Protecting the Endothelium

5008S

Opening a world of possibilities

FRESENIUS MEDICAL CARE

THE RENAL COMPANY

A LIFELONG COMMITMENT

From Promise to Proof

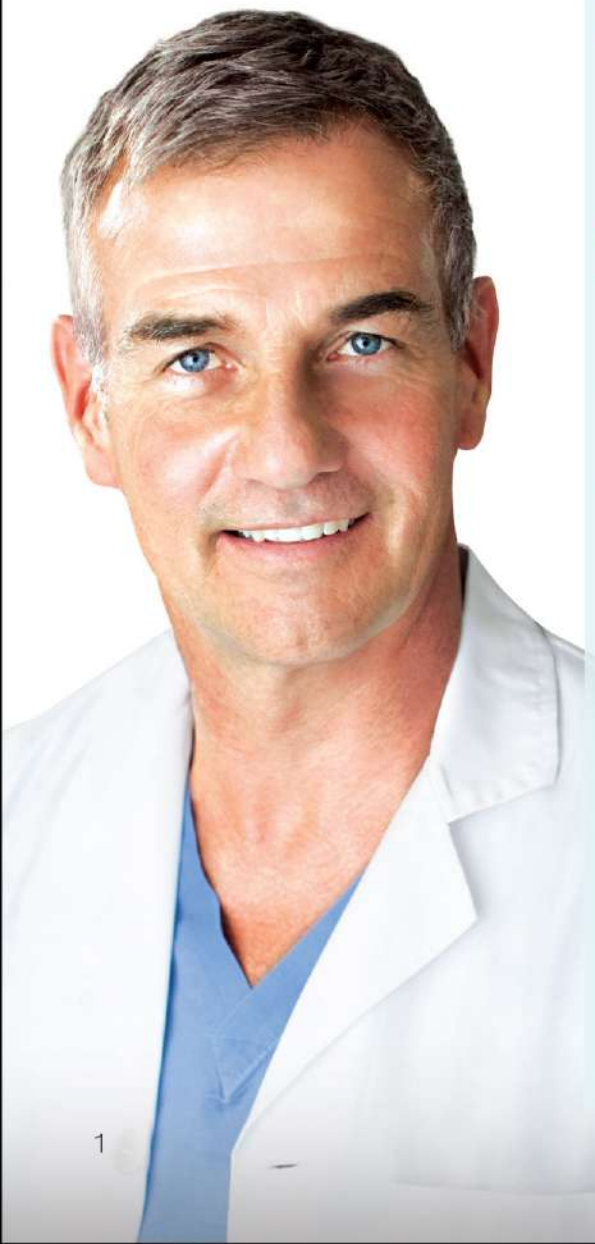
HighVolume**HDF improves survival**

HighVolume**HDF** with its numerous positive effects on dialysis-related cardiovascular risk factors is acknowledged as the most effective dialysis treatment modality[1], coming closer to the elimination profile of the natural kidney.

By achieving high substitution volumes, HighVolume**HDF** therapy is credited with more effective elimination of middle molecules. HighVolume**HDF** improves patient outcomes and exerts beneficial effects on the main cardiovascular risk factors:

- Serum β_2-m and phosphate level[2, 3, 4]
- Inflammatory response[5]
- Intradialytic haemodynamic stability[6]
- Anaemia control[7]

These factors contribute to better quality of life and improved patient survival.[8]



The Catalonian HighVolume**HDF study**

The Catalonian HighVolume**HDF** study data are clearly impressive — confirming our original conviction that every patient should get the chance to benefit from HighVolume**HDF**.

Improved Survival

30% risk reduction in all-cause mortality
p=0.01

33% risk reduction in cardiovascular mortality
p=0.06

55% risk reduction in mortality from infection
p=0.03

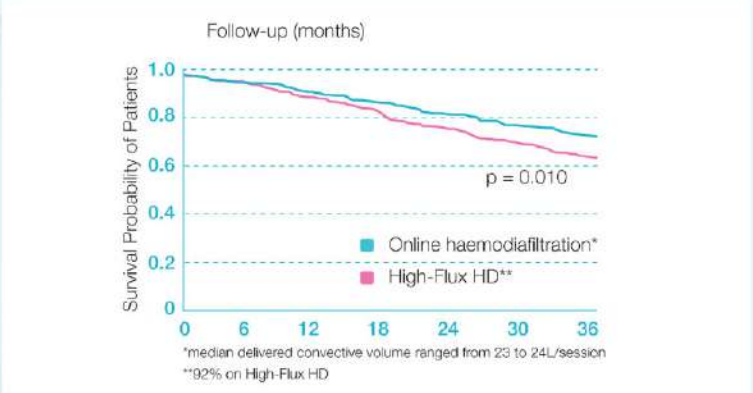
61% risk reduction in mortality from stroke
p=0.03

