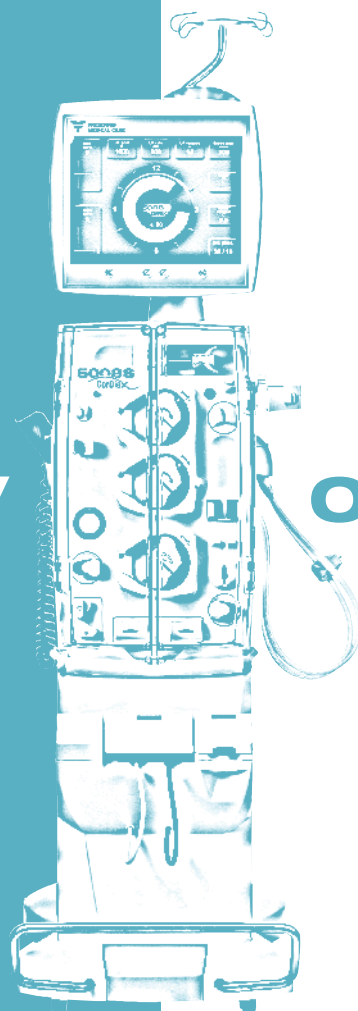


Cardioprotective Haemodialysis

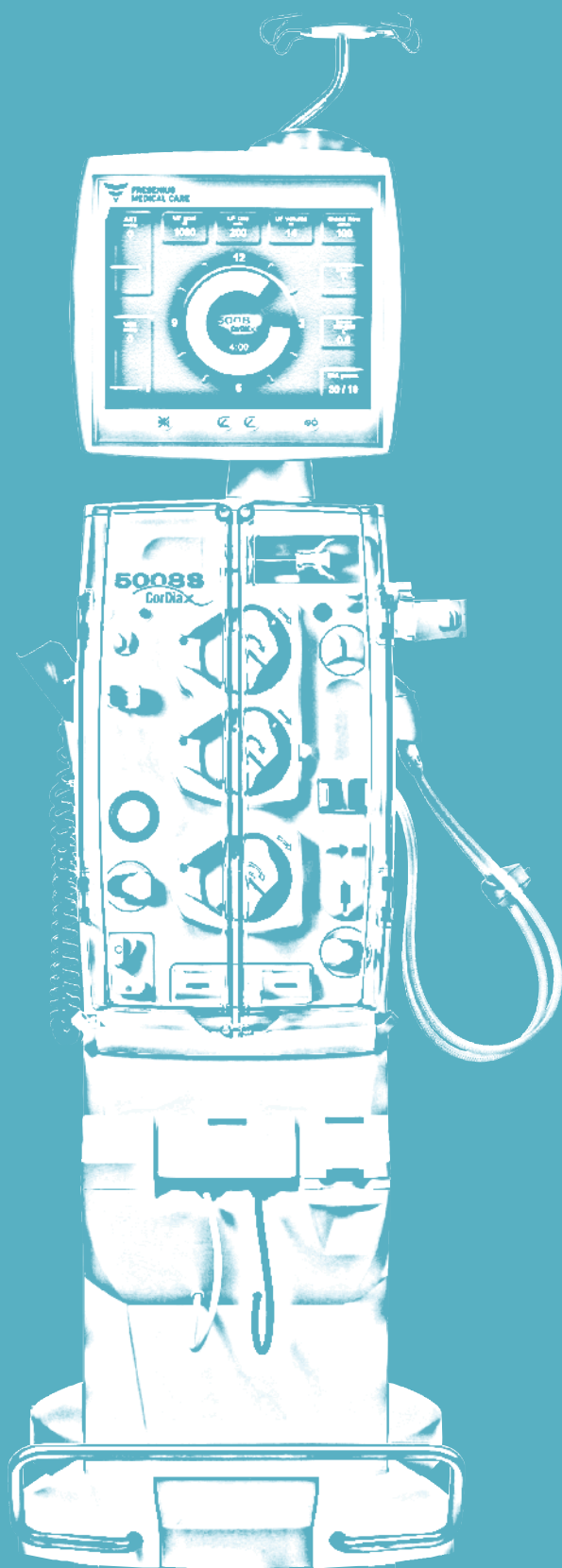
5008S CorDiax

Count on benefits from reliable technology

A real story of success



**FRESENIUS
MEDICAL CARE**



100%

of the
5008S CorDiax
devices can
perform HDF
as standard
treatment modality.



100% committed to Cardioprotective Haemodialysis – with the 5008S CorDiax

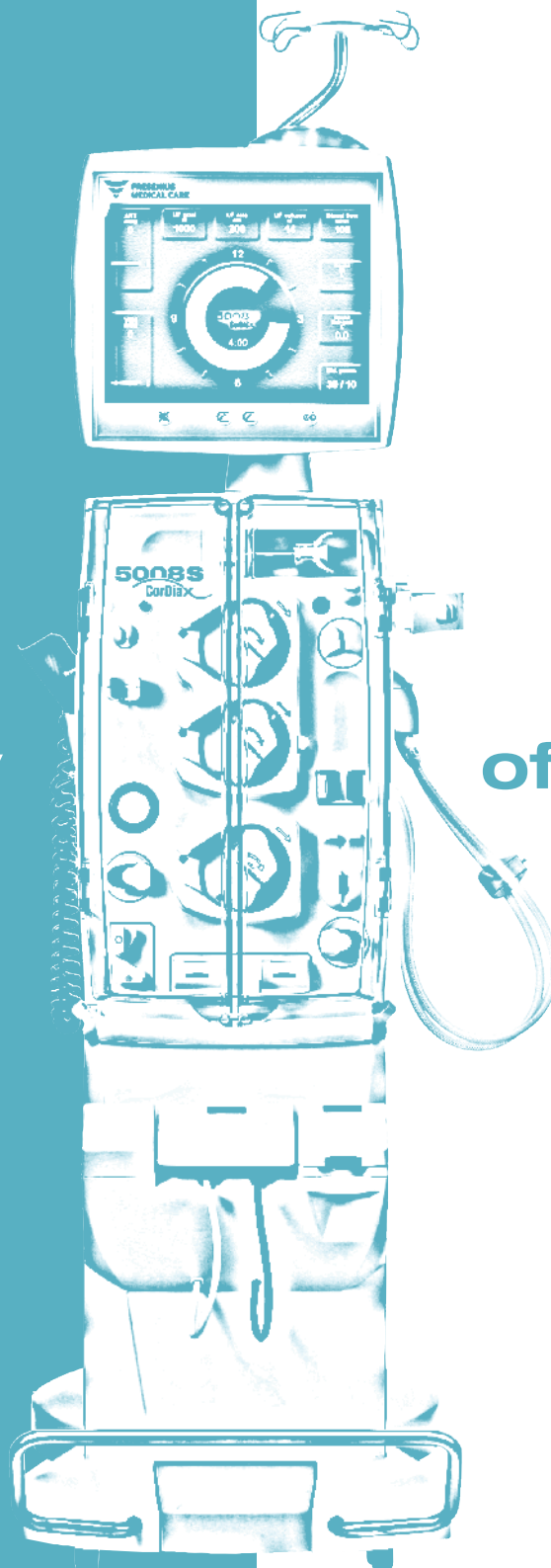
Fresenius Medical Care dedicates itself towards improving patients' lives. We are focussing all our efforts on fostering better clinical outcomes. Cardiovascular diseases are the most common comorbidities in patients with end-stage renal disease and are the leading cause of death in dialysis patients,^{1,2,3} thus posing a challenge for healthcare professionals in daily clinical practice.

Cardioprotective Haemodialysis contributes towards the reduction of risk factors for cardiovascular diseases and is close to our hearts, reflecting our commitment to continuously developing innovative products and therapies.

We aim to offer holistic solutions which patients and healthcare professionals can count on, driven by Cardioprotective Haemodialysis. Within our comprehensive portfolio, the 5008S CorDiax is an advanced solution for delivering cardioprotective therapies.

A real story

of success



There are **solutions** which are able **to improve dialysis therapy, safety features and convenience for patients** and also open up new possibilities. These solutions are **setting new standards in their category**. From the start, the 5008S CorDiax has written a **real story of success** and proved its innovative power by providing exceptional benefits for patients and dialysis professionals. With the 5008S CorDiax, Fresenius Medical Care has developed a therapy system **which set standards at its launch** in Advanced therapies, Patient safety, Convenient handling and Direct cost savings.

5008S CorDiax – Count on benefits from reliable technology.

Advanced
therapies

79%

of HDF sessions
achieve
HighVolume**HDF**
with AutoSub *plus*.⁴

Patient
safety

100%

of 5008S CorDiax
devices are
equipped with a
Venous Access
Monitor – setting
a standard in
this safety feature
category.

Convenient
handling

100%

saline bag-free
due to the
integrated
ONLINE*priming*
of the
5008S CorDiax.

