

Cardioprotective Haemodialysis

The new 5008 CorDiax

Beyond your expectations



Cardioprotective Haemodialysis **SPOT**

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).

SP

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 dialysers
 - 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
- HighVolumeHDF®
- Advanced Fluid Management

Protect your Patient

Cardioprotection – at the heart of long-term haemodialysis

Chronic kidney disease (CKD), as well as dialysis itself, can lead to cardiovascular alterations such as atherosclerosis and left ventricular hypertrophy (LVH), the largest causes of death in haemodialysis patients.¹

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.

The central point of Cardioprotective Haemodialysis is haemodiafiltration. By achieving high substitution volumes, HighVolumeHDF® therapy is credited with more effective elimination of middle molecules. With its numerous positive effects on cardiovascular risk factors, HighVolumeHDF® is currently considered as the most efficient renal replacement therapy.

Fresenius Medical Care is focused on continuous development and advancement to meet the changing requirements of dialysis today. Therefore, we are always in search of opportunities for improvement. The result of these efforts is our new product line CorDiax, which provides products for superior cardioprotective therapies.

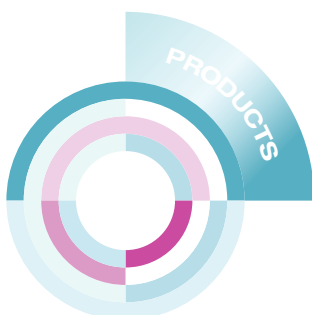
Our latest machine software upgrades the 5008 Therapy System to the CorDiax product line, where it builds a perfect synergy with our FX CorDiax dialysers.

The highlights of this software are an innovative method for performing HighVolumeHDF® – AutoSub *plus* – and sophisticated safety features for venous access monitoring, allowing you to provide highly safe and effective treatment to your patients.

In fact, the new 5008 CorDiax is impressive not only thanks to the best therapy modalities, but also due to the perfect fusion of easy handling and thoughtful use of dialysis-relevant resources, representing the following three cornerstones:

Best therapies

- Effective removal of middle molecular toxins
- Defining and achieving the optimal dry weight
- Individual temperature control
- Ensuring effective dialysis dose
- Highest level of patient safety
- The right fit for paediatric patients



References

1. de Jager D. et al., JAMA (2009); 302: 1782-1789.

Best handling

- Optimised ergonomics
- Comfortable handling due to automated workflows
- Easy, rapid and safe data management
- Well-designed user interface

Optimal use of resources

- Optimised workflows
- Efficient and sustainable
- Unmatched service-friendliness

Various therapy concepts complement each other, thanks to the flexibility of the new 5008 CorDiax. The 5008 CorDiax is a perfect system for advanced cardioprotective therapies to cope with the growing number of medically challenging patients.



Protect your Patient

Best therapies

Nephrologists are today increasingly confronted with medically challenging haemodialysis patients who often suffer from multiple comorbidities such as CVD or diabetes. They have to consider potential intradialytic side effects as well as the long-term prognosis of their patients.

Our mission is to optimise therapies to achieve the best possible patient outcomes. The goal of the 5008 CorDiax is to deliver Cardioprotective Haemodialysis with advanced safety for reduced cardiovascular complications and mortality.

Effective removal of middle molecular toxins

- AutoSub *plus* – Maximising substitution volumes in haemodiafiltration (HDF) for high convective removal of middle molecules, significantly reducing the patient's risk profile¹

Defining and achieving the optimal dry weight

- Precise quantification of the patient's fluid status using the BCM-Body Composition Monitor as the basis of our Advanced Fluid Management minimises the impact of impaired fluid status²
- Regulation of ultrafiltration based on relative blood volume changes using the Blood Volume Monitor (BVM) helps to achieve the prescribed dry weight and prevents intradialytic hypotensive episodes³

Individual temperature control

- Adapting dialysate temperature using the unique Blood Temperature Monitor (BTM) ensures the core body temperature remains constant, leading to better haemodynamic stability during dialysis⁴

Ensuring effective dialysis dose

- Online measurement of Kt/V with ONLINE Clearance Monitoring (OCM[®]) assures adequacy of delivered dialysis dose in accordance with standards^{5,6}
- Non-invasive measurement of total recirculation with BTM supports the early detection of vascular access problems

Highest level of patient safety

- Sophisticated safety features integrated in the 5008 CorDiax set a new benchmark for patient safety

The right fit for paediatric patients

Achieving the best possible patient outcomes is not limited to common dialysis treatment.

Fresenius Medical Care, as the world market leader in haemodialysis, is also committed to providing the best possible therapies suitable for the special requirements of paediatric patients.



References

1. Canaud B. et al., *Contrib Nephrol* (2007); 158: 216-224.
2. Wizemann V. et al., *Nephrol Dial Transplant* (2009); 24: 1574-1579.
3. Gabrielli D. et al., *J Nephrol* (2009); 22: 232-240.
4. Maggiore Q. et al., *Am J Kidney Dis* (2002); 40 (2): 280-290.
5. European Best Practice Guidelines for Haemodialysis (Part 1) (2002); 17 (suppl 7): 17-31.
6. Tattersall J. et al., *Nephrol Dial Transplant* (2007); 22 (suppl 2): ii5-ii21.



The 5008 CorDiax allows you to deliver the full benefits of Cardioprotective Haemodialysis – every day, for every patient.