Better patients' well-being

28% risk reduction in incidence of hypotensive episodes
p<0.001

Reduced treatment costs

22% risk reduction in all-cause hospitalisation
p=0.001



*median delivered convective volume ranged from 23 to 24L/session
**92% on High-Flux HD

HighVolume**HDF is Fresenius Medical Care**

The standard in cardioprotective haemodialysis

In order to achieve the full benefits of HDF therapy large convective volumes in post-dilution mode are required. In the past many users were concerned that these high volumes may lead to excessive haemoconcentration and subsequently high transmembrane pressures if the treatment settings are not continuously monitored and adjusted.

AutoSub *plus* – Automatically maximising substitution volumes for HighVolume**HDF**

The innovative AutoSub *plus* system is much more than just another automatic pressure control:

- Very precise information on the conditions in the dialysers is available – not just across the membrane but also along the blood flow pathway
- Several checks per minute enable the continuous optimization of the substitution rates
- The system is automatically activated at the start of treatment

AutoSub *plus* supports the nephrologist in to establishing HighVolume**HDF** as standard therapy.

vAm
VENOUS ACCESS MONITOR (VAM)

Safety creates confidence

In particular during HighVolume**HDF** where high blood flows are aspired for, monitoring of the venous access is essential as a blood loss would become critical within a very short time.

VAM increases the probability of early detection of venous needle dislodgement.

VAM makes a permanent contribution to superior patient safety by monitoring the most sensitive point of dialysis – the venous access.

References

1. Krick G., Ronco C. (eds), Contrib Nephrol. (2011); 175: 93-109.
2. Canaud B., Contrib Nephrol (2007); 158: 216-224..
3. Penne L. et al., Clin J Am Soc Nephrol (2010); 5: 80-86.
4. Davenport A., Nephrol Dial Transplant (2010); 25: 897-901.
5. Pedrini L. et al., Nephrol Dial Transplant, advanced access published Jan 18, 2011.
6. Locatelli F. et al., J Am Soc Nephrol (2010); 21: 1798-1807.
7. Bonforte G. et al., Blood Purif (2002); 20: 357-363.
8. Maduell F. et al., J Am Soc Nephrol (2013); 24: 487-497.

Cardioprotection – at the heart of long-term haemodialysis

Almost one in two patients with ESRD dies as a result of cardiovascular disease. That is why Cardioprotective Haemodialysis is a core principle of Fresenius Medical Care, as we work and strive to solve the challenges of modern dialysis. Each step we take is focused on minimising cardiovascular risks and extending patients' lives.

The 5008S offers premium therapy options and excellent usability combined with the optimal use of dialysis-relevant resources. The 5008S helps you protect your patients – everyday, every treatment.

1 ONLINE CLEARANCE MONITORING (OCM®)

Assures adequacy of delivered dialysis dose (Kt/V) in accordance with standards[1,2]

2 BLOOD PRESSURE MONITOR (BPM)

Fully automated and non-invasive blood pressure monitoring (systolic & diastolic blood pressure, MAP, pulse)

3 BLOOD TEMPERATURE MONITOR (BTM)

Ensures constant core body temperature for a better haemodynamic stability during dialysis[3]

References

1. European Best Practice Guidelines for Haemodialysis (Part 1) (2002); 17 (suppl 7): 17-31.
2. Tattersall J. et al., Nephrol Dial Transplant (2007); 22 (suppl 2): ii5-ii21.
3. Maggiore Q. et al., Am J Kidney Dis (2002); 40 (2): 280-290.

5008S

Opening a world of possibilities

The 5008S Therapy System allows you to deliver the full benefits of Cardioprotective Haemodialysis – everyday, for every patient.

vAm

VENOUS ACCESS MONITOR (VAM)

Optimised monitoring of the venous path increasing the probability of early detection of venous needle dislodgement

VenAcc

EXTERNAL WIRELESS WETNESS DETECTOR

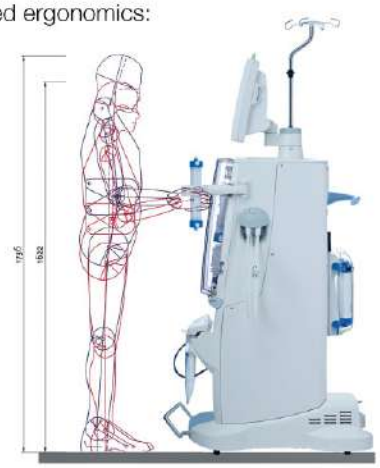
Special wetness detector for the quick detection of blood loss, especially in patients undergoing home or nocturnal dialysis as well as restless or confused patients