Direct cost
savings

~ 11,500

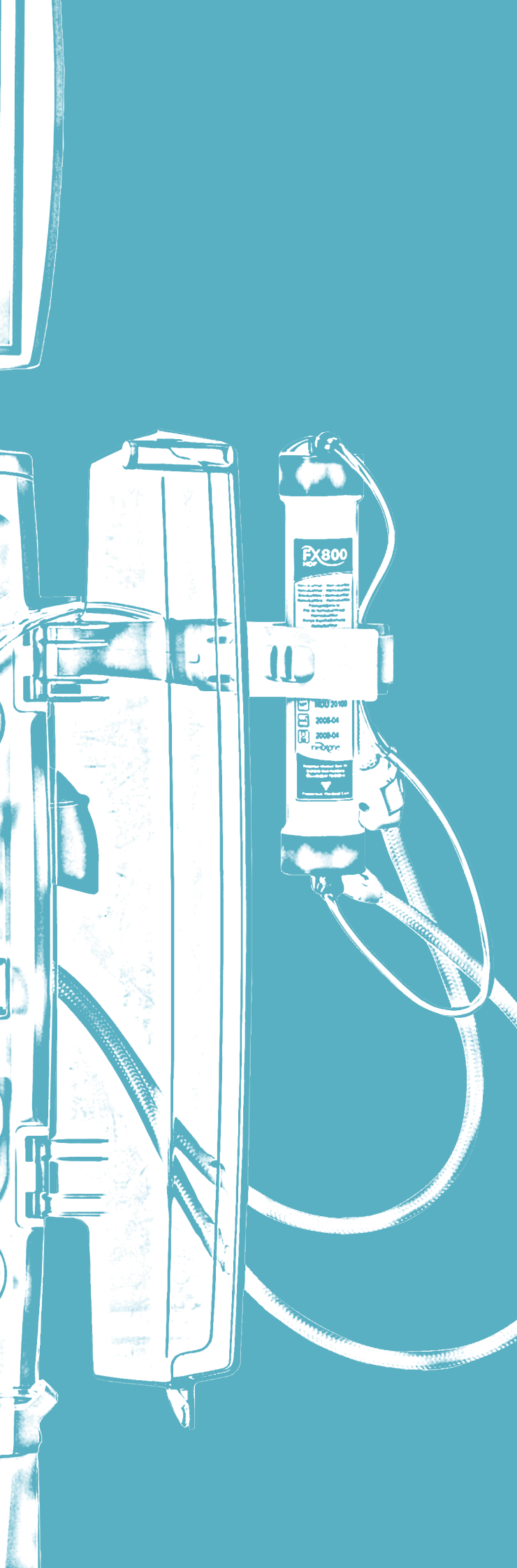
kg of waste
reduced
per year due to
ONLINE*priming*.*

*Own calculation shown in detail on p. 28.

Advanced therapies

79%

of HDF sessions
achieve
HighVolumeHDF
with AutoSub *plus*.⁴



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

Our mission with the 5008S CorDiax is to optimise therapies to achieve the best possible patient outcome. The goal of the 5008S CorDiax is to deliver Cardioprotective Haemodialysis with advanced safety features to reduce cardiovascular complications and mortality:

- Efficient removal of middle molecular toxins
- Facilitating the achievement of the individual dry weight
- Ensuring effective dialysis dose
- Easy assessment of vascular access
- Individual temperature control
- Advanced therapies for home patients

Cardioprotective Haemodialysis

With the 5008S CorDiax, we are aiming at delivering advanced therapies to reduce cardiovascular complications and improve patient survival.

Efficient removal of middle molecular toxins

Increased middle molecule levels such as β_2 microglobulin (B2M) are associated with an additional risk for the development of cardiovascular diseases in end-stage renal disease (ESRD) patients.^{5,6}

Improving the removal of middle molecular toxins, especially B2M, may lead to a reduction of cardiovascular risks and may be related to an improved survival rate for dialysis patients.^{5,6}

High-Flux haemodialysis

High-Flux haemodialysis has clear advantages over Low-Flux haemodialysis with regard to the removal of middle molecules such as B2M, therefore contributing to better outcomes in dialysis patients.^{7,8}

Cardioprotective Haemodialysis

The efficient removal of middle molecules in High-Flux haemodialysis may have a positive impact on cardiovascular risk factors, such as dyslipidaemia⁹, anaemia¹⁰ and amyloidosis^{11,12}.

HighVolumeHDF has a positive impact on all-cause mortality as well as cardiovascular mortality.^{13,14}

AutoSub *plus* automatically maximises substitution volumes, allowing for HighVolumeHDF in daily clinical practice.⁴

HighVolumeHDF – Advanced combination of two principles

As the combination of two principles, diffusion and convection, haemodiafiltration (HDF) allows the effective removal of small molecules as well as an increased removal of middle molecules, even better than with High-Flux haemodialysis (see Figure 1).^{6,15}

In recent years, several studies have confirmed the clinical benefits of HDF.^{14,16–19} These studies have demonstrated that large convection volumes in post-dilution mode are required in order to achieve and maximise the benefits of HDF therapy. The Catalanian high-volume HDF study shows a significant, 30% risk reduction in all-cause mortality for patients with high-efficiency post-dilution online HDF, compared to HD.¹⁶ The inverse relationship between the magnitude of convection volume and mortality risk has been reinforced by latest meta-analysis¹³ from the European Dialysis Working Group and was confirmed by investigators in the HDF Pooling Project.¹⁴ The analysis suggests that HDF reduces the risk of all-cause and cardiovascular mortality, especially with convection volumes of at least 23 L/session. However, reaching a large substitution volume for high convective transport could be frequently compromised by haemoconcentration and filter clotting.

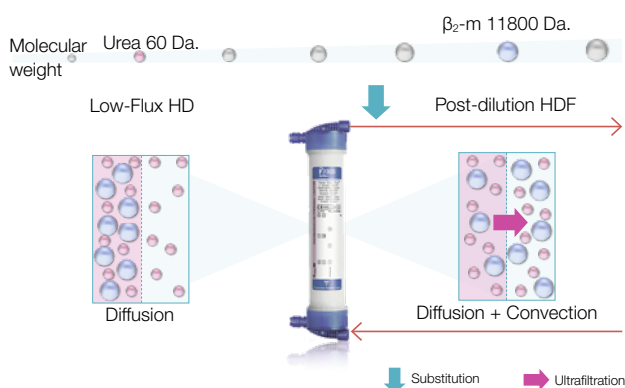


Figure 1: Schematic illustration of the effective removal of a broad range of substances with post-dilution HDF

AutoSub *plus* – Maximising substitution volume for HighVolumeHDF

AutoSub *plus* enables substitution volumes to be individually maximised for every patient, while simultaneously avoiding haemoconcentration and filter clotting. The unique AutoSub *plus* goes beyond conventional pressure control systems.

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 haemodiafilters, AutoSub *plus* is the first choice to achieve maximum substitution volumes in HighVolumeHDF.⁴

ONLINE*plus* technology – Production of sterile fluid for ONLINE*priming** and HighVolumeHDF

With the 5008S CorDiax, high volumes of sterile and non-pyrogenic fluid can be prepared cost-effectively by the filtration of ready-prepared dialysis fluid across the endotoxin-retaining DIASAFE®*plus* filters. This double-stage filtration process ensures removal of endotoxins and microorganisms from entering the substitution fluid for ONLINE*priming* and HighVolumeHDF, which has proven to be efficient and practical, and also conforming to the ISO standards.**

Highlights

- Providing state-of-the-art therapy without additional user effort
- High cost effectiveness due to production of sterile fluid for ONLINE*priming* and HighVolumeHDF
- Easy application in daily routines

Cardioprotective Haemodialysis

DIASAFE®*plus* filters enable the production of sterile and non-pyrogenic dialysis fluid and substitution fluid.***

The use of ultrapure dialysis fluid is associated with lower cardiovascular morbidity due to the reduction/prevention of chronic micro-inflammation.²⁰

*ONLINE*priming* comprises ONLINE preparation (rinsing), ONLINE bolus and ONLINE reinfusion.

**In accordance with ISO 23500-5 and ISO 11663.

***Internal unpublished data of Fresenius Medical Care Deutschland GmbH.

Facilitating the achievement of the individual dry weight

Advanced fluid management

Chronic volume overload is a common condition amongst patients with ESRD and is directly associated with cardiovascular diseases. Therefore, hydration status is an important and independent predictor of mortality in HD patients.^{21,22} However, the method of determining fluid status in dialysis patients could vary in routine clinical practice. As a result, accurate assessment of fluid status and body composition remains a major challenge.³⁴

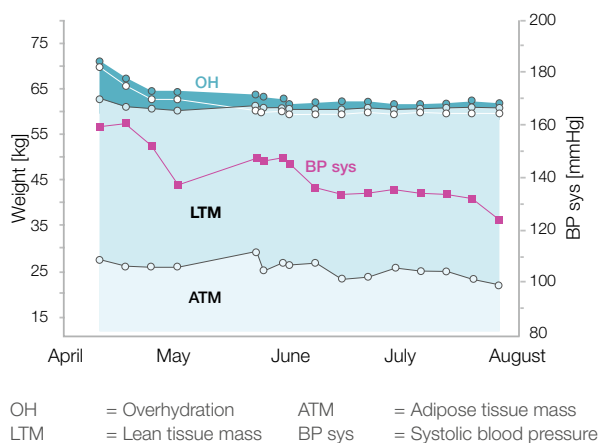


Figure 2: Monitoring a patient's fluid status
(Example measurement visualised in the Fluid Management Tool^{**})

BCM-Body Composition Monitor

The BCM-Body Composition Monitor is specifically designed for use in patients with ESRD, and is therefore fundamental to the Fresenius Medical Care's Fluid Management Therapy approach. The BCM-Body Composition Monitor allows a simple, non-invasive and objective assessment of a patient's overhydration³⁴ and key nutritional parameters* and, in combination with the Fluid Management Tool^{**}, supports the physician in determining a dialysis patient's individual fluid status (see Figure 2).



