (recirculation)	
Temperature/flow	37 °C/600 – 800 mL/min (adjustable)
Heat disinfection Diasteril®/Citrosteril® (recirculation)	
Temperature/flow	85 °C/600 – 800 mL/min (adjustable)
Disinfection Puristeril® 340/plus (recirculation)	
Temperature/flow	37 °C/600 – 800 mL/min (adjustable)

*Various programme combinations selectable. Technical changes reserved.

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