Fully Integrated Patient Surveillance Systems

Best Handling

Tailor-made to meet the needs of all operators

Optimised ergonomics:



The ergonomic handling of the 5008S assures outstanding usability and high convenience for the user

Individually adjustable, freely rotable flat-screen monitor (15" TFT) for perfect readability from every angle

Optimised 5008 bloodline system: easy, machine-assisted set-up & dismantling

Simple, one-handed and hygienic connection of bi*bag*® (dry bicarbonate supply)

Well-designed user interface

The central navigation system of the 5008S follows an "intuitively correct" user-guidance philosophy for the nursing staff:

- Centralised operation and information via a spacious touchscreen display
- Simple and logical data entry
- Sophisticated, stress-free handling of alarms during treatment
- Quick access to treatment information

Comfortable handling due to automated workflows

The 5008S ensures optimised workflows for all operators that complement and integrate into their daily routines:

- Graphical-assisted preparation screens
- Self-initiating functions at start of treatment
- Self-evident program settings minimize operational errors
- ONLINE Priming and ONLINE Bolus make saline solutions redundant
- Emergency button initiating four essential steps at once (blood flow reduction, ONLINE Bolus, stop UF-rate and start blood pressure measurement)
- Timer function for setting a reminder of a definable task
- Interface Heat Disinfection (IHD) cleans and disinfects the interface between RO-ring and dialysis machine with hot water (in accordance with ISO 23500)*

Easy-to-use therapy features thanks to ergonomic handling and safe data management

Easy, rapid and safe data management

Therapy documentation and data management are important processes in the daily treatment of dialysis patients. Fresenius Medical Care provides:

- Retrospective treatment data documentation available directly on the 5008S
- Individualised therapy by error-free prescription of treatment-relevant data and reliable documentation:
  - with PatientCard (current and previous three treatments of individual patients)
  - via Therapy Data Management System (TDMS)
- Advanced bed side monitoring via touchscreen in combination with TDMS

* requires heat-resistant RO-system such as AquaA HT or AquaC Uno H

Optimal use of resources

Efficient and sustainable

It is not only the advanced treatment options that make the 5008S unique, but also its eco- friendliness: with the 5008S, Fresenius Medical Care supports the sensible and sustainable use of resources by saving dialysate, water and energy. This in turn leads to significant cost savings.

- **ONLINE*plus*** technology for production of sterile, endotoxin-free and bicarbonate-buffered electrolyte solutions*
  - Extensive amounts of substitution fluid for HDF available
  - Eliminate the need for ready-made rinse solutions – priming, reinfusion and bolus with online fluid in all treatment modes (also in HD)

- **AutoFlow** automatically adjusts the dialysate flow rate to the effective blood flow rate during treatment
  - Substantial saving of water, waste water, concentrates and energy, leading to significant cost reductions (figure 1)
  - Automatic selection of AutoFlow factor based on treatment mode, always accomplishing an optimal ratio between economic considerations and treatment quality

- **EcoFlow** for minimised dialysate and energy consumption during preparation and after reinfusion while avoiding bacterial growth

- Highly efficient heat exchanger for a lower carbon-footprint:
  - Utilising the energy of waste dialysate to heat the incoming water
  - Power savings of up to 40% significantly reduce the annual emission of CO_2

- For a typical dialysis centre# the annual reduction of CO_2 emissions and the saving of energy and water are equal to the daily consumption and emissions of a town with around 7,500 inhabitants##

Dialysate flow savings with AutoFlow in ONLINE HDF without compromising K_{urea}

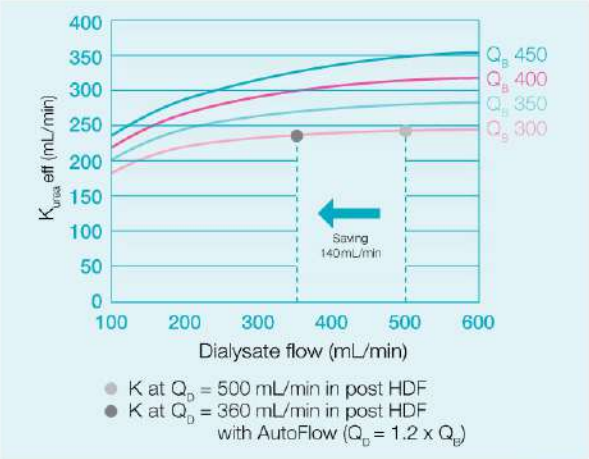


Figure 1: Internal data: Post-dilution ONLINE HDF with FX CorDiax 600
Hct = 35 %; Recirculation = 5 %