Protect your Patient

Effective removal of middle molecular toxins

HighVolumeHDF® – Perfectly put together

Haemodiafiltration is a combination of two principles – diffusion and convection. This allows the effective removal of smaller molecules as well as increased removal of larger solutes (see Figure 1). This outstanding clearance, specifically of middle weight molecules such as β_2 -microglobulin (β_2 -m), leads to a reduction of cardiovascular risks and to an improved survival rate for dialysis patients.^{1,2}

Recent publications have demonstrated that a large substitution volume in post-dilution mode (> 21 L per treatment) is required to achieve positive outcomes.³ However, reaching a large substitution volume for high convective transport is frequently compromised by haemoconcentration and filter clotting.

AutoSub *plus* – Maximising substitution volume for high-efficiency HDF

AutoSub *plus* enables substitution volumes to be maximised individually for every patient, while simultaneously avoiding haemoconcentration and filter clotting. The innovative AutoSub *plus* system goes beyond conventional pressure control. AutoSub *plus* continuously analyses the conditions directly in the fibre. From these analysis results, the substitution rate is permanently adapted to the current treatment conditions without any need for user interaction.

In combination with FX CorDiax HDF dialysers, AutoSub *plus* is the first choice to achieve maximum substitution volumes in post-dilution HDF (HighVolumeHDF®) in a highly safe manner compared to conventional methods.





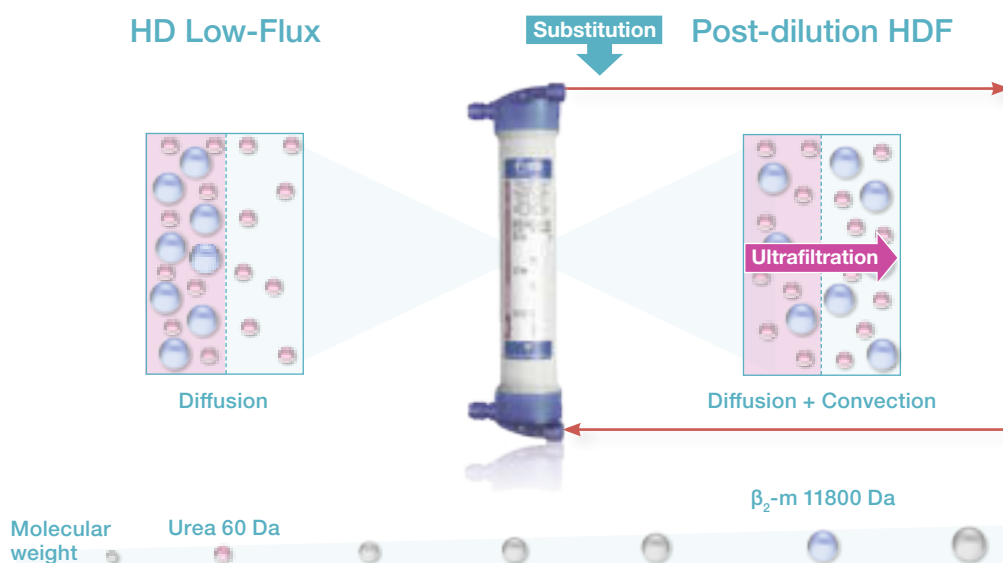
ONLINE production of sterile substitution fluid

With the 5008 CorDiax, high volumes of sterile and non-pyrogenic substitution fluid can be prepared cost-effectively by ONLINE filtration of ready-prepared dialysis fluid across the endotoxin-retaining Diasafe[®]plus filters. This double-stage process has proven its superior efficiency, practicability and safety in innumerable routine treatments. It provides reliable quality and safety by preventing residual endotoxins and microorganisms from entering the substitution fluid.*

SPOT on:

- Large substitution volume (> 21 L) during HighVolumeHDF[®] treatment significantly reduces all-cause mortality.³
- Achieving large substitution volumes with AutoSub plus in post-dilution HDF.
- Sterile and non-pyrogenic substitution fluid with Diasafe[®]plus filters.

Effective removal of a broad range of substances with post-dilution HDF



References

1. Cheung A. et al., J Am Soc Nephrol (2006); 17: 546-555.
2. Locatelli F. et al., J Am Soc Nephrol (2009); 20: 645-654.
3. Maduell F. et al., J Am Soc Nephrol (2013); 24: 487-497.

* in accordance with ISO 23500:2011 and ISO 11663:2009

Protect your Patient

Effective removal of middle molecular toxins

MIXED HDF – High convective transport under unfavourable patient conditions

Certain patients are unable to reach effective substitution volume targets in post-dilution HDF due to low blood flow or high blood viscosity. In order to achieve adequate convective transport for these patients as well, MIXED HDF is used to add a pre-dilution share to avoid the risk of haemoconcentration and filter clotting.

The 5008 CorDiax, with its two substitution pumps, enables the simultaneous combination of post- and pre-dilution techniques in MIXED HDF. It also makes the benefits of high convective transport accessible to patients not suitable for standard HDF treatment.¹

MIXED HDF made possible by two substitution pumps



Second substitution pump for MIXED HDF and single-needle

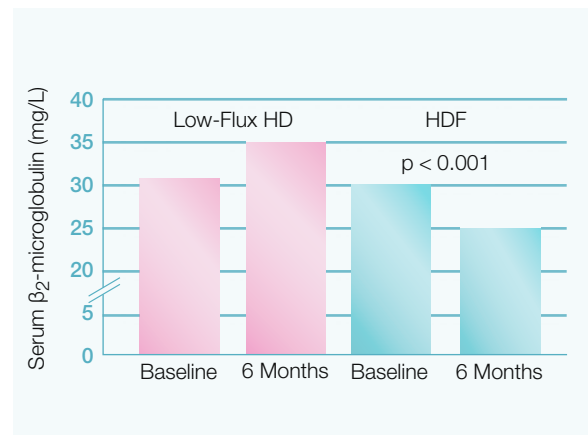
Benefits for the patient

HDF is the treatment modality which comes closest to the elimination profile of the natural kidneys. HighVolumeHDF[®], together with the 5008 CorDiax and FX CorDiax HDF dialysers, improves patient outcomes and has beneficial effects on:

- Serum β_2 -m and phosphate levels^{2, 3, 4, 5}
- Inflammatory response⁵
- Intradialytic haemodynamic stability^{6, 8}
- Anaemia control⁷

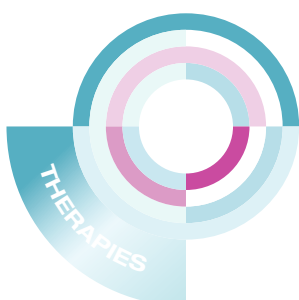
These factors contribute to better quality of life and patient survival.

Reduced β_2 -m levels with HDF³



β_2 -m levels in the CONTRAST study³

(Graph adapted from original publication)





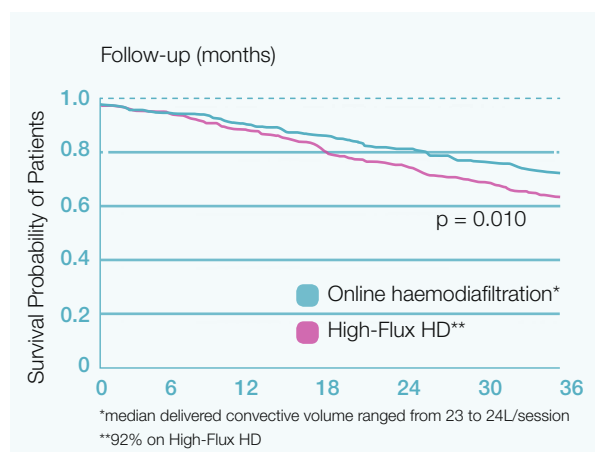
Benefits for the therapy provider

- Providing state-of-the-art therapy without additional user efforts
- High cost-effectiveness due to online production of sterile substitution fluid
- Easy application in daily routine

SPOT on:

- Improved patient outcomes through beneficial effects on cardiovascular risk factors.⁸
- HighVolumeHDF[®] as standard in cardioprotective therapies.

Reduced mortality with HighVolumeHDF[®]⁸



(Graph adapted from original publication)

References

1. Pedrini L. et al., *Kidney Int* (2003); 64 (4): 1505-13.
2. Canaud B. et al., *Contrib Nephrol* (2007); 158: 216-224.
3. Penne EL. 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* (2011); 26: 2617-2624.
6. Locatelli F. et al., *J Am Soc Nephrol* (2010); 21: 1798-1807.
7. Bonforte G. et al., *Blood Purification* (2002); 20: 357-363.
8. Maduell F. et al., *J Am Soc Nephrol* (2013); 24: 487-497.

Defining and achieving the optimal dry weight

Advanced Fluid Management

Chronic volume overload is a common condition among patients with ESRD and is directly associated with cardiovascular diseases. Thus, hydration status is an important and independent predictor of CVD-related morbidity and mortality in HD patients.¹ However, the determination of fluid status with existing clinical methods is either imprecise or not suited to the daily routine in dialysis centres.



Figure 1: BCM-Body Composition Monitor

BCM-Body Composition Monitor

The BCM-Body Composition Monitor is the first and most proven body composition device specifically designed for use in patients with ESRD, and is therefore the corner-stone of the Advanced Fluid Management therapy programme by Fresenius Medical Care. As the only device the BCM-Body Composition Monitor precisely measures and quantifies overhydration and key nutritional parameters and, in combination with the Fluid Management Software, allows the optimal fluid status of dialysis patients to be determined and achieved.

Fluid Management with the BCM-Body Composition Monitor as an integrated component of the 5008 CorDiax therapy concept provides non-invasive, fast and cost-effective measurements at the bedside and enables the continuous monitoring of the patient's dry weight (see Figure 2).

Monitoring the patient's dry weight

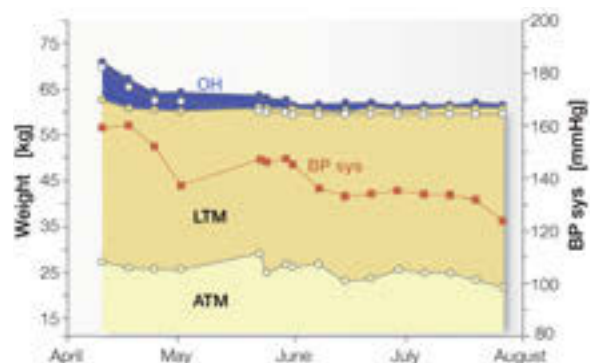


Figure 2: Patient data follow-up in Fluid Management Tool

- OH = Overhydration
- LTM = Lean Tissue Mass
- ATM = Adipose Tissue Mass
- BP sys = systolic blood pressure



References

1. Wizemann V. et al., Nephrol Dial Transplant (2009); 24: 1574-1579.
2. Boer W. et al., Nephrol Dial Transplant (2002); 17 (suppl 1): 127-128.



SPOT on:

- Reduced mortality with Advanced Fluid Management.¹
- Better control of the patient's fluid status helps avoiding chronic volume overload.¹
- Automatic adaptation of the ultrafiltration rate according to the relative blood volume change with BVM.