Figure 3: BCM-Body Composition Monitor

Fluid management with the BCM-Body Composition Monitor integrates with the 5008S CorDiax therapy concept by transferring diagnostic data (e.g. V – urea distribution volume) to the machine with the use of a standardised PatientCard (Fresenius Medical Care).

Cardioprotective Haemodialysis

Achieving normohydration and avoiding too high ultrafiltration rates through effective fluid management therapy is associated with better outcomes for dialysis patients.^{21–23}

Regulating the patient's fluid status through Advanced Fluid Management with the BCM-Body Composition Monitor as its key component may lead to reduced mortality²¹, better control of hypertension²⁴ and reduction in antihypertensive medication²⁴.

*Please note that parameters displayed should only be regarded as a guide and that a qualified medical diagnosis is always necessary.

**Must be purchased separately.

Ensuring an effective dialysis dose

The dialysis dose (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 (European Best Practice Guidelines for Haemodialysis) and becomes an essential parameter for documenting treatment quality.^{25,26}

OCM® – Online Clearance Monitor

With 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 conventional methods (e.g. Kt/V_{Daugirdas}) and can be monitored daily.²⁷

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

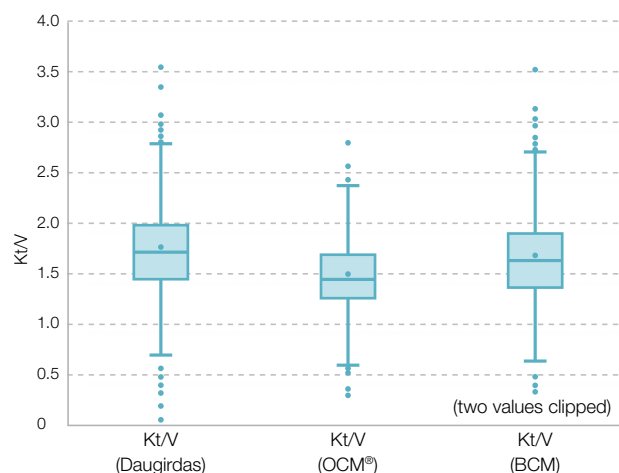


Figure 4: Kt/V^{BCM} is the closest to the gold standard²⁷
(Graph adapted from original publication)

Highlights

- Easy and transparent monitoring of the delivered dialysis dose and plasma sodium without additional effort and cost
- Monitoring of having achieved the prescribed dialysis dose which may lead to better patient outcome²⁵
- OCM® in combination with the BCM-Body Composition Monitor is a highly-reliable way to accurately measure the achieved dialysis dose (see Figure 4)

*OCM® measurement is not possible in the event of HF and ISO-UF treatment.

Easy assessment of vascular access

Advanced access management

High extracorporeal blood flow rates correspond to a high clearance of uraemic toxins. Problems with vascular access are increasing in the dialysis population due to age and comorbidities like diabetes, and may significantly reduce dialysis efficacy.

Assessing the quality of the vascular access is sophisticated and therefore not possible for daily quality assurance. The regular monitoring of blood flow and recirculation* can prevent serious complications associated with insufficient blood purification.²⁹

The Blood Temperature Monitor (BTM**), however, is able to measure the recirculation and therefore determine the corresponding vascular access flow²⁸ during treatment. This helps to evaluate the quality of vascular access and to monitor its trend.²⁹

Twister

The Twister is disposable to facilitate the determination of the vascular access flow by using the recirculation measurement with the help of the reverse-flow technique. It is placed between the dialysis needles and the patient's connection lines of the blood tubing set.

Highlights

- Early detection of vascular access dysfunction via recirculation measurement and vascular access flow determination ensures an effective dialysis dose^{29,30}
- Regular monitoring of vascular access condition by BTM recirculation measurement without user interaction and additional costs



Figure 5: Twister disposable

*Vascular access recirculation occurs if the actual blood flow is higher than the vascular access flow provided.

**Must be purchased separately.

Individual temperature control

Symptomatic hypotensive episodes due to an increase in body temperature are a well-known complication affecting patients during dialysis.³¹ Considering these side-effects, the stabilisation of core body temperature is one of the basic requirements of haemodialysis.

BTM – Blood Temperature Monitor

With the help of the unique BTM, an individual's predialytic body temperature can automatically be maintained throughout dialysis treatment. In the event that a change in the body temperature is required, the BTM can slightly adapt the temperature within the pre-set limits.

Highlights

- Fewer complications during treatment³¹
- No user interaction required due to automatic measurement and adaptation with BTM



Figure 6: BTM – Blood Temperature Monitor

Cardioprotective Haemodialysis

Better haemodynamic stability during dialysis treatment thanks to the BTM's unique temperature control.³¹

Advanced therapies

Advanced therapies for home patients

The 5008S CorDiax supports the full range of home haemodialysis therapies (e.g. long nocturnal, short daily, conventional), allowing healthcare professionals and patients to adjust therapies to the changing clinical and lifestyle needs of patients while maintaining dialysis treatment.

With its specially-tailored home version*, the 5008S CorDiax offers the full benefits from conventional HD to HighVolume**HDF** with enhanced safety features and easy handling.

- HighVolume**HDF** with FX CorDiax haemodiafilters for efficient toxin removal, with fully automatic adjustment of substitution rates (*AutoSub plus*), without the need for user intervention
- Built-in Venous Access Monitor (VAM) and optional wetness detector (VenAcc* device) for optimal monitoring of venous access
- Special user interface (as part of the specially-tailored home version*) adapted to the patient's needs

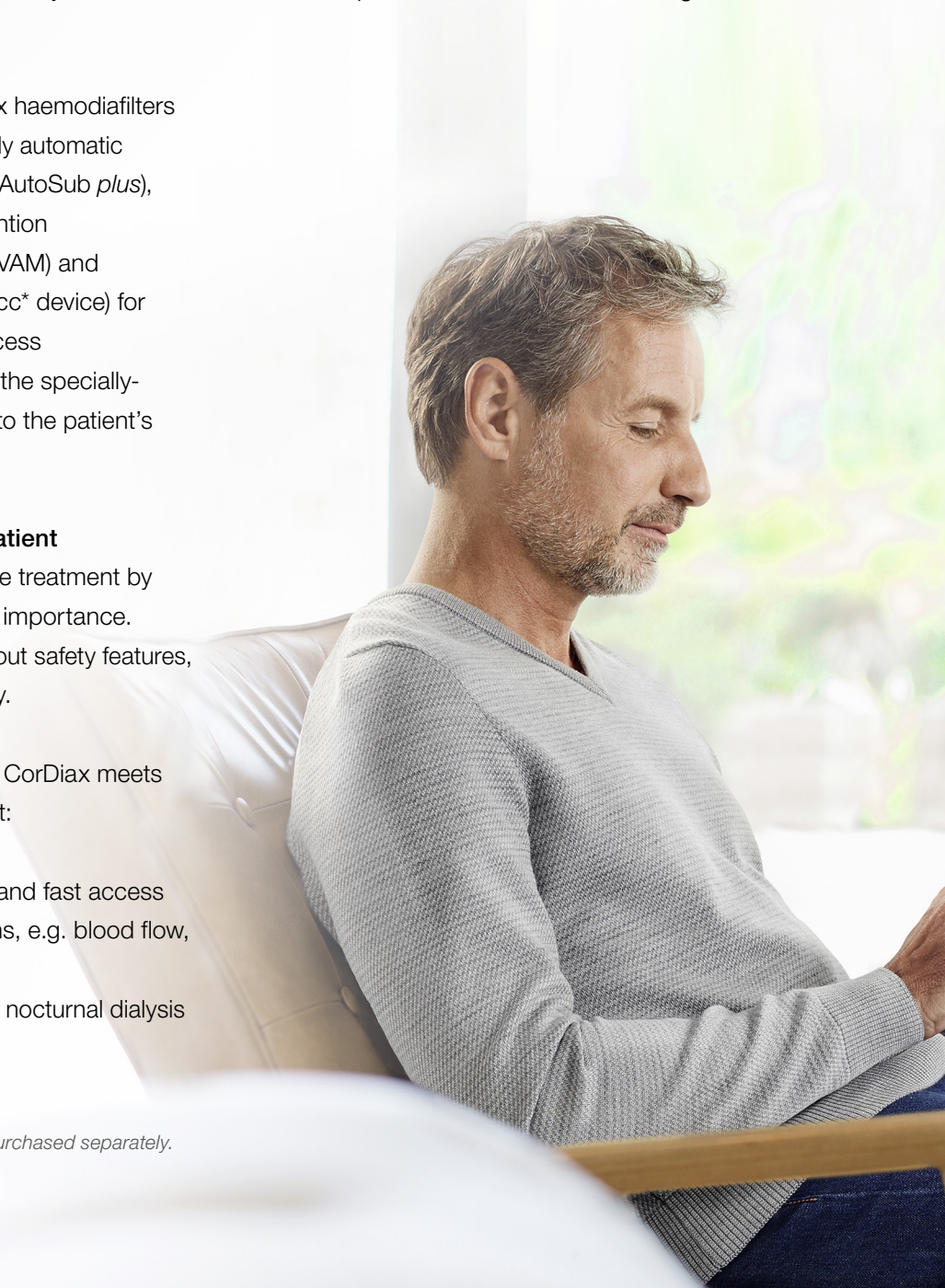
Easy and safe handling for the patient

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

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

- Patient-friendly screens 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
- Remote control (as part of the specially-tailored home version*) for simplified operation of the main functions. It also includes an emergency button which gives the patient the possibility to react immediately in a critical situation (e.g. blood pressure drop)
- *ONLINEpriming* for the simple preparation of the extracorporeal circuit without saline bags



**Some features are optional and must be purchased separately.*



Products customised for dialysis at home

Fresenius Medical Care provides a complete portfolio of products and services which are suited for the home environment:

- The AquaC UNO H* is specially designed for home dialysis. This single reverse osmosis system supplies high-quality dialysis water for HD and HDF therapies. With its compact size, the AquaC UNO H fits well in homes of various sizes and minimises home disturbance through its low-noise emission design.