* in accordance with ISO 23500:2011 and ISO 11663:2009
\# dialysis centre with 25 machines
\## data on file, Fresenius Medical Care

The 5008S – Combining sustainability and cost-effectiveness for highest efficiency

Unmatched service-friendliness

- Interactive, real-time hydraulic flow chart for rapid error diagnosis and easy maintenance
- Superior accessibility to all hydraulic and electronic parts in and around the machine
- Simple repair using "snap-lock" technology – fast and easy exchange of components
- Easy and comprehensive diagnosis of faults and detailed technical error memory with Service Software and Service Card
- High reliability due to long-lasting components, which are readily available should they need replacing

Product Configuration

Product Configuration – 5008S

	5008S
Therapy highlights	
HighVolumeHDF® – pre- and post-dilution	● / ●
AutoSub *plus* – automatically maximising substitution volumes in a highly safe manner	●
HighVolumeHDF® during Single Needle treatment	○
Blood Temperature Monitor (BTM) – regulation of temperature and recirculation measurement	○
Home Haemodyalisis – Advanced therapies for home patients	○
Safety features	
Integrated Venous Access Monitor – increased probability of detection of venous needle dislodgement	●
Dynamic Pressure Monitoring – detection of paravasal bleeding ("infiltration")	●
VenAcc external device for detection of venous needle disconnection	○
Basic features	
Dialysis fluid ultrafilter system – sterile and non-pyrogenic fluid for ONLINE use	●
ONLINE Priming, bolus and reinfusion in HD / HDF / SN – no saline required in all treatment modes*	● / ● / ●
OCM® Kt/V Measurement with transfer of V from BCM-Body Composition Monitor in HD / HDF	● / ●
Single-needle double-pump	○
PatientCard – prescription and documentation of treatment parameters	●
Interface heat disinfection – fulfilling all requirements of ISO 23500	●
Advanced service tools for fast diagnostic and maintenance with interactive hydraulic and pneumatic flow charts and remote access	●
Compliance to latest requirements of IEC 60601	●
Timer function for setting a reminder of a definable task	●
Eco-friendly features	
Heat exchanger with high efficiency	●
AutoFlow – automatic adaptation of dialysate flow for optimal balance of dialysate consumption and treatment efficiency	●
EcoFlow – water and energy saving during standby conditions.	●
(For more details please refer to the Technical Data)	● = *standard*, ○ = *optional*

* safety advice: It is recommended that you stock sodium chloride in case it might be required

Best therapies

Advanced therapy options such as HighVolume**HDF** enable Cardioprotective Haemodialysis – for best possible patient outcomes

Best handling

Sophisticated design guarantees outstanding usability and convenient handling for all users

Optimal use of resources

Efficient and sustainable use of dialysis- relevant resources result in excellent cost- effectiveness

Advanced therapies for home patients

Dialysis therapy has a huge impact on the quality of life of a patient. That is why Fresenius Medical Care is striving to develop the best possible therapies and make them accessible for all patients. The 5008S with its specially tailored home version offers the full benefits of ONLINE HDF combined with our highest safety features and easy handling for self care or home treatment.

- ONLINE HDF with the FX CorDiax dialysers for highly efficient toxin removal with fully automatic adjustment of substitution rates (AutoSub *plus*), without the need for user intervention
- Venous Access Monitor (VAM) and optional wetness detector (VenAcc device) for optimal monitoring of venous access
- Special user interface adapted to the patient's needs

Easy and safe handling for the patient

When a dialysis patient performs the treatment by himself, different aspects gain in importance. What counts most are confidence about safety and therapy efficiency and easy usability.

Taking this into account the 5008S meets the needs of a home dialysis patient perfectly:

- Specific patient screen for easy and fast access to the relevant treatment fuctions, e.g. blood flow, alarm handling or UF settings
- Dimmable screen for undisturbed nocturnal dialysis
- Rotatable monitor for good visbility of treatment parameters
- Induction-loaded remoted control for simplifed operation of the main functions (acoustic and visual) with 'find key function'
- Romote control including an emergency button which gives the patients the possiblity to react immediately in a critical situation (e.g. blood pressure drop)
- ONLINE priming for simple preparation of the extracorporeal circuit without saline bags

