Cardioprotective Haemodialysis

4008S classix

Quality treatment to suit your budget

Cardioprotective Haemodialysis SPOT

FRESENIUS MEDICAL CARE

Protect your Patient

Cardioprotective Haemodialysis

The reduction of risk factors for cardiovascular diseases (CVD) is core to the development of dialysis systems and products at Fresenius Medical Care. Outstanding cardioprotection must be reflected in all levels of product development and application.

Wide-ranging cardioprotection

There have been tremendous improvements in the quality and efficacy of haemodialysis (HD) therapy in recent years. Despite this, cardiovascular diseases (CVD) remain the leading cause of death for patients with end-stage renal disease (ESRD).

Cardioprotective

Services

Over 30 years of experience in dialysis at your service.

- Project Planning and Consulting
- Training and Education
- Technical Services
- Water Quality Service (WQS)
- Medical Information Services

Products

State-of-the-art technologies enable advanced cardioprotective therapies.

- CorDiax product line:
  - 5008 CorDiax and 5008S CorDiax
  - FX CorDiax haemo*dia*filter
  - BCM-Body Composition Monitor
- Classix product line:
  - 4008S classix
  - FX classix dialysers
- Therapy Data Management System (TDMS)
- Online Purification Cascade (OPC)

Moreover, both overall and cardiovascular mortality are markedly greater in ESRD patients than in the general population. This is why we put Cardioprotective Haemodialysis on the SPOT. A comprehensive approach that includes services, products and therapies is needed to achieve the best therapeutic performance – meaning improved clinical outcomes and better quality of life, enhanced control of therapy costs, and simpler, safer handling.

Haemodialysis

Outcomes

Achieving better outcomes with cardioprotective therapies.

- Reduced mortality risk
- Fewer cardiovascular complications
- Optimised use of resources

Therapies

Cardioprotective therapies designed by the world market leader in haemodialysis.

- High-Flux dialysis
- HighVolume**HDF**®
- Advanced Fluid Management

Protect your Patient

Cardioprotection – at the heart of long-term haemodialysis

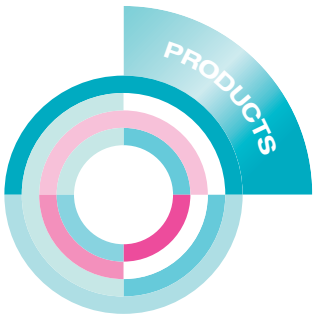
Both, chronic kidney disease (CKD) and dialysis itself can lead to cardiovascular alterations such as atherosclerosis and left ventricular hypertrophy (LVH).
Even though the quality and efficacy of haemodialysis therapy have greatly improved in recent years, cardiovascular disease (CVD) remains the leading cause of death in haemodialysis patients.

Fresenius Medical Care's mission is to enable nephrologists to provide the best possible therapy for their long-term haemodialysis patients, in order to minimise the risk of CVD.

We strive to continuously refine and develop new dialysis therapies and products to improve the clinical outcomes of dialysis patients. We set the standards for both convective therapies and standard haemodialysis as we are fully aware of our responsibility to provide high quality treatment no matter if HDF or HD.

The 4008S classix allows you to utilise the benefits of Cardioprotective Haemodialysis and continues the outstanding success of the 4008 series.
It combines technological enhancement with a clear emphasis on delivering the highest quality HD treatment, while maintaining its proven reliability and cost-efficiency. The 4008S classix fulfils this promise with its fundamental features:

- Online assessment of dialysis efficiency and dose (OCM®)
- Ultrapure dialysis fluid (DIASAFE® *plus*)
- Hygienic dry bicarbonate concentrate supply (bi*b*ag®)



SPOT on:

Cardioprotective
Haemodialysis set
as standard by:

- OCM®
- DIASAFE® *plus*
- bi*bag*®

Protect your Patient

Assuring quality in operations

Operational efficiency

Haemodialysis involves a large number of demanding manual operations all around the haemodialysis machine. The ergonomic design and the logical operating structure of the 4008S classix permit easy handling as well as fast and intuitive programming of the treatment parameters. Important treatment values are represented graphically on the 10.4” TFT-LCD monitor, which supports easy comprehension of the ongoing treatment, and provides a fast overview of the treatment history. The Blood Pressure Monitor (BPM) is fully integrated, which further simplifies handling for the therapy providers.