Nearly no user interaction is required due to its fully-automatic heat disinfection functionality. Two water efficiency options (OPTION Eco** & OPTION FREE**) facilitate significant water saving potential. The OPTION FREE is especially designed for longer patient absence since hygienic conditions can be maintained for up to 30 days without a water connection. That saves water compared to the standard operation setup.

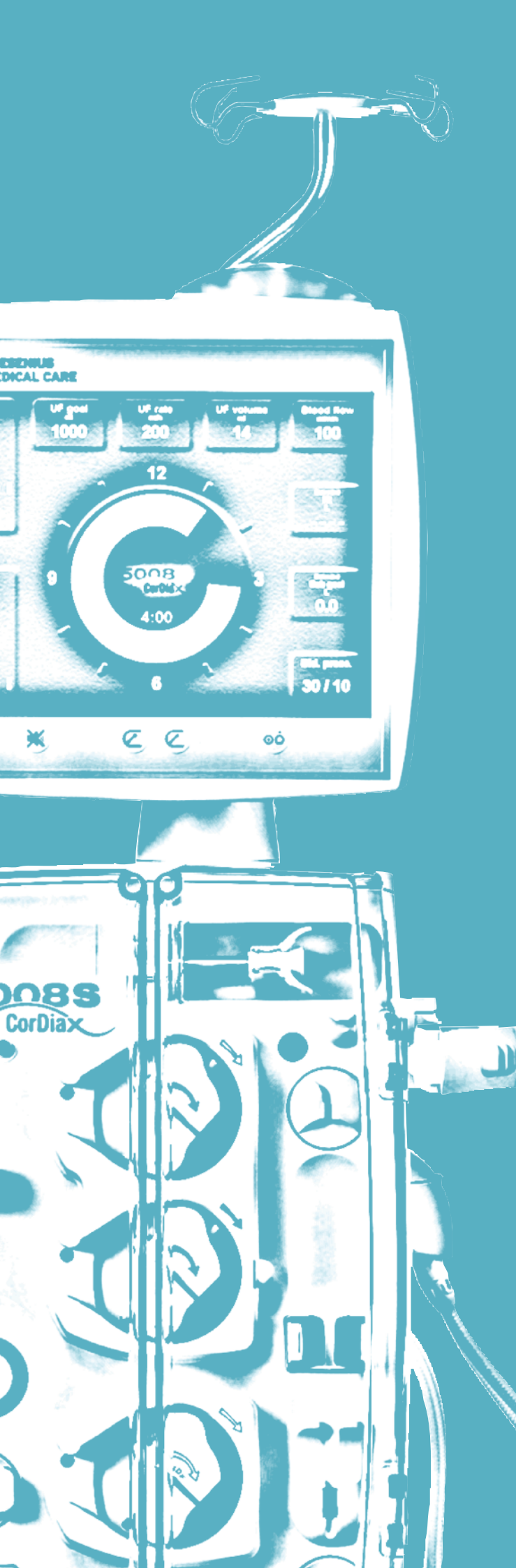
- The smartbag® and bibag concentrate sets are designed for easy handling. Thanks to the innovative packaging, the storage space required and afteruse waste are significantly reduced.

Cardioprotective Haemodialysis

The 5008S CorDiox combines Cardioprotective Haemodialysis and the comfort of home.

Home haemodialysis patients can also benefit from HighVolume**HDF**, which has positive effects on survival and cardiovascular outcomes.^{9,10,16}

**OPTION Eco and OPTION FREE are optional features on the AquaC UNO H and are not part of the 5008S CorDiox and must be purchased separately.



Patient safety

100%

of 5008S CorDiax devices are equipped with a Venous Access Monitor – setting a standard in this safety feature category.

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.

The challenge is to think beyond existing technologies and approach well-known problems with innovative solutions, striving for patient safety.

The sophisticated built-in safety features offer improved patient safety, while reducing undesirable incidences and simultaneously simplifying daily routines. The nursing staff is also supported by addressing the following safety topics:

- **Reduced risk of external blood loss**
- **Early detection of paravasal bleeding**
- **Reduction of coagulation risk**
- **Prevention of haemolysis**
- **Precise fluid removal**



Reduced risk of external blood loss

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 5008S CorDiax offers various proven solutions to minimise the risk of external blood loss.

VAM – Venous Access Monitor

The VAM offers dynamic and highly-sensitive monitoring of the venous pressure (see Figure 7) and is able to recognise drops in pressure of 15 mmHg onwards. Therefore, it offers an improved control of the venous path, compared to conventional pressure measurements. This results in the increased likelihood of early detection of venous needle dislodgement by informing the user via an alarm.

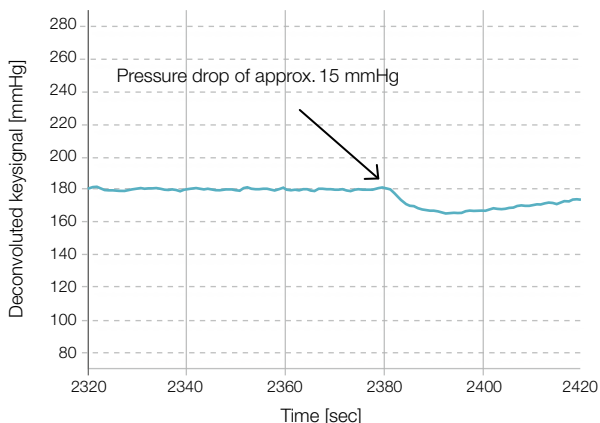


Figure 7: Monitoring of venous pressure with the VAM*

VenAcc**

The VenAcc, an external wetness detector, is designed for the quick detection of blood loss, and is recommended for patients undergoing home and nocturnal dialysis.

In addition to VAM and VenAcc, a leakage sensor and the door concept enable the immediate recognition of leakages in the extracorporeal blood system.



Figure 8: VenAcc device with single-use sensor patch disposable

*Internal unpublished data of Fresenius Medical Care Deutschland GmbH.

**Must be purchased separately.

Early detection of 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 5008S CorDiax allows the early detection of paravasal bleeding and the prevention of large haematomas with Dynamic Pressure Monitoring, which reduces the risk of undetected paravasal blood loss.

Reduction of coagulation risk

Contact with any foreign material 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 5008S CorDiax provides non-invasive, air-free arterial pressure monitoring (see Figure 9) without a blood-air interface which may reduce the risk of coagulation during dialysis.³²



Figure 9: Arterial pressure dome

Prevention of haemolysis

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

The 5008S CorDiax enables the detection of potential haemolysis risks by closing the safety gap between the blood pump and venous bubble catcher with Blood Line Kinking and Filter Clotting Detection.

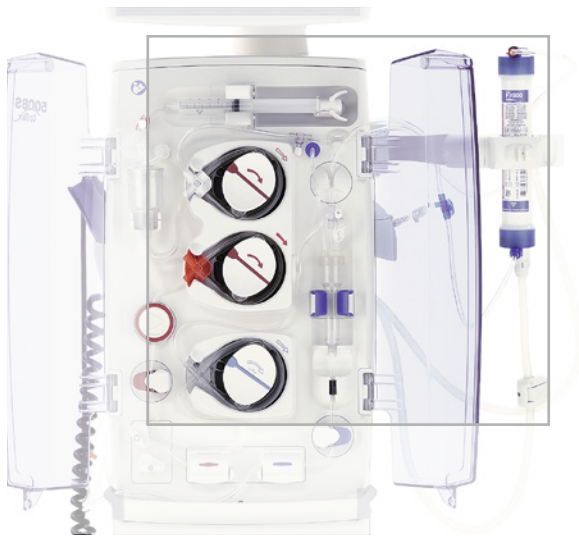


Figure 10: Blood Line Kinking and Filter Clotting Detection

Precise fluid removal

The removal of excess fluid 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 total fluid withdrawn from the patient and the fluid volume substituted must be balanced.

