FX CorDiax
Designed to Dialyse. Built for Cardioprotection
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.

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

Cardioprotective Haemodialysis

Wide-ranging cardioprotection

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.

- CorDix product line:
  - 5008 CorDix and 5008S CorDix
  - FX CorDix haemodialyfilter
  - BCM-Body Composition Monitor
- Classix product line:
  - 4008S classix
  - FX classix dialysers
- Therapy Data Management System (TDMS)
- Online Purification Cascade (OPC)
Moreover, both overall and cardiovascular mortality are markedly greater in ESRD patients than in the general population. This is why we put Cardioprotective Haemodialysis on the SPOT. A comprehensive approach that includes services, products and therapies is needed to achieve the best therapeutic performance – meaning improved clinical outcomes and better quality of life, enhanced control of therapy costs, and simpler, safer handling.

Haemodialysis

Outcomes
Achieving better outcomes with cardioprotective therapies.
- Reduced mortality risk
- Fewer cardiovascular complications
- Optimised use of resources

Therapies
Cardioprotective therapies designed by the world market leader in haemodialysis.
- High-Flux dialysis
- HighVolume HDF®
- Advanced Fluid Management
The effects of chronic kidney disease (CKD) as well as the effects of dialysis itself can lead to cardiovascular diseases [e.g. atherosclerosis and left ventricular hypertrophy (LVH)], the largest causes of death in haemodialysis patients. Improved middle molecule removal, through enhanced High-Flux membranes for haemodiafiltration, can substantially reduce these risks.

A number of large, multi-centre studies show that the use of High-Flux membranes improves patient survival and quality of life.
reducing the induction of inflammatory cascades that are central to many aspects of CVD.

State-of-the-art technologies such as Fresenius’ Nano Controlled Spinning (NCS™) and INLINE steam sterilisation are the result of continual innovation at Fresenius Medical Care.

Advances in material and production technologies have permitted improvements in the wall structure by opening up the support region of the membrane. The Helixone®plus membrane in the new FX CorDiax dialysers improves the clearance of middle molecules while the loss of essential blood components such as albumin is curtailed. The Helixone®plus membrane upgrades the FX-class® dialyser into the CorDiax product line, which provides products for superior cardioprotective therapies.
The new FX CorDiaz

Advances in fibre design allow better removal of uraemic toxins

- The fibre support region underneath the inner surface has been “opened up”, optimising porosity and therefore also the convective filtration (“flushing”) of larger uraemic toxins such as \( \beta_2 \)-microglobulin (\( \approx \) 11,800 Da) or myoglobin (\( \approx \) 17,000 Da).
- At the same time the size of the pores of the inner surface area was not increased to avoid flushing of albumin.

FX CorDiaz eliminates more middle molecules than FX

Maduell et al. determined middle molecule removal of FX CorDiaz 60 compared to FX 60 in HDF postdilution treatments. Significantly higher removal rates were observed with FX CorDiaz for

- Urea (60 Da)
- \( \beta_2 \)-microglobulin (11.8 kDa)
- Myoglobin (17.2 kDa)
- Prolactin (22.9 kDa)
- \( \alpha_1 \)-microglobulin (33 kDa)

The authors concluded that “… treating patients with online haemodialfiltration and FX CorDiaz 60 instead of FX 60 dialysers results in significantly increased reduction ratios of middle sized molecules without clinically relevant changes in albumin loss.

1 Maduell et al.; ERA-EDTA Congress 2013, May 20, Poster Number MP 390.
- The benefits of the advanced fibre design is not limited to better middle molecule removal. The reduced transmembrane resistance of the FX CorDiax improves the removal of low molecular weight substances, e.g. phosphate.

![Phosphate clearance graph](image)

Comparison of aqueous in-vitro clearances of phosphate ($Q_b = 300 \text{ mL/min}, Q_D = 500 \text{ mL/min}$). Investigations carried out by EXcorLab GmbH, an Accredited Calibration and Testing Laboratory.