BVM – Blood Volume Monitor

Intradialytic hypotensive episodes are one of the most serious side effects of haemodialysis. The main reason for blood pressure instability is a reduction in blood volume as a result of excessive fluid removal. The infusion of saline solution and the reduction of the ultrafiltration rate are common measures to stabilise the patient in case of hypotensive events. Frequently, the prescribed dry weight is not achieved, exposing the patient to the risks of overhydration and poor dialysis efficacy.

In order to prevent excessive fluid removal, the Blood Volume Monitor (BVM) provides an automatic adaptation of the ultrafiltration rate according to the measured relative blood volume change (see Figure 3).

Blood volume control helps avoiding the vicious circle of intradialytic hypotension and subsequent postdialytic volume overload that can lead to hypertension and ultimately to cardiovascular disease.² BVM is an essential part of Fresenius Medical Care's Advanced Fluid Management, which enhances the patient's cardiovascular stability.



Figure 4: BVM – Blood Volume Monitor



Figure 3: Blood volume control

Protect your Patient

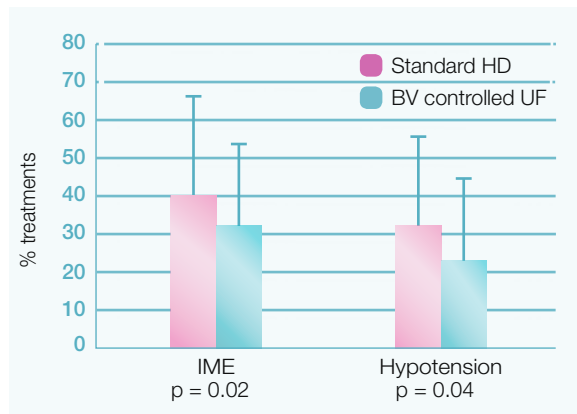
Defining and achieving the optimal dry weight

Advanced Fluid Management – Benefits for the patient

Achieving normohydration and avoiding excessive ultrafiltration through effective Fluid Management therapy is associated with better outcomes for dialysis patients.¹ Regulating the patient's fluid status through Advanced Fluid Management with the BCM and BVM as its key components may lead to:

- Reduced cardiovascular mortality¹
- Better control of hypertension²
- Reduction in antihypertensive medication²
- Fewer intradialytic complications and hypotensive episodes thanks to individualised ultrafiltration rate^{3,4}
- Diminished risk of hypernatraemia
- Improved patient well-being

Less intradialytic morbidity and fewer hypotensive episodes with blood volume controlled ultrafiltration⁴

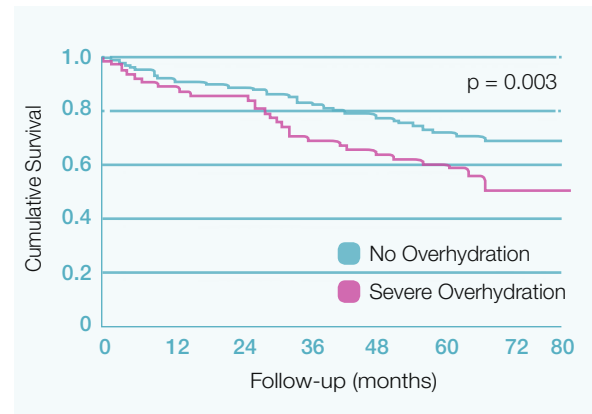


Impact on intradialytic morbid events and hypotension
(Graph adapted from original publication)

Benefits for the therapy provider

- Easy to use
- Practical in daily routine
- Fewer complications during treatment period
- Automatic adaptation of ultrafiltration – no need for infusion of saline solution

Overhydration – a major risk factor for mortality¹



Impact of fluid status on survival of HD patients¹
(Graph adapted from original publication)





Individual temperature control

BTM – Blood Temperature Monitor

Symptomatic hypotension due to an increase of body temperature is a well-known complication affecting patients during dialysis.⁵ In view of these observations, the stabilisation of core body temperature is one of the basic requirements of HD treatment.

With the help of the unique Blood Temperature Monitor (BTM), an individual's pre-dialytic body temperature can automatically be maintained throughout dialysis treatment. In the event that a modification of the body temperature is required, the BTM can slightly change the temperature within the set limits.

Benefits for the patient

- Significantly improved cardiovascular stability during treatment⁵

Benefits for the therapy provider

- Fewer complications during treatment
- No user interaction required due to automatic measurement and adaptation

SPOT on:

- Better haemodynamic stability during dialysis treatment thanks to unique temperature control with BTM.



BTM – Blood Temperature Monitor

References

1. Wizemann V. et al., Nephrol Dial Transplant (2009); 24: 1574-1579.
2. Machek P. et al., Nephrol Dial Transplant (2010); 25: 538-544.
3. Veljancic L. et al., Int J Artif Organs (2011); 34 (4): 357-364.
4. Gabrielli D. et al., J Nephrol (2009); 22: 232-240.
5. Maggiore Q. et al., Am J Kidney Dis (2002); 40(2): 280-290.