The 5008S CorDiax provides:

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



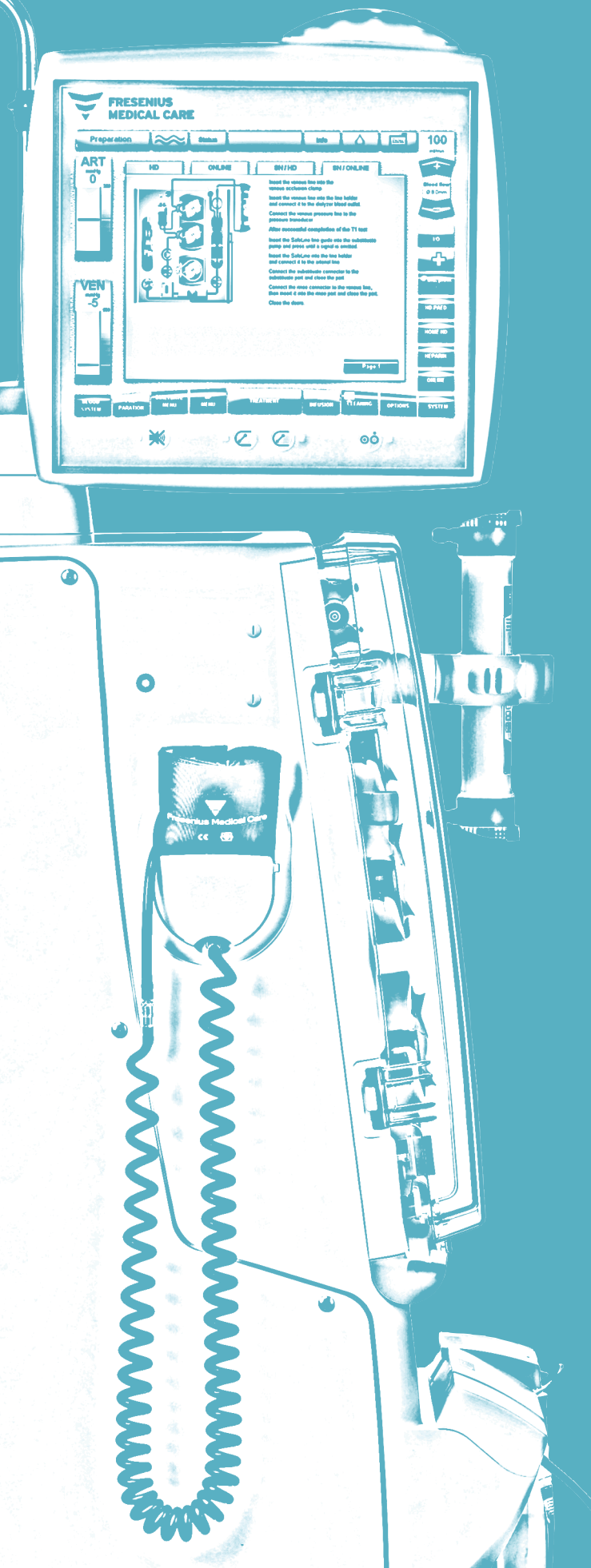
By counting on proven advanced features, the 5008S CorDiax contributes to patient safety.

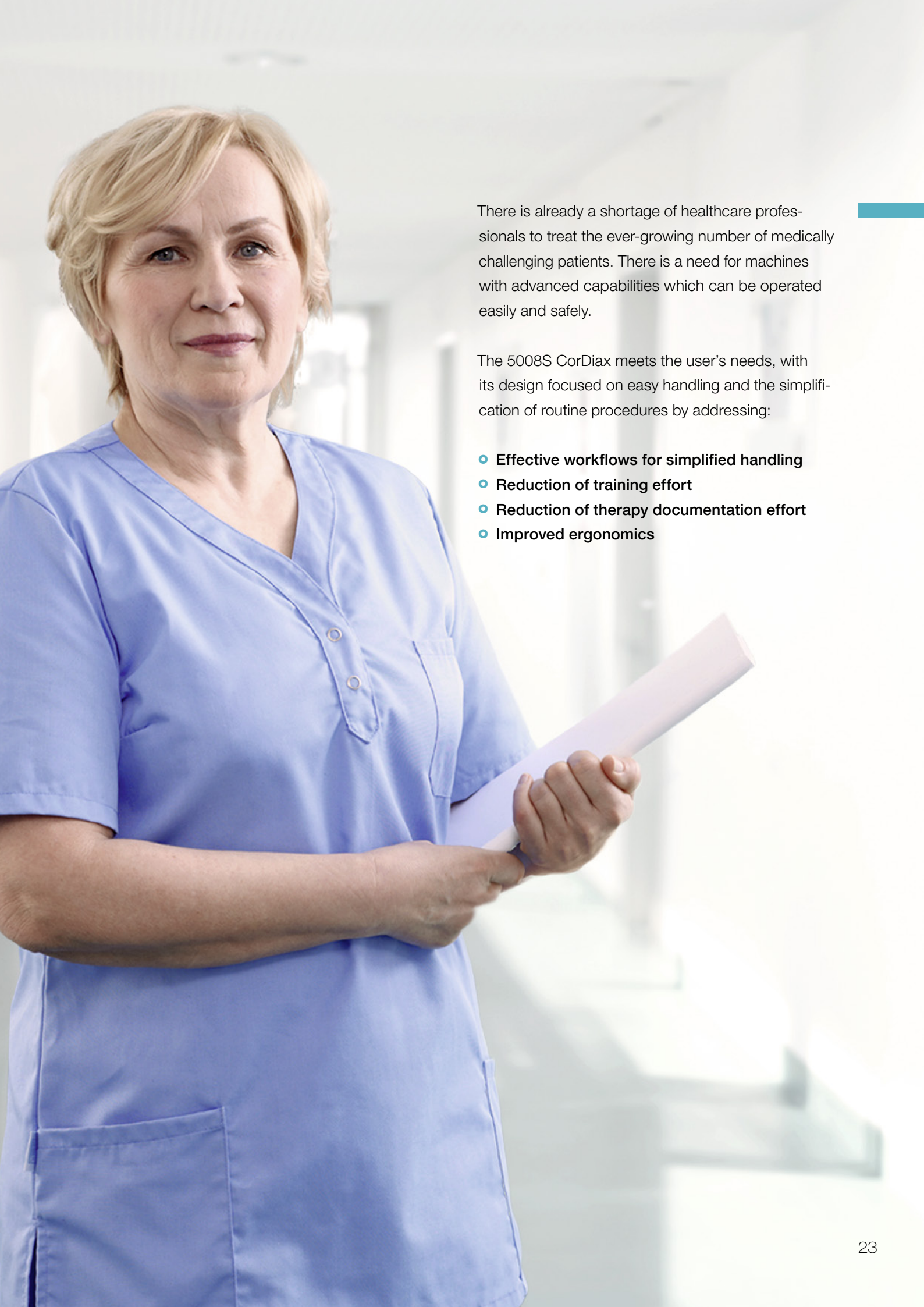
In the development of these safety features, we have united innovative ideas and state-of-the-art technologies to achieve the best possible results. Fresenius Medical Care, the world market leader in dialysis, with over 30 years of expert knowledge, is committed to improving patient safety – because conforming to standards alone is not enough.

Convenient handling

100%

saline bag-free due
to the integrated
ONLINE priming of
the 5008S CorDiax.





There is already a shortage of healthcare professionals to treat the ever-growing number of medically challenging patients. There is a need for machines with advanced capabilities which can be operated easily and safely.

The 5008S CorDiax meets the user's needs, with its design focused on easy handling and the simplification of routine procedures by addressing:

- **Effective workflows for simplified handling**
- **Reduction of training effort**
- **Reduction of therapy documentation effort**
- **Improved ergonomics**

Convenient handling

Effective workflows for simplified handling

The 5008S CorDiax ensures effective workflows for all operators which fit into their daily routines.

ONLINEpriming

ONLINEpriming means that preparation (rinsing), bolus and reinfusion can be performed ONLINE (see page 9 – ONLINEplus technology). This is a well-established and proven standard in the 5008S CorDiax for an automated, saline bag-free operation. It improves operators' daily routines by reducing manual workload.

- Saline bags/bottles and waste bags no longer need to be carried, prepared, connected, disconnected, drained or discarded
- Fewer logistics efforts and less storage capacities are required
- Fewer connection steps and closed fluid circuit reduce the risk of errors and (cross-) contamination for staff and patients
- Ad-hoc availability of bolus administration in case of emergency (e.g. hypotensive episode)
- ONLINEpriming is standard for all blood tubing sets of the 5008 series (e.g. AV-Set ONLINEplus 5008-R, AV-Set ONLINE-Priming 5008S-R) and is applicable for HD, HF and HDF therapies and in Double- and Single-Needle modes



Figure 11: Substitute and rinse port

Intuitive user interface

The 5008S CorDiax's user interface follows an intuitive user-guidance:

- Simple and logical data entry and quick access to treatment protocol
- Sophisticated, stress-free handling of alarms during treatment with an integrated support function
- Centralised operation and information via a large touchscreen display (see Figure 12)

In addition, the 5008S CorDiax offers features to improve the dialysis workflow:

- Machine-assisted procedures (e.g. set-up and dismantling)
- Self-initiating functions at treatment start (e.g. Auto T1 Test) and automated procedures (e.g. level set in the venous bubble catcher, bibag emptying) to reduce the number of handling steps
- Emergency button to initiate four essential steps at once (blood flow reduction, ONLINE Bolus, UF Stop and blood pressure measurement start via the Blood Pressure Monitor (BPM*))
- Timer function to set a reminder for definable tasks (e.g. drug administration)



Figure 12: Touchscreen display

*Must be purchased separately.

Convenient handling

Reduction of training effort

The shortage of qualified healthcare staff requires dialysis machines to be operated easily and safely.

The 5008S CorDiax's workflow with reduced handling steps and an intuitive user interface leads to reduced initial training.

