

Hemodialysis

Introducing the new 4008A

Your partner for
life
changing
dialysis



 **FRESENIUS
MEDICAL CARE**

The new 4008A

Trust in us, because your patients trust in you

We live to change lives

From your first consultation to long after the treatment phase, Fresenius Medical Care is your partner in life-changing dialysis. With the new 4008A, we have opened the doors to life-changing dialysis for more people than ever before, regardless of location or social situation.

Because all aspects of the dialysis treatment have the potential to be life-changing, no detail has been overlooked:

- Life changing safety and handling standards
- Life changing medical benefits
- Life changing customer services

Bringing dialysis to more patients

A substantial number of patients with end-stage renal disease (ESRD) need better access to renal replacement therapy (RRT)

- The number of patients receiving RRT projected for Asia will be rising from 0.968 million people in 2010 to 2.162 million (1.571–3.014 million) by 2030¹
- In Asia the number of patients receiving RRT in 2010 ranges from 17 % to 34 %¹
- Asia shows a treatment gap of at least 1.907 million patients needing but not receiving RRT in 2010¹

1. Liyanage T et al. Worldwide access to treatment for end-stage kidney disease: a systematic review. *www.thelancet.com* Published online March 13, 2015 [http://dx.doi.org/10.1016/S0140-6736\(14\)61601-9](http://dx.doi.org/10.1016/S0140-6736(14)61601-9)



We care about kidneys

With more than three decades of experience in dialysis and innovative research, Fresenius Medical Care is the world's leading provider of products and services for people undergoing dialysis.

We are involved in all aspects of finding solutions for chronic kidney disease:

- Research and development of new therapies
- Manufacturing our dialysis products
- Offering comprehensive therapy options within our clinics

Because we are familiar with all these areas of kidney care, we are able to offer different therapies to suit to the needs of each individual patient.

We continuously benchmark ourselves against the latest medical standards. This is a commitment to our patients as well as to our partners in the healthcare system.

Fresenius Medical Care – Creating a future worth living. For patients. Worldwide. Every day.



48 mil.
Treatments



320,000
Patients served



3,700
Clinics



37
Production sites



114,000
Employees

The new 4008A

Life changing safety and handling standards

The new 4008A at a glance

Patient monitoring +

Cost efficiency +

Battery back up +



+ Intuitive touch screen

+ Cleaning programs

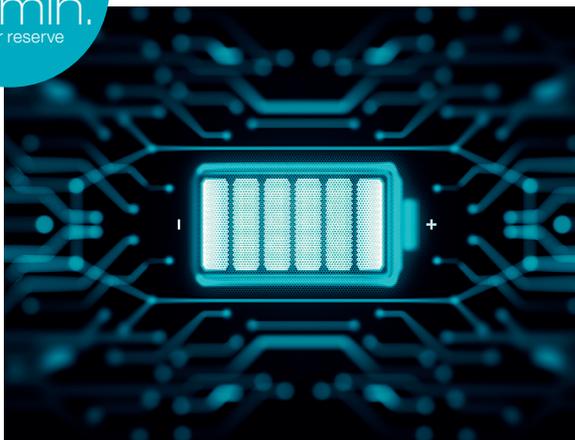
+ DIASAFE[®]plus

Intuitive touch screen interface allowing outstanding usability and convenience

- High resolution with chronological workflow indicators from preparation to re-infusion and cleaning
- Centralized functions with simple and logical data entry
- Color coded status of treatment flow following the same color coding philosophy as the 5008S and 6008 devices



1. **Blue** can be selected
2. **Green** active
3. **Grey** not active/cannot be selected



20 minutes battery back up during power outage

- Improved safety for patients
- Battery time allows staff to safely terminate the dialysis treatment in case of power failure
- Reduced stress for patients and HCPs

Standard cleaning programs between treatments to reduce the risk of contamination

- Outstanding usability and convenience
- Intuitive access to the cleaning menu
- Screen lock feature to perform a through cleaning of the monitor



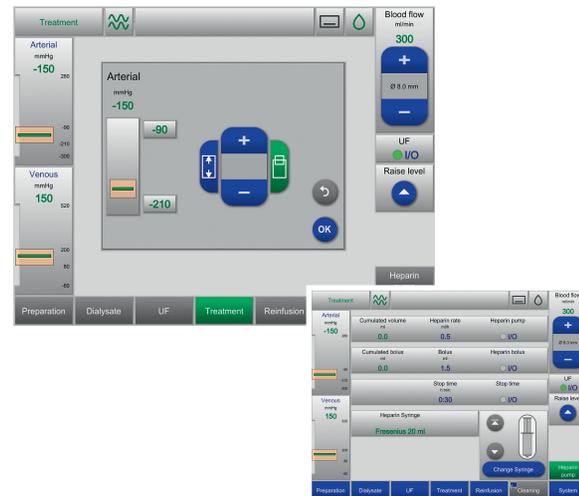
The new 4008A

Life changing safety and handling standards

Essential patient monitoring

Immediate notification in case of changes in the treatment parameters originally set.