Protect your Patient

Ensuring effective dialysis dose

OCM[®] – Online Clearance Monitor

Kt/V is a well-established parameter for measuring the adequacy of dialysis treatment. The regular measurement of delivered Kt/V is required by guidelines and becomes an important parameter for documenting treatment quality.^{1,2}

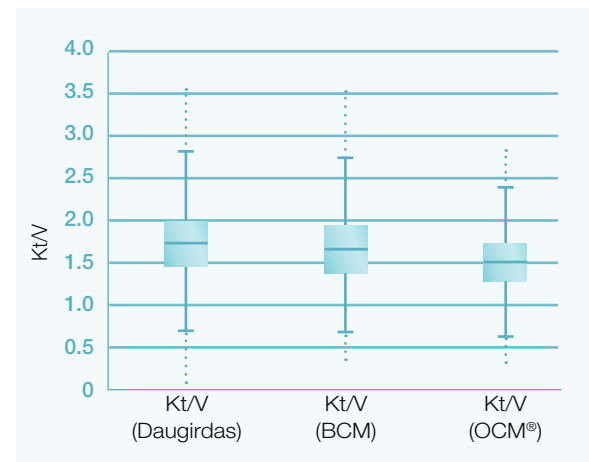
Up to now, conventional measurement techniques have been performed only once every one to three months in a process requiring laboratory values. Since there was no information available on the quality of treatment administered on a daily basis, an immediate response regarding quality issues was not possible.

With the Online Clearance Monitor (OCM[®]), the dialysis dose Kt/V is measured automatically and non-invasively during each dialysis treatment.* OCM[®] measures the effective *in vivo* urea clearance (K) and calculates the accumulated cleared plasma volume (Kt). To determine Kt/V, the value for urea distribution volume (V) is required, which is precisely measured with the BCM-Body Composition Monitor. This results in a Kt/V which comes closest to the gold standard and can be monitored daily.³

In addition to the delivered dialysis dose, the OCM[®] also measures the patient's level of plasma sodium. This information is a useful treatment aid as it allows the sodium concentration of the dialysis fluid to be adapted to the patient's individual plasma sodium level.

Online Clearance Monitoring (OCM[®]) is a well-established method and a standard feature of the 5008 CorDiax.

Kt/V_{BCM} is closest to the gold standard³



(Graph adapted from original publication)



* OCM[®] measurement is not possible in case of single needle and HF or ISO-UF treatment



SPOT on:

- OCM® in combination with BCM is a highly reliable way to accurately measure the achieved dialysis dose.
- Easy and non-invasive monitoring of prescribed Kt/V during dialysis.
- Early detection of potential recirculation ensures effective dialysis dose.

BTM recirculation measurement

High blood flow rates correspond to a high clearance of uraemic toxins. Shunt recirculation is a common problem in dialysis when the actual blood flow is higher than the access flow provided. The resulting recirculation has insufficient vascular access, which can significantly reduce dialysis efficacy.

Assessing the quality of the access is difficult and hence not possible for daily quality assurance. The Blood Temperature Monitor, however, is able to measure potential recirculation during treatment and helps to evaluate the quality of vascular access and to monitor its trend.

Benefits for the patient

- Better patient outcome due to the prescribed dialysis dose being reached¹
- Non-invasive monitoring
- Effective dialysis dose (Kt/V) ensured thanks to early detection of potential recirculation and shunt problems

Benefits for the therapy provider

- Immediate transparency for fulfilling treatment quality requirements (Kt/V)
- Easy monitoring of delivered dose without extra costs
- Early detection of problems during dialysis treatment
- Runs automatically, meaning, no action is required
- Continuous monitoring of access condition without user interaction

References

1. Tattersall J. et al., Nephrol Dial Transplant (2007); 22 (suppl 2): ii5-ii21.
2. European Best Practice Guidelines for Haemodialysis (Part 1) (2002); 17 (suppl 7): 17-31.
3. Ahrenholz P. et al., Blood Purif (2011); 32: 271-277.

Protect your Patient

Highest level of patient safety

Dialysis patients undergo dialysis treatment three times a week over a period of many years. Therefore, safety is one of the most important aspects of dialysis. In addition to the basic safety requirements each dialysis system already provides, sophisticated safety systems have to focus on the remaining challenges posed by modern renal replacement therapy:

- External bleeding
- Paravasal bleeding
- Haemolysis
- Coagulation
- Fluid removal

The challenge is to think beyond state-of-the-art technologies and approach well-known problems with innovative solutions, striving for superior patient safety.

The intelligent safety features of the 5008 CorDiax offer highest patient safety while minimising undesirable incidences and simultaneously easing daily routines and supporting the nursing staff's responsibility as therapy providers.

External bleeding

Sudden dislodgement of the venous needle, partial disconnection of the Luer-Lock connections or any other untight connections can cause the patient to lose a critical amount of blood, which can even lead to death within a few minutes.

The 5008 CorDiax offers various novel solutions to minimise the risk of external blood loss:

- Venous Access Monitor (VAM) – optimised monitoring of the venous path increasing the probability of early detection of venous needle dislodgement
- Special wetness detector, VenAcc, for the quick detection of blood loss, especially in patients undergoing home or nocturnal dialysis as well as restless or confused patients
- Sensors and front doors which enable a fast recognition of leakages in the extracorporeal blood system



VenAcc device with disposable single-use sensor patch



**SPOT on:**

- Facing the challenges of haemodialysis today with sophisticated safety features.

Paravasal bleeding

Venous needle dislodgement during dialysis may result in undetected internal blood loss, which is a serious complication during dialysis: when the venous needle perforates the vessel, blood leaks out into the surrounding tissue and causes large haematomas.

The 5008 CorDiax allows:

- Early detection of paravasal bleeding and prevention of large haematomas with Dynamic Pressure Monitoring – no more undetected paravasal blood loss

Haemolysis

A serious complication during dialysis is mechanically induced haemolysis which is primarily caused by kinking of the blood tubing. Conventional dialysis machines do often not detect kinking of the blood line between the blood pump and the venous bubble catcher, which is a potential cause of haemolysis.