E-learning*

Moreover, an e-learning tool dedicated to the 5008S CorDiax creates a basic understanding of how the machines are set up, how to conduct and end a treatment, in order to prepare the learners for a live training session. It can also be used as an additional learning tool to follow up on operators' hands-on training.** This makes it easy to learn user procedures during the training period, which results in time savings.

Reduction of treatment documentation effort

Therapy documentation and data management are time-consuming processes in dialysis patients' daily treatments. When using the 5008S CorDiax, therapy documentation is supported by:

- Online therapy documentation in combination with Therapy Data Management System (TDMS*)
 - Advanced bedside documentation via touchscreen and data Xchange panel (dXp)
 - Automated treatment data monitoring
- Offline treatment documentation on the PatientCard (current prescription and previous three treatments of individual patients)



Figure 13: Data Xchange panel

*Must be purchased separately.

**Please note: It is not meant to replace the required application training.

Improved ergonomics

The 5008S CorDiax's ergonomic handling offers convenience for users:

- 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 (see Figure 14)
- Simple, one-handed and hygienic bibag (dry bicarbonate supply) connection

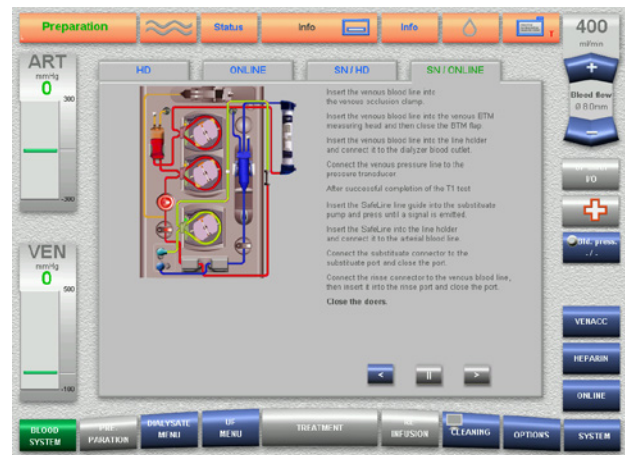


Figure 14: Machine-assisted set-up screen



Direct cost savings

~ 11,500

**kg of waste reduced
per year due to
ONLINEpriming.***

***Assumptions:**

Waste includes discarded fluid within saline solution and waste bag and discarded bags (discarded fluid waste ~ 90%, discarded plastic waste ~ 10%).

The calculation is based on an amount of 10,000 treatments, each making use of 1x NaCl 0.9% Frekaflex 1,000 mL and 1x NaCl 0.9% Frekaflex 500 mL, 1x Waste bag, 1x AV-set Online plus 5008-R and 1x FX CorDiax 800.

Only preparation (rinsing) and reinfusion are considered.

The waste reduced per treatment amounts to approximately 1.15 kg.

(Internal unpublished data of Fresenius Medical Care Deutschland GmbH)

The challenge for dialysis providers nowadays is to focus on investments that enable the most efficient use of limited resources. Increasing economic pressure further requires that intelligent solutions provide the best possible dialysis therapy for all patients in a cost-effective manner.

Fresenius Medical Care has taken up this challenge with the 5008S CorDiax, allowing to perform advanced therapies in an efficient way, involving both economic and environmental aspects.

The 5008S CorDiax delivers efficiency in an environmentally sustainable manner, which positively impacts the use of resources including dialysis fluid, energy and waste. Thus, the 5008S CorDiax offers environmentally-friendly and economical benefits. Additionally, it supports nursing staff in all working processes, which potentially saves nursing time.

From a service perspective, the 5008S CorDiax is characterised by quality and reliability, resulting in the potential for further savings.

The 5008S CorDiax counts on:

- **Efficient and sustainable operations**
- **Effective workflows**
- **Advanced service-friendliness**



Direct cost savings

Efficient and sustainable operations

In addition to advanced treatment options and economic benefits, the 5008S CorDiax is also favourable in terms of eco-friendliness.³³ Herewith, Fresenius Medical Care supports the sensible and environmentally sustainable use of resources by saving water, concentrates and energy in the use phase. This in turn leads to further cost savings. The 5008S CorDiax uses several features for environmentally-friendly haemodialysis:

- ONLINE^{plus} technology for the production of sterile, endotoxin-free and bicarbonate buffered electrolyte solutions
 - No need for ready-made rinse solutions due to ONLINE^{priming} in all treatment modes (also in HD)*
- Waste disposal of saline solution and waste bag is not required, due to the integrated substitute and rinse port
- Reduced environmental footprint since the manufacturing, transport and disposal of saline solution and waste bag is now obsolete
- AutoFlow automatically adjusts the dialysate flow rate to the effective blood flow rate during treatment
- AutoFlow could provide reduced operating costs due to savings of water, waste water, concentrates and energy (see Figure 15)
- Automatic selection of AutoFlow factor based on treatment mode, always accomplishing an optimal ratio between economic considerations and treatment quality

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



- EcoFlow automatically reduces the dialysate flow to 100 mL/min during idle time. This reduces dialysate and energy consumption during preparation and after reinfusion, while avoiding bacterial growth.
- Heat exchanger for energy savings during the use phase due to utilising the energy from waste dialysate to heat the incoming water

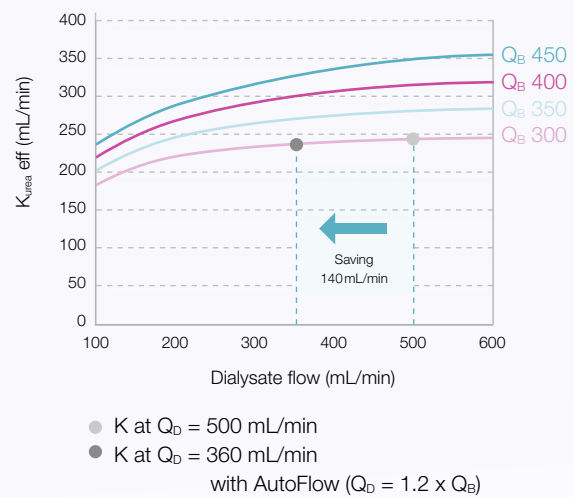


Figure 15: Dialysate flow savings with AutoFlow without compromising K_{urea} *

*Internal unpublished data of Fresenius Medical Care Deutschland GmbH.



Direct cost savings

Effective workflows

The challenge nowadays is to treat an increasing number of patients with the same amount of nursing staff, making efficiency in dialysis treatments highly important. In order to improve processes and therefore achieve economic advantages for the dialysis centre, the 5008S CorDiax offers improved workflows for nursing staff by providing:

- Highly-automated assistance for all users:
 - Multiple automated processes (e.g. Auto On/Off, emergency function) to reduce interactions and work-related pressure
 - *ONLINEpriming* simplifies handling and logistics procedures (e.g. the procurement, transport, storage and disposal of saline solution and waste bags)
- The full integration of the Therapy Data Management System (TDMS) allows for minimal handling steps for startup and reduces the time needed to manage data
- Animated screens support the quick learning of user procedures, which leads to less time and effort required during the training period

Figure 16: Easy and comprehensive diagnosis of faults and detailed technical error memory with Service Software and Service Card

Advanced service-friendliness

Fresenius Medical Care is known for providing high-quality, reliable products and services. The 5008S CorDiax contributes to support and facilitate daily routines with its unmatched service-friendliness:

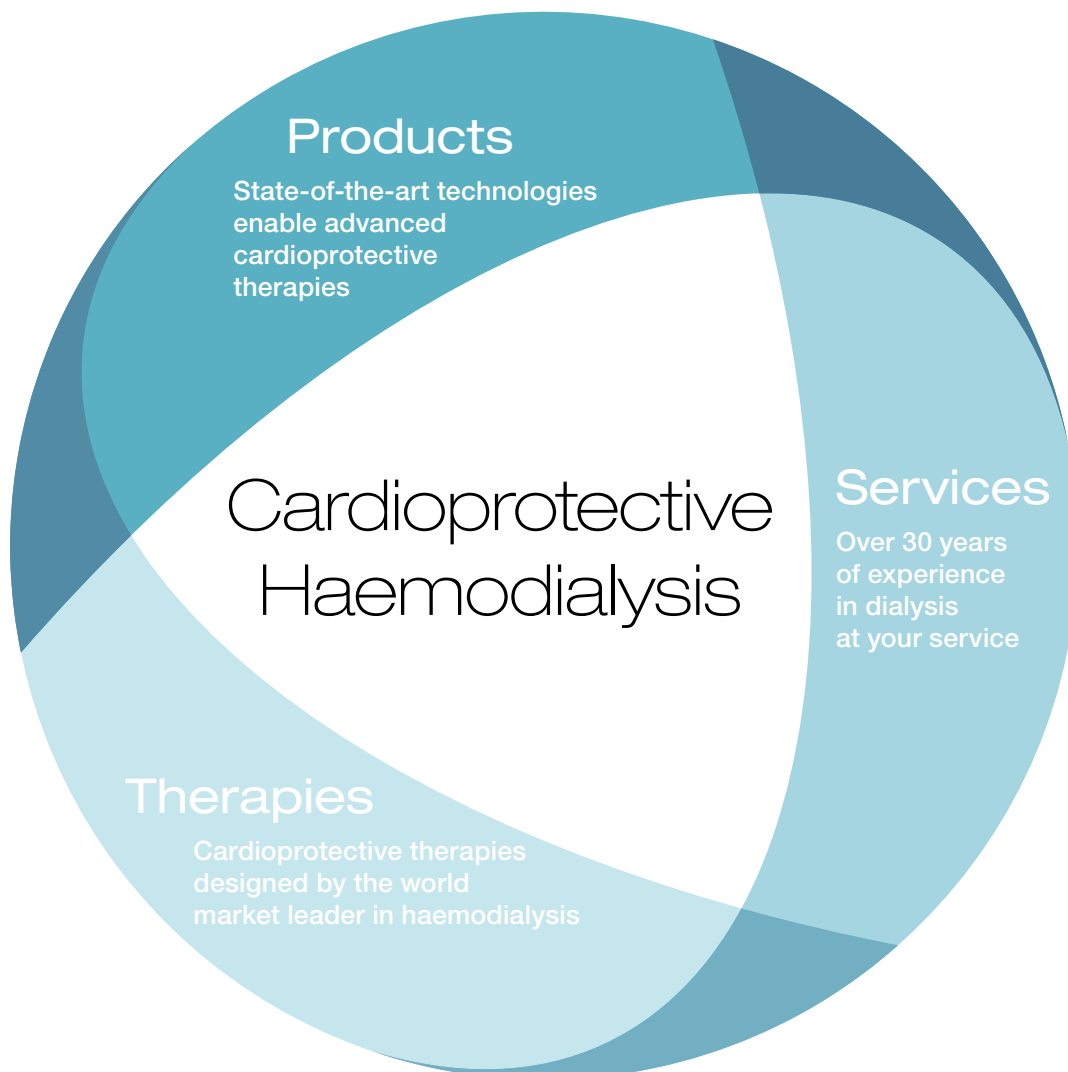
- Interactive, real-time hydraulic flow chart for rapid error diagnosis and easy maintenance
- Remote service: Quick diagnostic inspection via remote access to the dialysis machine
- Accessibility to all hydraulic and electronic parts in and around the machine
- Simple repair using snaplock technology – fast and easy replacement of components
- Easy and comprehensive diagnosis of errors and detailed technical error memory with Service Software and the Service Card (Figure 16)
- High reliability due to long-lasting components, which are readily available, should they need to be replaced
- Advanced diagnostics for pneumatics, which allow the technician to check all single pneumatic components by means of an interactive construction plan
- 24-month maintenance intervals



An holistic approach you can count on

Fresenius Medical Care provides an holistic approach for Cardioprotective Haemodialysis by combining therapies, products and services for improved patient outcomes. Due to our comprehensive portfolio, we are able to provide solutions which contribute to the efficient management of cardiovascular risk factors and better day-to-day clinical handling.

Cardioprotective Haemodialysis aims to help health-care professionals be confident that they are providing the best possible care and outcomes for their patients. We are passionate about Cardioprotective Haemodialysis, offering advanced therapies, a comprehensive portfolio and extensive experience for better care and clinical efficiency.



Products

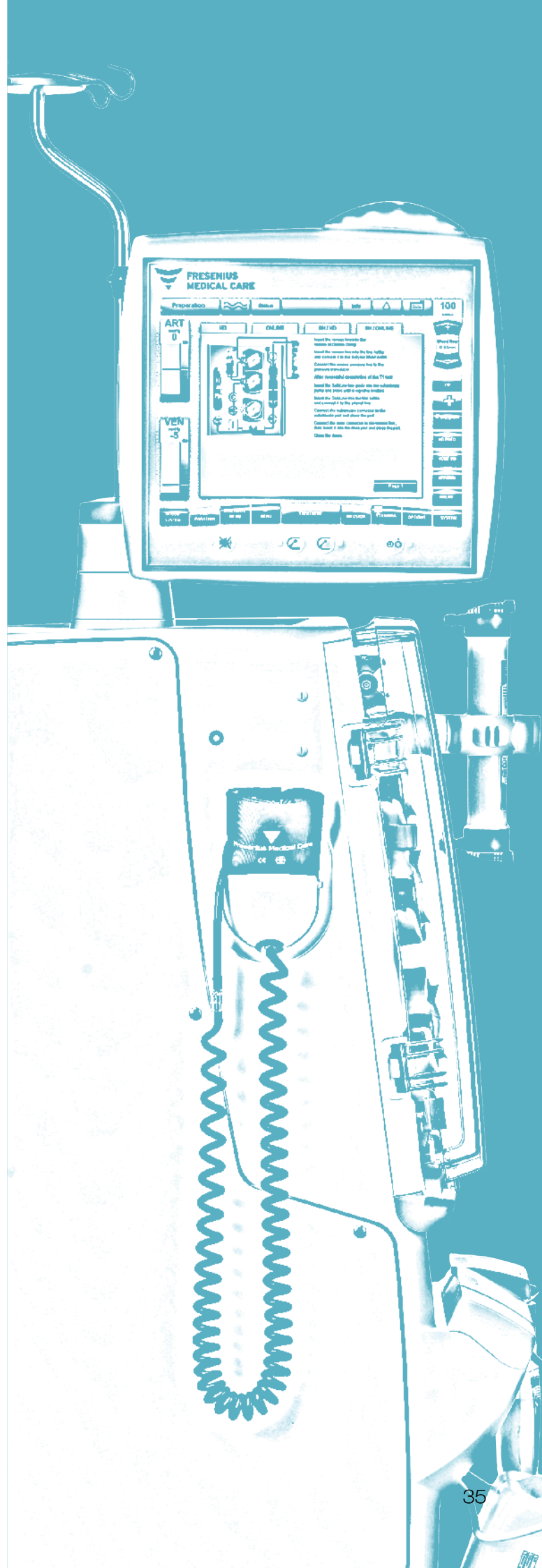
- Therapy systems, e.g.
 - 6008 CAREsystem
 - 5008S CorDiax
- FX Dialysers, e.g.
 - FX CorDiax dialysers
 - FX classix dialysers
- VenAcc
- BCM-Body Composition Monitor
- Fluid Management Tool (FMT)
- Therapy Data Management System (TDMS)
- Online Purification Cascade (OPC)
- AquaC UNO H

Therapies

- HighVolumeHDF
- High-flux haemodialysis
- Advanced Fluid Management
- Advanced Access Management

Services

- Project planning and consulting
- Training and education (e.g. e-learning)
- Technical services
- Water Quality Service (WQS)
- Medical information services



5008S CorDiax – Product Configuration

	5008S CorDiax
Therapy highlights	
ONLINE HDF – pre- and post-dilution	● / ●
AutoSub <i>plus</i> – automatically maximising substitution volumes in a highly safe manner	●
ONLINE HDF during Single-needle treatment	○
Blood Temperature Monitor (BTM) – regulation of temperature and recirculation measurement	○
Home haemodialysis – advanced therapies for home patients	○
Safety features	
Integrated Venous Access Monitor – increased probability of the detection of venous needle dislodgement	●
Dynamic Pressure Monitoring – detection of paravasal bleeding ("infiltration")	●
VenAcc external device for the detection of venous needle disconnection	○
Blood Line Kinking and Filter Clotting Detection – prevention of haemolysis	●
Leakage sensors in the hydraulics and extracorporeal blood circuit module	●
Basic features	
Dialysis fluid ultrafilter system – sterile fluid for ONLINE use	●
ONLINE <i>priming</i> = ONLINE preparation (rinsing), ONLINE bolus and ONLINE 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	●
Advanced service tools for fast diagnostics and maintenance, with interactive hydraulic and pneumatic flow charts and remote access	●
Timer function for setting a reminder for a definable task	●
Eco-friendly features	
Heat exchanger for energy savings during use phase	●
AutoFlow – automatic adaptation of dialysate flow for the optimal balance between 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

5008S CorDiax – Technical Data

General data	
Dimensions 5008S CorDiax	1,680 x 520 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
Central supply	2 central acid concentrates (optional)
Electrical data	
Power supply	110 to 240 V AC ± 10%, 50 to 60 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: volt-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 measurement	
Display range	–300 mmHg to +300 mmHg
Accuracy	± 7 mmHg
Resolution	5 mmHg
Alarm reaction	Dynamic, static, immediately
Venous pressure measurement	
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 through tubing, 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
Dialysate concentration (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% (Double-Needle)
Bicarbonate dry concentrate	bibag
Dialysis fluid filter system	DIASAFE®plus
ONLINEplus	ONLINE Haemo(dia)filtration
Substitution rate	25 to 600 mL/min
Accuracy	± 10%
Balancing accuracy	± 0.1% relative to the total dialysis fluid 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)	
Body temperature change	Accuracy ± 0.2 °C
Body temperature control	Allowed change rate ± 0.5 °C/h
Recirculation measurement	Accuracy ± 2%
BPM (optional)	
Display range	Systole: 60 mmHg to 250 mmHg Diastole: 40 mmHg to 200 mmHg MAP: 45 mmHg to 235 mmHg Pulse: 40 to 200 1/min
Accuracy	≤ ± 5 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 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)
Disinfection Puristeril® 340/plus (recirculation)	
Temperature/flow	37 °C/600 to 700 mL/min (adjustable)

*Various programme combinations selectable.