- In a postdilution HDF treatment the use of FX CorDiax 100 dialysers resulted in a significantly higher clearance of $\beta_2$-microglobulin than FX 100 and Polyflux® 210H dialysers. The albumin loss was low and similar for all dialysers.²

![Albumin loss graph](image)

Comparison of albumin loss in a post-dilution HDF treatment ($Q_a = 350 \text{ mL/min}, Q_D = 800 \text{ mL/min}, Q_S = 80 \text{ mL/min}$)²

<table>
<thead>
<tr>
<th>Dialyser</th>
<th>Albumin loss (g/4h)</th>
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<tr>
<td>FX CorDiax 100</td>
<td>1.74 ± 1.01</td>
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<tr>
<td>FX 100</td>
<td>2.10 ± 1.00</td>
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<tr>
<td>Polyflux® 210H</td>
<td>1.31 ± 0.12</td>
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</tbody>
</table>

The new FX CorDiaz

Clearing middle molecules improves survival rates

The use of High-Flux membranes instead of Low-Flux membranes improved patient survival rates.

- A meta-analysis of 33 randomised controlled trials and 3,820 patients showed a reduction in cardiovascular mortality of 17%.
- All-cause mortality in diabetics and patients with albumin ≤ 4 g/dl was significantly improved.

![Graph of cardiovascular events comparison between Low-Flux HD (N = 1,302) and High-Flux HD (N = 1,310).](image)

Comparison of cardiovascular mortality when High-Flux instead of Low-Flux dialysers were used

(Graph adapted from original publication)

![Graph of survival probability of patients with serum albumin ≤ 4 g/dL.](image)

Comparison of all-cause mortality when High-Flux instead of Low-Flux dialysers were used

(Graph adapted from original publication)

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1 Palmer S.C. et al., Cochrane Database of Systematic Reviews (2012); Issue 9.
Cardioprotective Haemodialysis

Innovation at all Levels
FX-class® Design
Several state-of-the-art technologies have been combined to create the distinctive, functional features of FX-class® dialysers, which are refined and optimised for performance, safety and handling:

- Design of dialyser housing and fibre bundle for more uniform dialysate flow.
- Refined blood inlet port for improved haemodynamics.

Advances in material and production technologies have permitted improvements in the wall structure of the Helixone® plus membrane of the FX CorDiax.

- More porous Helixone® plus membrane wall for higher clearance of middle molecules.

**Optimised dialysate flow**
The 3-dimensional microwave structure of the fibre ensures uniform radial dialysate flow around each fibre within the bundle by preventing fluid channelling, thereby further enhancing clearance values and improving the overall performance of the dialyser.

**Better haemodynamics**
The lateral blood-inlet port ensures more homogenous blood flow in the dialyser header, preventing stagnation zones. The design essentially eliminates the risk of kinking, contributing to improved safety.

**Enhanced convection**
The more open structure of the Helixone® plus membrane support region serves to reduce diffusion resistance and increases convective filtration. This facilitates clearance of a broad range of uraemic toxins, especially the middle molecules.
Kind to the environment
Advanced design goes beyond direct functionality, it also has to be easy on the environment. FX-class® dialysers weigh less than half as much as previous dialysers, and at the same time use ecologically friendly plastics. This means a lower carbon-footprint as a result of fewer materials, less packaging, less fuel for transport and cleaner waste management. Due to less priming volume and easy preparation, costs are reduced as well.

SPOT on:
- Optimised performance due to radial dialysate flow.
- Enhanced clearance of middle molecules enabled by a more porous support region of the membrane.
The Pure Difference
INLINE Steam Sterilised Dialysers
Protect your Patient

Clean and safe

FX-class® dialysers are sterilised using the unique INLINE steam sterilisation process specifically developed by Fresenius Medical Care.

During the INLINE steam sterilisation process, both the blood and the dialysate compartments are rinsed continuously with steam > 121°C. Since no additional chemicals are needed for cleaning or sterilisation, the finished dialysers have extremely low levels of residuals.