In combination with the Therapy Data Management System (TDMS) daily dialysis practice can be organised in a more effective and efficient manner taking full advantage of an online data acquisition and management tool.

OCM® – Online Clearance Monitor

In the meantime numerous studies have demonstrated that morbidity and mortality rates are closely correlated to the delivered dialysis dose. [1, 2]

The Online Clearance Monitor (OCM®) enables the continuous monitoring of:

- The effective in-vivo urea clearance (K)
- The accumulated cleared plasma (Kt) or the current dialysis dose administered (Kt/V)
- The plasma sodium concentration: possible deviations to the prescribed therapy goal can be detected and corrected immediately during treatment* without incurring additional expenses for disposables or staff efforts

The non-invasive and precise Kt/V assessment is consistent with conventional blood sample-based methods enabled by urea distribution volume V measured with the BCM-Body Composition Monitor. [3]

* OCM measurement is not possible in Single needle and ISO-UF mode

Settings for Blood Pressure Monitor (BPM)

Settings for Online Clearance Monitor (OCM®)

Delivering quality in therapy

DIASAFE® *plus* – Dialysis Fluid Filter

The quality and purity of the dialysis fluid are of major concern in modern-day renal replacement therapies, as large volumes of dialysis fluid come into contact with the patient's bloodstream during each treatment. Endotoxins present in contaminated dialysis fluid may elicit undesirable acute reactions and influence the long-term outcome of patients on chronic haemodialysis.

The DIASAFE® *plus* dialysis fluid filter enables the safe production of ultrapure dialysis fluid. This is attributed to the excellent endotoxin-retention capabilities of its Fresenius Polysulfone® fibres and an intelligent safety concept, based on:

- Functional control of filter integrity
- Automatic surveillance of filter lifetime
- Aseptic connection technology

Ultrapure dialysate fluid is acknowledged to be an integral part of all contemporary dialysis equipment.

Naturally the DIASAFE® *plus* is an essential part of the basic configuration of all current Fresenius Medical Care dialysis machines.

bi*b*ag® – Dry Bicarbonate Concentrate

To avoid the potential risk of microbiological contamination through liquid bicarbonate concentrate, the bicarbonate buffer is always supplied as a dry substance.

In addition to this excellent hygienic standard, the bi*b*ag® is characterised by:

- Easy and ergonomic handling
- Minimum storage space required
- Ecological benefits due to reduced waste volume and less transport weight

1. Hakim R, Breyer J, Ismail N, Schulmann G: Effects of dose of dialysis on morbidity and mortality. Am J Kidney Dis (1994); 23:661-669
2. Port F, Ashby V, Dhingra R, Roys E, Wolfe R: Dialysis dose and body mass index are strongly associated with survival in hemodialysis patients. J Am Soc Nephrol (2002); 13:1061-1066
3. Lindley EJ, Chamney PW, Wuepper A, Ingles H, Tattersall JE, Will EJ: A comparison of methods for determining urea distribution volume for routine use in on-line monitoring of haemodialysis adequacy. Nephrol Dial Transplant (2009); 24(1):211-6

DIASAFE® *plus* – Dialysis Fluid Filter

bi*b*ag® – Dry Bicarbonate Concentrate

Protect your Patient

Quality treatment to suit your budget

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 4008S classix continues the success story of the well known 4008 series, by combining best quality HD treatment, proven reliability and operational efficiency.