Simplifed screen for control of key treatment parameters

Technical Data 5008S

General data	
Dimensions 5008S CorDiax	1,680 x 350 x 780 mm (H x W x D) at dialysis chair/bed level (width at base: 520 mm, depth with canister holder: 900 mm)
Weight	approx. 114 kg
Water supply	
Water inlet pressure	1.5 to 6.0 bar
Water inlet temperature	5 to 30 °C; for "integrated hot rinse" 85 to 95°C
Max. drain height	1 m
Flush (optional)	Rinsing of the water supply area
Concentrate supply	
Supply pressure	0 to 100 mbar; 1 m max. suction height with Central Delivery System (CDS): 0.05 to 2.0 bar 2 central acid concentrates (optional)
Electrical data	
Power supply	100 to 240 V AC ± 10%, 50 to 60 Hz
Current consumption	Approx. 6A (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. 24V/24 W). LAN (RJ 45) port for data exchange with Therapy Data Management System (optional)

Extracorporeal circuit	
Arterial pressure monitoring	
Display range	-300 mmHg to +300 mmHg
Accuracy	± 7 mmHg
Resolution	5 mmHg
Alarm reaction	dynamic, static, immediate
Venous pressure monitoring	
Display range	-100 mmHg to +500 mmHg
Accuracy	± 7 mmHg
Resolution	5 mmHg
Arterial blood pump	
Blood flow range	30 to 600 mL/min
Accuracy	± 10 %
Resolution	10 mL/min
Single needle system (optional)	With 2 blood pumps, internal pressure/pressure control with variable stroke volume (max. 60 mL/min)
Air bubble detector	Ultrasound transmission measurement on blood line, additional capacitive level and infrared optical monitoring
Heparin pump	Delivery range: 0.5 to 10 mL/h Bolus function: 1.0 to 20.0 mL Syringe size: 20 mL, 30 mL

Dialysis fluid circuit	
Dialysis fluid flow range	
Selectable	0 to 1000 mL/min (steps of 100 mL/min)
AutoFlow (selectable)	Automatic adaptation of the dialysate flow to the effective blood flow
EcoFlow	Stand-by flow during preparation and after reinfusion
Dialysis fluid temperature	34 to 39 °C
Dialysis fluid conductivity	
Range	12.8 to 15.7 mS/cm
Accuracy	± 0.1 mS/cm
Resolution	0.1 mS/cm
Dialysis fluid acid component	
Mixing ratio	Adjustable, e.g. 1+44, 1+34
Adjustment range	125 to 151 mmol/L, depending on the concentrate used ± 10 % of the base value
Dialysis fluid bicarbonate component	
Default mixing ratio	1+27.6 (others possible)
Adjustment range	20.0 to 40.0 mmol/L (depending on the concentrate used; steps of 0.5 mmol/L)
OCM®	Online Clearance Monitoring
Accurate Clearance K	± 6 %
Bicarbonate dry concentrate	bi*bag*®
ONLINEplus	
Dialysis fluid filter system	DIASAFE® *plus*
Online Haemo(dia)filtration	
Substitution rate	25 to 600 mL/min
Accuracy	± 10 %
Balancing accuracy	± 0.1 % related to the total dialysate volume
Pressure holding tests	Event controlled
Ultrafiltration	
UF rate	0 to 4000 mL/h (in steps of 10 mL)
Pump volume accuracy	± 1 %
Parameters displayed	UF goal, UF time, UF rate, UF volume
Blood leak detector	
Sensitivity	≤ 0.5 mL blood/min (Hct = 25 %) flow rate 100 mL/min to 1000 mL/min
BTM (optional)	
Temperature measurement	Accuracy ± 0.2 °C
Body temperature control	Allowed change rate ± 0.5 °C/h
Recirculation measurement	Accuracy ± 2 %
BPM (optional)	
Display range	Systole: 30 mmHg to 280 mmHg Diastole: 10 mmHg to 240 mmHg MAP: 20 mmHg to 255 mmHg Pulse: 20 to 245 1/min
Accuracy	± 3 mmHg
Resolution	1 mmHg

Disinfection and cleaning programmes*	
Rinse	
Temperature/flow	37 °C / 600 to 700 mL/min (adjustable)
Hot rinse (recirculation)	
Temperature/flow	85 °C / max. 600 mL/min
Flow for cool down rinse	600 to 700 mL/min (adjustable)
Cleaning Sporotal® 100 (recirculation)	
Temperature/flow	37 °C / 600 to 700 mL/min (adjustable)
Heat disinfection Diasteril®/Citrosteril® (recirculation)	
Temperature/flow	85 °C / 600 to 700 mL/min (adjustable)
Cold disinfection Puristeril® 340/plus (recirculation)	
Temperature/flow	37 °C / 600 to 700 mL/min (adjustable)

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