Purity ensured – with steam

No chemical residuals with INLINE steam sterilisation

No need for gamma sterilisation – high energy ionising radiation can degrade and alter the material chemistry, producing potential cytotoxic and carcinogenic residuals inside the dialyser.¹

Low rinsing volumes

Minimal preparation time – since dialysers are clean on arrival, rinsing times prior to use are substantially reduced.

Less rinsing – lower costs

Lower rinsing volumes mean reduced preparation times and costs.

¹ Shintani H. et al., Journal of Analytical Toxicology (1989); 13: 354-357.
² Müller T. F. et al., Nephron (1998); 78: 139-142.
SPOT on:
- Reduced risk of blood contact with toxic residuals.¹
- Activation of the complement system is reduced.²

Integrity test: Air pressure is applied to the fibre bundle from one side while the other side contains sterile water. If any leakages were present in the membrane, air would pass the membrane and create bubbles.
Purity by Design
Superior Endotoxin Retention
What are endotoxins?

Endotoxins are large molecules from the outer membrane wall of gram-negative bacteria. Chemically, endotoxins are lipopolysaccharides (LPS), having lipid and polysaccharide components.

Microbial contamination of water or fluid conduits can therefore lead to the presence of endotoxins in dialysis fluid.

While intact endotoxins are relatively large molecules, their smaller endotoxin fragments may pass across dialysis membranes into the patient’s blood via backdiffusion or backfiltration.

Greater protection through active prevention

Once in the patient’s blood, endotoxins can induce complement and leucocyte activation, leading to inflammatory responses. Sometimes, these may result in acute reactions such as fever, headaches, convulsions or low blood pressure. In the longer term, they may also contribute to chronic conditions such as amyloidosis, an increased need for EPO, immune disorders or accelerated atherosclerosis. Atherosclerosis and cardiovascular diseases are the most frequent causes of death for dialysis patients.

Inflammatory responses simulated by blood-membrane interactions and bacterial dialysate contaminants

[Diagram showing Endotoxins, Complement Activation, Membrane-Leucocyte Interaction, Reactive Oxygen Species, Cytokine Release (IL-1, IL-6, TNF-α), and Complement + Endotoxin Mediated Leucocyte Activation]
Membranes, such as Helixone®, which have a high endotoxin retention capacity, protect the patient from inflammation, particularly when ultrapure dialysate is not available.1

Endotoxin adsorption per cm² membrane surface area after 120 min in-vitro dialysis with contaminated dialysate (endotoxin from bacterial culture filtrates; initial concentration 50 EU/mL).1

(Graph adapted from original publication)

How to prevent endotoxins entering dialysis fluids

- Improved overall hygiene management.

- Mandatory use of ultrapure dialysis fluid by using dialysis fluid filters such as DIASAFE® plus to remove residual endotoxins from dialysis fluid.

- Use of dialysis membranes with high endotoxin retention capacities, particularly when ultrapure dialysate is not available (e.g. Helixone® or Helixone® plus).

Open up to Porosity
Enhanced Middle Molecule Removal
Key to optimal middle molecule removal

Solute encounter resistance while traversing the membrane wall. Resistance to solute transport is affected, in part, by pore size at the inner surface and the porosity of the membrane wall.

Furthermore, wall structure and thickness as well as inner fibre dimensions and 3-dimensional microwave structure play important roles in transmembrane flux.

The new membrane structure of Helixone® plus allows the easy passage of middle molecules across the more porous support region of the membrane.

- The structure of the support region is crucial to overall performance.
- Membrane porosity, together with the pore size, regulates the transport of middle molecules.
Refined membrane architecture

New production technology combined with INLINE steam sterilisation allows crucial enhancements of membrane porosity, reducing flow resistance and improving transport across the membrane.

- Significantly improved removal of middle molecules while preventing the loss of useful substances, such as serum albumin.

