Protecting the Endothelium

5008S
Opening a world of possibilities

FRESENIUS MEDICAL CARE
THE RENAL COMPANY
A LIFELONG COMMITMENT
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, 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 β₂-m and phosphate level
- Inflammatory response
- Intradialytic haemodynamic stability
- Anaemia control

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

The Catalanian HighVolume HDF study

The Catalanian 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

Follow-up (months)

- Survival Probability of Patients

  Follow-up (months)

  - p = 0.010

  - Cardio Haemodialysis*
  - High-Flux HD**

*median delivered convective volume ranged from 23 to 24L/session
**52% 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.

References
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.

References
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 rotatable 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 bibag® (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, 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 bedside monitoring via touchscreen in combination with TDMS

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

- **ONLINEplus** 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 CO₂

- For a typical dialysis centre the annual reduction of CO₂ 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_era**

![Graph showing dialysate flow savings with AutoFlow](image)

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

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* in accordance with ISO 23500:2011 and ISO 11663:2009
* dialysis centre with 26 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 – 5008S

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<td>HighVolumeHDL® – pre- and post-dilution</td>
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<td>AutoSub:plus – automatically maximising substitution volumes in a highly safe manner</td>
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<td>HighVolumeHDL® during Single Needle treatment</td>
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<td>YenAcc external device for detection of venous needle disconnection</td>
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<tr>
<td>ONLINE Printing, bolus and reinfusion in HD / HDF / SN – no saline required in all treatment modes*</td>
<td>●/●/●</td>
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<tr>
<td>OCM® KUV Measurement with transfer of V from BCM Body Composition Monitor in HD / HDF</td>
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<td>Single-needle double pump</td>
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<td>PatientCard – prescription and documentation of treatment parameters</td>
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<td>Interface heat disinfection – fulfilling all requirements of ISO 23550</td>
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<td>Advanced service tools for fast diagnostic and maintenance with interactive hydraulic and pneumatic flow charts and remote access</td>
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<td>Compliance to latest requirements of IEC 60601</td>
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<td>Timer function for setting a reminder of a definable task</td>
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*For more details please refer to the Technical Data*

● = standard, ○ = optional

* safety advice: It is recommended that you stock sodium chlorides 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 CorDiex 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 (VenAco 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 functions, e.g. blood flow, alarm handling or UF settings
- Dimmable screen for undisturbed nocturnal dialysis
- Rotatable monitor for good visibility of treatment parameters
- Induction-loaded remote control for simplified operation of the main functions (acoustic and visual) with ‘find key function’
- Remote control including an emergency button which gives the patients the possibility to react immediately in a critical situation (e.g. blood pressure drop)
- ONLINE priming for simple preparation of the extracorporeal circuit without saline bags

Simplified 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) 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 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 VAC ± 10%, 50 to 60 Hz
- **Current consumption**: Approx. 0.8 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 output (alternating contact max. 24 V/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 +200 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: 1 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 AutoFlow (selectable)
- **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 to 40 mmol/L, (depending on the concentrate used; steps of 0.5 mmol/L)

#### ONLINEplus
- **Dialysate fluid filter system**: DIASAFE™ plus
- **Online Hemodiafiltration**: Substitution rate: 25 to 600 ml/min; Accuracy: ± 10%
- **Balancing accuracy**: ± 0.1% related to the total dialysate volume

#### 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**: Systolic: 30 mmHg to 260 mmHg
- **Diastolic**: 10 mmHg to 240 mmHg
- **Max.**: 200 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/600 to 700 ml/min (adjustable) |
| Cleaning Sporotol® 100 (recirculation) | Temperature/flow: 37°C/600 to 700 ml/min (adjustable) |
| Heat disinfection Diasterol®/Citrolister® (recirculation) | Temperature/flow: 85°C/600 to 700 ml/min (adjustable) |
| Cold disinfection Puristerol® 340/plus (recirculation) | Temperature/flow: 37°C/600 to 700 ml/min (adjustable) |