The 5008 CorDiax reduces the risk of mechanical haemolysis by

- Closing the safety gap between the blood pump and venous bubble catcher with Blood Line Kinking & Filter Clotting Detection – enabling faster detection of potential haemolysis risks

Protect your Patient

Highest level of patient safety

Coagulation

Contact with any material foreign to the body or contact with air increases the likelihood of blood coagulating within the extracorporeal blood circuit. As a consequence, anticoagulants are given to prevent clotting. The amount of heparin should be as low as possible, meaning the air and blood contact during dialysis needs to be minimised.

The 5008 Cordiax enables:

- Non-invasive, air-free arterial pressure monitoring (see Figure 1) without a blood-air interface to reduce the risk of coagulation during dialysis



Figure 1: Arterial pressure dome

Fluid removal

Removal of excess water is one of the key tasks of a dialysis machine. The removal of a precise amount of fluid is crucial for the well-being of the patient, as too much ultrafiltration could potentially result in hypotension or muscle cramps. In HighVolumeHDF® this task is even more complex as the balance between the total fluid withdrawn from the patient and the fluid volume substituted has to be adhered to exactly.

The 5008 CorDiax provides:

- Balancing chamber that guarantees in combination with UF pump the precise removal of the prescribed amount of fluid
- Continuous monitoring of the tightness of the complete hydraulic system by leakage sensors and integrity tests to avoid uncontrolled fluid loss



**SPOT on:**

- Setting a new benchmark in patient safety with the 5008 CorDiax.

Patient safety with Fresenius Medical Care means superior security on every level thanks to the highly-innovative safety features of the 5008 CorDiax. In the development of these safety features, we have united innovative ideas and state-of-the-art technologies to achieve the best possible results.

Fresenius Medical Care provides greater safety during all forms of treatment for both patients and operators. What's more, as the world market leader in dialysis, with over 30 years of expert knowledge, we are committed to setting new benchmarks in patient safety – because conforming to standards alone is not enough.

**Patient Safety by Fresenius Medical Care –
Where new benchmarks are set.**

Protect your Patient

Paediatric therapy

The right fit for paediatric patients

Children with ESRD require special care during haemodialysis treatment. Their smaller body volume, constant growth and increased metabolism are special challenges for the paediatric nephrologist. Moreover, children are usually long-term patients with a high exposure to biomaterials. All these requirements have to be considered when developing a treatment system for paediatric use.

Our 5008 CorDiax is the first haemodialysis machine to be validated for the treatment of paediatric* patients. It offers the best possible dialysis therapy:

- HighVolumeHDF® with AutoSub *plus* for highly efficient removal of uraemic toxins even with reduced blood flow rates
- Haemodynamic stability is ensured during treatment thanks to the non-invasive monitoring of relative blood volume changes (BVM)
- Supervision of hydration and nutritional status during continuous growth: easy and precise determination of dry weight and body mass with the BCM-Body Composition Monitor
- FX CorDiax 40 highly efficient membrane designed for smaller body weight

The specifically developed paediatric treatment option adapts all relevant parameters to fit children's needs while simultaneously fulfilling the highest safety requirements:

- Special paediatric user-setup with more sensitive thresholds
- Blood flow range limited according to body weight
- Reduced blood flow for a gentle dialysis start
- Special children cuff for comfortable, automatic blood pressure measurement
- Increased probability of early detection of venous needle dislodgement (VAM)
- Increased safety for active children with the optional device for detecting venous needle disconnection (VenAcc)

The 5008 CorDiax with the paediatric treatment option comes with special disposables for paediatric patients:

- Phthalate-free bloodlines (no DEHP)
- Bloodlines and dialysers to reduce the extracorporeal blood volume, which are particularly suited to low blood flow rates



* for use in children >10kg body weight

** confirmed for intensified dialysis regimens



Benefits for the children

- Increased well-being during treatment**
- Promotion of catch-up growth**,¹
- Reduction of left ventricular hypertrophy (LVH)**,²
- Improved safety for children who move thanks to venous access monitoring features
- Non-invasive monitoring systems

Benefits for the therapy provider

- Application of HighVolumeHDF[®], acknowledged as the best therapy in haemodialysis
- Validated and approved safety and user concept

SPOT on:

- 5008 CorDiax – the first haemodialysis machine validated for treatment of paediatric patients.



Special screensaver for paediatric treatment mode

References

1. Fischbach M. et al., Nephrol Dial Transplant (2010); 25: 867-873.
2. Fischbach M. et al., Nephrol Dial Transplant (2004); 19: 2360-2367.

Protect your Patient

Best handling

There is already a lack of qualified staff capable of offering high-quality haemodialysis therapy options to a growing number of medically challenging patients. This has resulted in an increased requirement for dialysis machines that can be operated easily and safely.

The 5008 CorDiax ably meets the demand for easy operability. With a design focused on easy-handling and usability, it is completely adapted to the user's needs. All components of the 5008 CorDiax are aligned to simplify routine procedures in order to give nursing staff much needed time for individual patient care.

The 5008 CorDiax provides outstanding practicability thanks to:

- Optimised ergonomics
- Comfortable handling due to automated workflows
- Easy, rapid and safe data management
- Well-designed user interface

All these characteristics enable the full benefits of Cardioprotective Haemodialysis to be provided in everyday use.





The 5008 CorDiax – Created by users
for users.