SPOT on:

- Optimised membrane porosity for enhanced removal of middle molecules.
Protect your Patient

Extended survival

Use of High-Flux membranes enhances the removal of uraemic toxins, particularly middle molecules such as $\beta_2$-microglobulin.

A growing body of evidence has emerged in recent years demonstrating that use of High-Flux dialysis membranes as well as advanced treatment modalities such as HighVolume HDF\textsuperscript{®} may contribute towards reduced risk of death.

The results of the MPO study indicate the beneficial effect of High-Flux membranes in terms of reduced mortality for patients with serum albumin levels $\leq$ 4.0 g/dL or diabetes.$^1$

Kaplan-Meier survival curves for the subpopulation of patients with diabetes (log-rank test $p = 0.039$)$^1$

(Graph adapted from original publication)
Reduced complications

Enhanced middle molecule removal contributes towards reducing the complications of haemodialysis as well as improving long-term patient outcomes by affecting:\(^2\)

- **Inflammation** – lower CRP levels.\(^3\)
- **Anaemia** – haemoglobin levels improve at lower EPO doses.\(^4\)
- **Amyloidosis** – efficient removal of \(\beta_2\)-microglobulin and other middle molecules can reduce the relative risk of developing amyloidosis by up to 50 %.\(^5, 6\)
- **Immune dysfunction** – aberrant suppression of IFN-\(\gamma\) may be corrected.\(^7\)

The clinical benefits of High-Flux HDF are described in more detail in the chapter “Clinical Benefits of the Removal of Middle Molecules”.

SPOT on:

- High-Flux dialysis can reduce secondary diseases.
- Prolonging patients’ lives.\(^1\)
- Control of anaemia and amyloidosis.
Evolution of fibre design

Reducing the inner fibre diameter from 200 µm to 185 µm acts to increase internal filtration, thereby increasing the pressure gradient along the length of the fibre. This results in a greater pressure difference between the blood and dialysate compartments. Together with structural refinements to the support region of the fibre, this enables improvements in both diffusive and convective transport, which is of particular importance when performing High-Flux haemodialysis.
- Modification of the inner diameter increases the pressure gradient between blood and dialysate compartments.

- The result is improved clearance of middle molecules such as vitamin B$_{12}$, inulin, β$_2$-microglobulin and myoglobin.\(^8\)

- The increased pressure gradient combined with structural refinements to the membrane (support region) enhances diffusive as well as convective filtration, especially when performing High-Flux haemodialysis with FX CorDiax.

\[\begin{array}{|c|c|}
\hline
\text{Inner diameter of membrane [µm]} & \text{β$_2$-microglobulin Clearance (mL/min)} \\
\hline
175 & 70 \\
200 & 60 \\
250 & 50 \\
\hline
\end{array}\]

\[\begin{array}{|c|c|}
\hline
\text{Inner diameter of membrane [µm]} & \text{Urea Clearance (mL/min)} \\
\hline
175 & 210 \\
200 & 200 \\
250 & 190 \\
\hline
\end{array}\]

\[Q_b = 250 \text{ mL/min}, \quad Q_c = 500 \text{ mL/min}\]

Reduced inner diameter improves middle molecule elimination\(^8\)

(Graph adapted from original publication)

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5 Koda Y. et al., Kidney Int (1997); 52: 1096-1101.
6 Locatelli F. et al., Kidney Int (1999); 55: 288-293.
Guidelines recommend High-Flux dialysers

Clinical practice guidelines in Europe recommend the use of High-Flux haemodialysers:

**European Renal Best Practice Advisory Board; Guideline 2.1:**
“Synthetic High-Flux membranes should be used to delay long-term complications of haemodialysis therapy ... even in low-risk patients...”