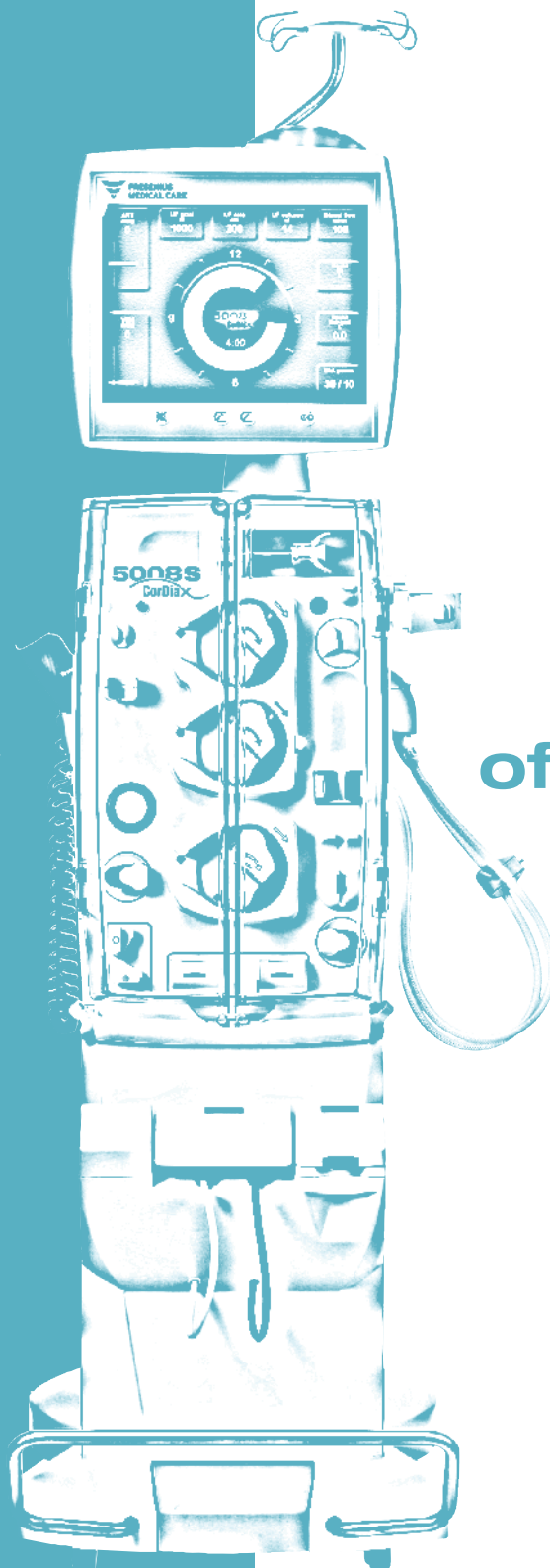
Technical changes reserved.

References

- 1 Mark P.B., *Strategies to manage cardiovascular risk in chronic kidney disease*, Nephrol Dial Transplant (2018); 33:23-25.
- 2 Gansevoort R.T. et al., *Chronic kidney disease and cardiovascular risk: epidemiology, mechanisms, and prevention*, Lancet (2013); 382: 339-352.
- 3 de Jager D.J. et al., *Cardiovascular and Noncardiovascular Mortality Among Patients Starting Dialysis*, JAMA (2009); 302(16): 1782-1789.
- 4 Marcelli D. et al., *High-Volume Postdilution Hemodiafiltration Is a Feasible Option in Routine Clinical Practice*, Artificial Organs (2015); 39(2): 142-149.
- 5 Liabeuf S. et al., *Plasma beta-2 microglobulin is associated with cardiovascular disease in uremic patients*, Kidney Int (2012); 82: 1297-1303.
- 6 Cheung A.K. et al., *Serum β -2 Microglobulin Levels Predict Mortality in Dialysis Patients: Results of the HEMO Study*, J Am Soc Nephrol (2006); 17: 546-555.
- 7 Chazot C. et al., *Effect of Membrane Permeability on Cardiovascular Risk Factors and β 2m Plasma Levels in Patients on Long-Term Haemodialysis: A Randomised Crossover Trial*, Nephron (2015); 129: 269-275.
- 8 Vanholder R. et al., *Review on uremic toxins: Classification, concentration, and interindividual variability*, Kidney Int (2003); 63: 1934-1943.
- 9 Wanner C. et al., *Effect of dialysis flux and membrane material on dyslipidaemia and inflammation in haemodialysis patients*, Nephrol Dial Transplant (2004); 19: 2570-2575.
- 10 Merello Godino J.I. et al., *Results from EuClid® (European Clinical Dialysis Database): Impact of shifting treatment modality*, Int J Artif Organs (2002); 25(11): 1049-1060.
- 11 Koda Y. et al., *Switch from conventional to high-flux membrane reduces the risk of carpal tunnel syndrome and mortality of hemodialysis patients*, Kidney Int (1997); 52: 1096-1101.
- 12 Locatelli F. et al., *Comparison of mortality in ESRD patients on convective and diffusive extracorporeal treatments*, Kidney Int (1999); 55: 286-293.
- 13 Mostovaya I.M. et al., *Clinical Evidence on Hemodiafiltration: A Systematic Review and a Meta-analysis*, Seminars in Dialysis (2014); 27(2): 119-127.
- 14 Peters S.A.E. et al., *Haemodiafiltration and mortality in end-stage kidney disease patients: a pooled individual participant data analysis from four randomized controlled trials*, Nephrol Dial Transplant (2016) 31: 978-984.
- 15 Locatelli F. et al., *Effect of Membrane Permeability on Survival of Hemodialysis Patients*, J Am Soc Nephrol (2009); 20: 645-654.
- 16 Maduell F. et al., *High-Efficiency Postdilution Online Hemodiafiltration Reduces All-Cause Mortality in Hemodialysis Patients*, J Am Soc Nephrol (2013); 24: 487-497.
- 17 Ok E. et al., *Mortality and cardiovascular events in online haemodiafiltration (OL-HDF) compared with high-flux dialysis: results from the Turkish OL-HDF Study*, Nephrol Dial Transplant (2013); 28: 192-202.
- 18 Grooteman M.P.C. et al., *Effect of Online Hemodiafiltration on All-Cause Mortality and Cardiovascular Outcomes*, J Am Soc Nephrol (2012); 23(6): 1087-1096.
- 19 Canaud B. et al., *Mortality risk for patients receiving hemodiafiltration versus hemodialysis: European results from the DOPPS*, Kidney Int (2006); 69(11): 2087-2093.
- 20 Lederer S.R. and Schiff H., *Ultrapur Dialysis Fluid Lowers the Cardiovascular Morbidity in Patients on Maintenance Hemodialysis by Reducing Continuous Microinflammation*, Nephron (2002); 91: 452-455.
- 21 Wizemann V. et al., *The mortality risk of overhydration in haemodialysis patients*, Nephrol Dial Transplant (2009); 24: 1574-1579.
- 22 Zoccali C. et al., *Chronic Fluid Overload and Mortality in ESRD*, J Am Soc Nephrol (2017); 28(8): 2491-2497.
- 23 Assimon M.M. et al., *Ultrafiltration Rate and Mortality in Maintenance Hemodialysis Patients*, Am J Kidney Dis (2016); 68(6): 911-922.
- 24 Machek P. et al., *Guided optimization of fluid status in haemodialysis patients*, Nephrol Dial Transplant (2010); 25: 538-544.
- 25 Tattersall J. et al., *EBPG guideline on dialysis strategies*, Nephrol Dial Transplant (2007); 22 (suppl 2): ii5-ii21.
- 26 European Best Practice Guidelines for Haemodialysis (Part 1) (2002); 17 (suppl 7): 17-31.
- 27 Ahrenholz P. et al., *Determination of Dialysis Dose: A Clinical Comparison of Methods*, Blood Purif (2011); 32: 271-277.
- 28 Krivitski N.M., *Theory and validation of access flow measurement by dilution technique during hemodialysis*, Kidney Int (1995); 48: 244-250.
- 29 Fontseré N. et al., *Observational Study of Surveillance Based on the Combination of Online Dialysate and Thermodilution Methods in Hemodialysis Patients with Arteriovenous Fistulas*, Blood Purif (2014); 37(1): 67-72.
- 30 Badr B. et al., *Transonic, thermodilution, or ionic dialysate to manage vascular access: Which method is best?*, Hemodialysis International (2014); 18: 127-135.
- 31 Maggiore Q. et al., *The Effects of Control of Thermal Balance on Vascular Stability in Hemodialysis Patients: Results of the European Randomized Clinical Trial*, Am J Kidney Dis (2002); 40 (2): 280-290.
- 32 Kessler M. et al., *Anticoagulation in Chronic Hemodialysis: Progress Toward an Optimal Approach*, Seminars in Dialysis (2015); 28(5): 474-489.
- 33 Mesic E. et al., *Dialysate saving by automated control of flow rates: Comparison between individualized online hemodiafiltration and standard hemodialysis*, Hemodialysis International (2011); 15(4): 522-529.
- 34 Moissl U. et al., *Body fluid volume determination via body composition spectroscopy in health and disease*, Physiol. Meas (2006); 27: 921-933.2.

A real story

of success





**FRESENIUS
MEDICAL CARE**

Head office: Fresenius Medical Care Deutschland GmbH · 61346 Bad Homburg v. d. H. · Germany
Phone: +49 (0) 6172-609-0 · Fax: +49 (0) 6172-609-2191
www.FreseniusMedicalCare.com