Protect your Patient

Best handling

Optimised ergonomics

The ergonomic handling of the 5008 CorDiax assures outstanding usability and high convenience for the user (see Figure 1):

- Individually adjustable, freely rotatable flat-screen monitor (15" TFT) for perfect readability from every angle
- Clearly structured and well laid-out Extracorporeal Blood Module (EBM) offers extremely easy, machine-assisted set-up and dismantling of tubing systems
- Simple, one-handed and hygienic connection of bibag® (dry bicarbonate supply)

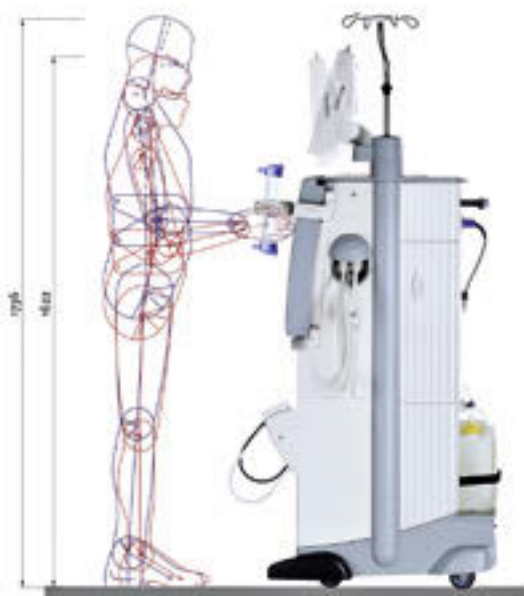


Figure 1: Ergonomic handling

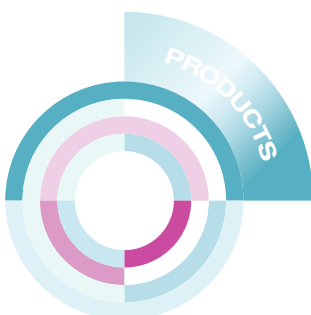
Comfortable handling due to automated workflows

The 5008 CorDiax ensures optimised workflows for all operators at a high level, which fit into their daily routines:

- Graphical-assisted preparation screens (see Figure 2)
- Self-initiating functions at start of treatment, e.g. Auto T1-Test, reduce number of handling steps
- Self-evident program settings minimise 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



Figure 2: 5008 set-up screen



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

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 5008 CorDiax (current and previous three treatments)
- 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

Well-designed user interface

The central navigation system of the 5008 CorDiax follows an “intuitively correct” user-guidance philosophy for the nursing staff:

- Centralised operation and information via a spacious touchscreen display (see Figure 3)
- Simple and logical data entry
- Sophisticated, stress-free handling of alarms during treatment
- Quick access to treatment information

SPOT on:

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



Figure 3: Touchscreen display

Protect your Patient

Optimal use of resources

Increasing numbers of dialysis patients and restricted health care resources require novel solutions to provide the best dialysis therapy for all patients. The challenge for dialysis providers nowadays is to focus on investments that enable the most efficient use of limited resources.

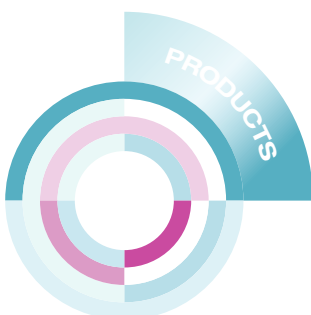
Fresenius Medical Care has taken up this challenge with the introduction of the 5008 CorDiax. With its new software, the 5008 CorDiax allows you to perform advanced renal replacement therapies in a highly efficient way, involving both economical and ecological aspects.

By saving dialysis-relevant resources, the 5008 CorDiax offers a cost-effective treatment for implementation into the daily routine, while achieving a high level of sustainability. In this way, it fully takes into consideration the financial constraints faced by the health sector. Moreover, it supports nursing staff in all working processes, which results in them saving valuable time.

The 5008 CorDiax:

- Optimised workflows
- Efficient and sustainable
- Unmatched service-friendliness

Due to its fully integrated components and its eco-friendliness, the 5008 CorDiax allows the realisation of numerous synergies for an optimised use of dialysis-relevant resources.





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

Protect your Patient

Optimal use of resources

Optimised workflows

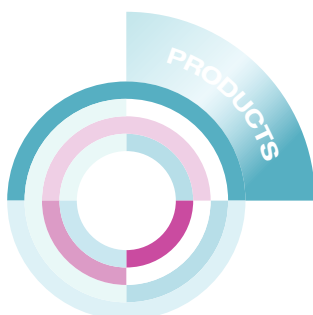
The innovative and highly-automated features of the 5008 CorDiax ensure highest availability and reliability for both operator and patient. In this way, the 5008 CorDiax supports nursing staff by optimising daily workflows while at the same time providing a high level of patient safety.

- Highly automated assistance for all users:
 - Diverse Auto-On/Off functions with full system integration of water technology and IT
 - Multiple automated tests during preparation – no need for nurse interaction
 - ONLINE solution preparation simplifies handling procedures
 - Five fully-automated heat and cold disinfection programs with preconnected disinfectants
- Full integration in our Therapy Data Management System (TDMS) allows for minimal handling steps for start-up and significantly reduces time needed to manage data
- Animated screens support quick learning of user procedures – less time and effort required during training period
- Interface Heat Disinfection (IHD) cleans and disinfects the interface between RO-ring and dialysis machine with hot water (in accordance with ISO 23500)*

Efficient and sustainable

It is not only the advanced treatment options that make the 5008 CorDiax unique, but also its eco-friendliness: with the 5008 CorDiax, 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
 - No more 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 (see 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



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

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

in accordance with ISO 23500:2011 and ISO 11663:2009

dialysis centre with 25 machines

SPOT on:

- Optimised workflows thanks to innovative technologies simplify daily working processes for nursing staff.
- Efficient and sustainable use of dialysis-relevant resources thanks to *ONLINEplus* technology, *AutoFlow*, *EcoFlow* and heat exchanger.