**The Renal Association (UK):**
“Suggest that high-flux dialysers should be used instead of low-flux dialysers to provide haemodialysis. Evidence of improved patient survival with the use of high-flux membranes is restricted to incident patients, who have lower serum albumin concentrations (< 4 g/L) or have diabetes mellitus, and prevalent patients who have been on haemodialysis > 3.7 years”

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Advance the Experience

HighVolume HDF®
In recent years, there has been increased interest in more efficient haemodialysis treatment modalities. The main emphasis today is on the efficient removal of a wide range of uraemic toxins, particularly larger middle molecules such as $\beta_2$-microglobulin, a surrogate of middle molecules. However, excessive loss of useful substances such as albumin needs to be curtailed.

The high removal of larger solutes during HighVolumeHDF® is achieved through a combination of two principles: diffusion and convection at high substitution volumes. Solute removal by convection occurs along a pressure gradient facilitated by the ultrafiltration of fluid across a highly permeable membrane.

HighVolumeHDF® improves patient outcomes and exerts beneficial effects on the main cardiovascular risk factors:

- Intradialytic haemodynamic stability\(^1\)
- Anaemia\(^2\)
- Inflammation\(^3\)
- Serum $\beta_2$-m and phosphate levels\(^4,5,6\)

HighVolumeHDF® is currently considered as the most efficient renal replacement therapy.
Improved survival

The Catalonian high-volume HDF study, on behalf of the Estudio de Supervivencia de Hemodiafiltración On-Line (ESHOL) study group, is a multi-centre, prospective randomised controlled trial, which showed a wide range of benefits for patients being treated with high-efficiency post-dilution HDF (HighVolumeHDF®). Achieving a mean delivered total substitution volume of 21L/session should therefore be the target for every HDF treatment.

The primary outcome all-cause mortality was significantly reduced for the patients being treated with HighVolumeHDF®.

Results from the Catalonian high-volume HDF study. *median delivered convective volume ranged from 23 to 24L/session **92% on High-Flux HD

<table>
<thead>
<tr>
<th>Improved survival</th>
<th>Reduced treatment costs</th>
<th>Better patient well-being</th>
</tr>
</thead>
<tbody>
<tr>
<td>30% risk reduction in all-cause mortality (p=0.01)</td>
<td>22% risk reduction in all-cause hospitalisation (p=0.001)</td>
<td>28% risk reduction in incidence of hypotensive episodes (p&lt;0.001)</td>
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<tr>
<td>55% risk reduction in mortality from infection (p=0.03)</td>
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<tr>
<td>61% risk reduction in mortality from stroke (p=0.03)</td>
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</tbody>
</table>

3 Pedrini L. et al., Nephrol Dial Transplant, advanced access published Jan 18, 2011.
Protect your Patient

FX CorDiax haemodiaﬁlter – Superior by design

HighVolume\textsuperscript{HDF} therapy requires specially designed filters. Stepping up to this challenge, we developed the FX CorDiax haemodiaﬁlter for HighVolume\textsuperscript{HDF} with the most efficient removal of middle molecules while minimising albumin loss.

- **Increased fibre lumen for better flow conditions**
  An increase of its inner diameter results in a substantially reduced pressure drop within a hollow fibre according to the Hagen Poiseuille law. Differences in the capillary diameter of a dialyser can therefore affect its performance and the quality of the treatment provided to a patient. The inner diameter of FX-class\textsuperscript{haemodiaﬁlters} is 210 \textmu m compared to 185 \textmu m of FX-class\textsuperscript{HD filters}. The larger inner diameter facilitates improved flow conditions which allowed for a significantly higher convective volume in a HDF treatment.\textsuperscript{1}

\begin{figure}
\includegraphics[width=\textwidth]{image}
\caption{Reduced dialyser inlet pressure of FX 800 (210 \textmu m) vs. FX 80 (185 \textmu m)\textsuperscript{1}
\(p < 0.001\)}
\end{figure}

\begin{figure}
\includegraphics[width=\textwidth]{image}
\caption{The 210 \textmu m fibre lumen of FX CorDiax haemodiaﬁlters optimises blood flow conditions within the dialyser for maximal HighVolume\textsuperscript{HDF} performance.}\textsuperscript{1}
\end{figure}