Proven quality

The latest member of a long established and highly successful 4008 series

- Advanced dialysis fluid circuit with highly-precise volumetrically controlled ultrafiltration
- Consistently reliable hydraulics

Advanced treatment

High-quality HD treatment to protect your patient

- OCM® (Online Clearance Monitor)
- DIASAFE® *plus* (Dialysis Fluid Filter)
- bi*b*ag® (Dry Bicarbonate Concentrate)
- Single needle or SN Click-Clack
- ISO-UF programme

Operational efficiency

Cost effective use of resources

- Easy, fast and intuitive handling
- TDMS (Therapy Data Management System)
- BPM (Blood Pressure Monitor)
- CDS (Central Concentrate Delivery System)

Protect your Patient

Proven quality
The latest member of a long established and highly successful 4008 series

Advanced treatment
High-quality HD treatment to protect your patient

Operational efficiency
Cost effective use of resources

Technical Data 4008S classix

General data	
Dimensions 4008S	1370 x 500 x 650 mm (H x W x D) (including shunt interlock and pedestal)
Weight	approx. 86 kg
Water supply	
Water inlet pressure	1.5 to 6.0 bar
Water inlet temperature	5°C to 30°C; for "integrated hot rinse" 85°C to 95°C
Max. drain height	1 m
Concentrate supply	
Supply pressure	0 to 100 mbar; 1 m max. suction height
Central supply	1 central acid concentrate (optional)
	0 to 500 mbar
Electrical data	
Power supply	100 to 240 V AC, 50 to 60 Hz
Current consumption	Approx. 9 A (at 230 V) and 15 A (at 110 V)
External connections	Network interface for data exchange with Therapy Data Management System (optional); input/output for connection of external auxiliary equipment; alarm input/output (e.g. for nurse call); diagnosis for in-house computer diagnosis
Battery	18 V; 3 Ah (maintenance free)
Extracorporeal circuit	
Arterial pressure monitoring	
Display range	- 300 mmHg to + 280 mmHg
Accuracy	±10 mmHg
Resolution	20 mmHg
Venous pressure monitoring	
Display range	- 60 mmHg to + 520 mmHg
Accuracy	±10 mmHg
Resolution	20 mmHg
Transmembrane pressure monitoring	
Display range	- 60 mmHg to + 520 mmHg
Resolution	20 mmHg
Arterial blood pump	
Blood flow range	15 to 600 mL/min
Accuracy	± 10%
Resolution	5 mL/min
Single needle system (optional)	With 2 blood pumps, internal pressure/pressure control with variable stroke volume (max. 50 mL/min)
Air bubble detector	Ultrasonic transmission measurement on blood line, additional optical monitoring in venous clamp
Heparin pump	Delivery range: 0 to 10 mL/h Bolus function: max. 5 mL per bolus Syringe size: 20 mL
Dialysis fluid circuit	
Dialysis fluid flow range	
Selectable	0 – 300 – 500 – 800 mL/min
AdaptedFlow* (selectable)	Dialysate flow adapted to the effective blood flow
Dialysis fluid temperature	
Selectable	35°C to 39°C
Dialysis fluid conductivity	
Range	12.8 to 15.7 mS/cm (25°C)
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 150 mmol/L
Dialysis fluid bicarbonate component	
Default mixing ratio	1 + 27.6 (others possible)
Adjustment range	- 8 to + 8 mmol/L
OCM®	Online Clearance Monitoring
Accurate Clearance K	± 6%
Bicarbonate dry concentrate	bi*bag*®
Dialysis fluid filter system	DIASAFE®*plus*
Balancing accuracy	± 0.1 % according to the total dialysate volume
Pressure holding tests	Cyclic
Ultrafiltration	
UF rate	0 to 4000 mL/h (in steps of 1 mL/h)
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) at max. flow 800 mL/min
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 mL/min
Hot rinse (recirculation)	
Temperature/flow	84 °C / 450 mL/min
Integrated hot rinse	
Temperature/flow	84°C / 450 mL/min
Cleaning Sporotal®100 (recirculation)	
Temperature/flow	37 °C / 600 mL/min
Heat disinfection Diasteril®/Citrosteril® (recirculation)	
Temperature/flow	84° C / 450 mL/min
Disinfection Puristeril® 340/plus (recirculation)	
Temperature/flow	37 °C / 600 mL/min

* Not available in all countries.
** Various programme combinations selectable.
Technical changes reserved.

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