- 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 inhabitants¹

Dialysate flow savings with AutoFlow without compromising K_{urea}

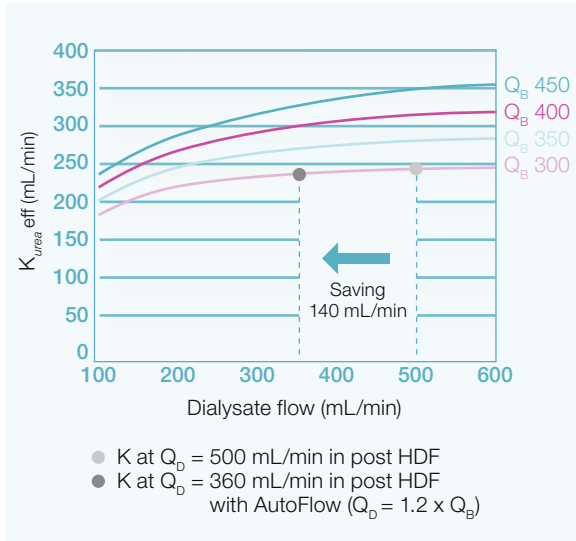


Figure 1: Internal data: Post-dilution with FX CorDiox 600
Hct = 35%; Recirculation = 5%

1. Data on file, Fresenius Medical Care

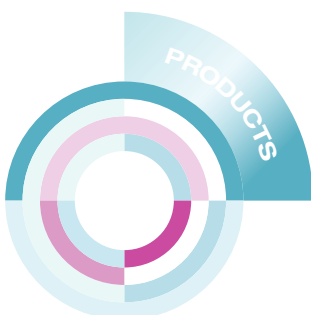
Protect your Patient

Optimal use of resources

Unmatched service-friendliness

Fresenius Medical Care stands for superior quality, reliability and safety, as well as outstanding usability and service. As a result, our products make a significant contribution to supporting you and easing your daily routine. In particular, our 5008 CorDiax is characterised by its unmatched service-friendliness – from simple handling to technical services:

- 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
- Remote maintenance: quick diagnostic inspection via remote access to the dialysis machine
- Advanced diagnostics for pneumatics, which allow the technician to check all single pneumatic components by means of an interactive construction plan
- 24 months maintenance



Product Configuration – 5008 CorDiax highlights



	5008 CorDiax
Therapy highlights	
HighVolumeHDF® – pre- and post-dilution	● / ●
AutoSub <i>plus</i> – automatically maximising substitution volumes in a highly safe manner	●
HighVolumeHDF® during Single Needle treatment	○
MIXED HDF – simultaneous pre- and post-dilution	○
Blood Temperature Monitor (BTM) – regulation of temperature and recirculation measurement	○
Blood Volume Monitor (BVM) – adaptation of ultrafiltration rate based on blood volume changes	○
Paediatric treatment option for patients with body weight 10-40 kg	○
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	○
5008 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

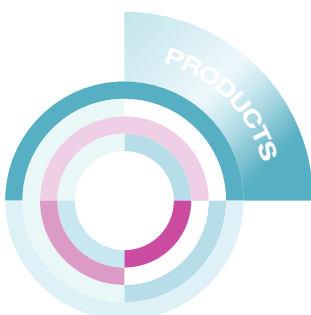
* safety advice: It is recommended that you stock sodium chloride in case it might be required

Protect your Patient

The 5008 CorDiax – Beyond your expectations

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. Hence why the 5008 CorDiax is the fundamental element in our SPOT programme. It offers premium therapy options and excellent usability combined with the optimal use of dialysis-relevant resources. The 5008 CorDiax helps you to protect your patient – day by day.

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





Best therapies

Advanced therapy options such as HighVolumeHDF® 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

therapies
handling
resources



General data	
Dimensions 5008	1620 x 480 x 720 mm (H x W x D) (depth with extended concentrate rack approx. 860 mm)
Weight	approx. 125 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
Central supply	2 central acid concentrates (optional) 1 central bicarbonate concentrate (optional)
Electrical data	
Power supply	100 to 240 V AC ± 10%, 47 to 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 (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 (effective)	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	Ultrasonic 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)
Auto Flow (selectable)	Automatic adaptation of the dialysate flow to the effective blood flow
Eco Flow	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	biBag®
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%
BVM (optional)	
Relative Blood Volume (RBV)	1.7% (absolute)
Haematocrit (Hct)	± 2.9 Hct % (if plasma protein concentration range is 60 to 85 g/L)
Haemoglobin (Hb)	± 0.8 g/dl
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 800 mL/min (adjustable)
Hot rinse (recirculation)	
Temperature/flow	85°C / max. 600 mL/min
Flow for cool down rinse	600 to 800 mL/min (adjustable)
Cleaning Sporotal® 100 (recirculation)	
Temperature/flow	37°C / max 900 mL/min
Heat disinfection Diasteril®/Citrosteril® (recirculation)	
Temperature/flow	85°C / max 900 mL/min
Cold disinfection Puristeril® 340/plus (recirculation)	
Temperature/flow	37°C / max 900 mL/min

* Various programme combinations selectable.
Technical changes reserved.



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