\textsuperscript{1} Vega Vega O. et.al.; ERA-EDTA Congress 2012, Poster 457—FP.
When Performance is Priority
Clinical Benefits of the Removal of Middle Molecules
Improved survival with High-Flux membranes

On top of traditional cardiovascular risk factors, increased middle molecule levels such as β₂-microglobulin (β₂-m) pose an additional risk for the development of cardiovascular diseases (CVD) in end stage renal disease (ESRD) patients. The European Uremic Toxin Work Group (EUTox) confirmed the power of β₂-m to predict overall and cardiovascular mortality and cardiovascular events in patients at different stages of CKD.¹

Thus, enhanced middle molecule removal contributes towards improving long-term patient outcomes and reducing dialysis related complications.

Kaplan-Meier estimates of the probability of cardiovascular event-free survival of predialysis patients, as a function of median plasma β₂-m level¹

(Graph adapted from original publication)
Cardioprotective Haemodialysis

- **Dyslipidaemia** – the use of High-Flux Helixone® membranes improves plasma lipid profiles, reducing levels of LDL (low-density lipoprotein) and VLDL (very low-density lipoprotein) and increasing those of protective HDL (high-density lipoprotein). The levels of triglycerides and oxidised LDL, an indicator of oxidative stress and a specific risk factor for atherosclerosis, are also significantly reduced using Helixone® membranes.

![Graph](image)

Improving plasma lipid profiles: reduction of ox-LDL and triglycerides with FX 100 dialysers

(Graph adapted from original publication)
Cardioprotective Haemodialysis

- **Amyloidosis** – a debilitating complication of long-term haemodialysis, amyloidosis involves the build-up of β₂-microglobulin. FX-class® High-Flux dialysers efficiently remove β₂-microglobulin and other middle molecules, reducing the risk of carpal tunnel syndrome.⁴,⁵

- **Inflammation** – specialised production processes such as INLINE steam sterilisation as well as the high endotoxin retention properties of FX-class® dialysers contribute to reducing the levels of endotoxin exposure during haemodialysis. This results in the reduced induction of inflammatory responses.²

With High-Flux membranes, it was possible to progressively reduce the EPO dose while maintaining Hb control.⁶

(Graph adapted from original publication)
**Anaemia management** – it was shown that High-Flux membranes improved control of anaemia in EPO hypo-responsive patients while allowing a progressive reduction in the exogenous EPO dose by 25 to 45%.\(^7\) Hence, High-Flux membranes offer the potential to reduce EPO costs.

Recovery of haemoglobin (Hb) levels was significantly better after 6 months for patients treated with High-Flux vs Low-Flux membranes. Further, in this patient group the mean EPO dose was significantly lower.\(^7\)

(Graph adapted from original publication)

The FX CorDiax allows the enhanced removal of middle molecules which, together with other factors, contributes towards improved survival.

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3. Wanner C. et al., JASN (2002); 13 (SU-P0645): 600A.
## Performance Data

### Sieving coefficients of FX CorDiax High-Flux Dialysers and Haemodia filters

<table>
<thead>
<tr>
<th>Molecular weight (Dalton)</th>
<th>Albumin</th>
<th>Myoglobin</th>
<th>β₂-microglobulin</th>
<th>Inulin</th>
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<tr>
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<td>66,500</td>
<td>&lt; 0.001</td>
<td>0.5</td>
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</table>

- **Membrane material**: Hellion® plus
- **Sterilisation method**: INLINE steam
- **Housing material**: Polypropylene
- **Potting compound**: Polyurethane
- **Units per box**: 24

### FX CorDiax High-Flux Dialysers

<table>
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<tr>
<th>Molecular weight (Dalton)</th>
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### FX CorDiax Haemodia filters

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### Ultrafiltration coefficients (mL/h x mmHg)

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