- Standard safety features such as blood leak detector, air detector, and arterial/venous pressure monitoring
- Standard conductivity alarm
- Heightened patient-trust of the dialysis process



Setting the standard in handling

The design of the 4008A allows improved handling and maneuvering of the device – ideal for relocation and transportation.

- Dimensions:
 - Height: 149 cm
 - Width: approx. 63 cm
 - Depth: approx. 80 cm
- Maximum total weight of 100 kg
- Compact design

DIASAFE[®]plus

DIASAFE[®]plus enables the safe production of ultrapure dialysis fluid for all treatments:

- Standard on the new 4008A
- Reduces bacterial & endotoxin concentration¹
- Contributes to the delivery of ultrapure dialysis fluid to ISO standards*
- Convenient & hygienic handling

* ISO 11663: Quality of dialysis fluid for haemodialysis and related therapies
1. Weber C et al. Novel Online Infusate-Assisted Dialysis System Performs Microbiologically Safely. *Artificial Organs* 2000; 24(5): 323–328.



Our approach to cost efficiency

Affordable to patients without compromising essential safety features

- Ultrapure dialysis fluid with DIASAFE[®]plus as standard
- Implementation of non-binding bloodlines
- Support by trained experts from Fresenius Medical Care: Application training, technical training and clinical support

4008A



Preservation of residual renal function¹

Life changing medical benefits

Preservation of residual renal function¹

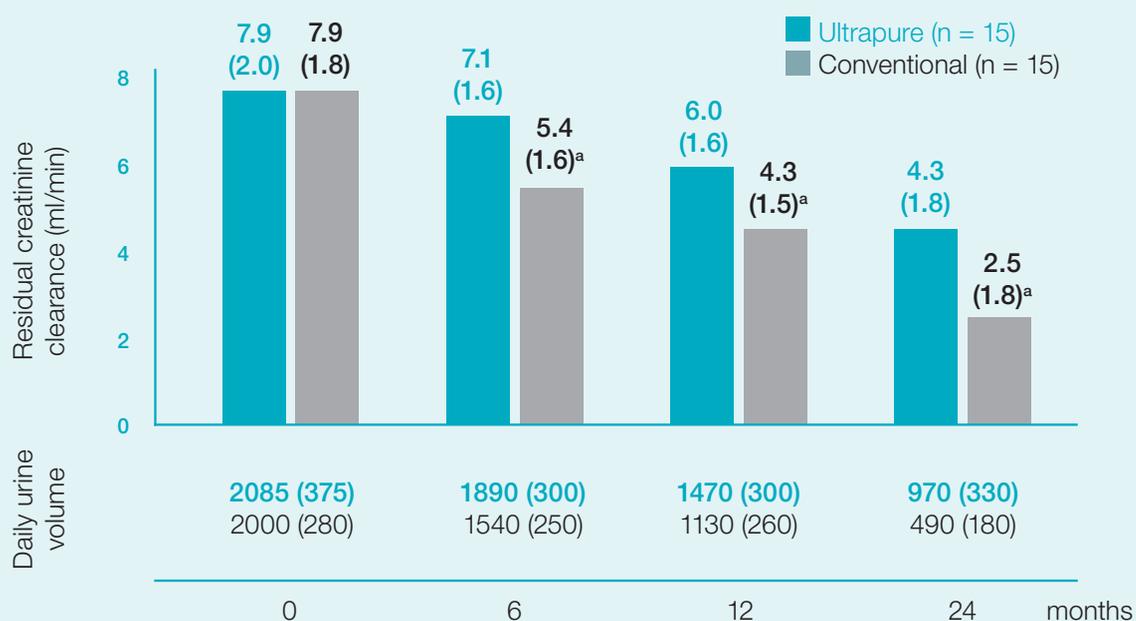
Residual Renal Function has been shown to influence quality of life and mortality of hemodialysis patients¹

- Residual Renal Function (RRF) is the ability of native kidneys to eliminate water and uremic toxins in patients with ESRD
- Even in small amounts, preserving RRF lowers mortality and may improve quality of life^{1,2,3}
- Ultrapure dialysis fluid as a standard in all treatments may contribute to the preservation of RRF⁴

“Residual renal function has been shown to influence adequacy of hemodialysis, quality of life and mortality of hemodialysis patients”¹



Preservation of RRF among patients receiving conventional versus ultrapure dialysis fluid (mean ± SD)⁴



^a p < 0.05 vs corresponding value in patients treated with ultrapure dialysis fluid.

Study design:

30 patients starting hemodialysis were randomly assigned to ultrapure or conventional dialysis fluid. During the 24-month study period, creatinine clearance, CRP and IL-6 levels, hydration status, number of hypotensive episodes and blood pressure recordings were assessed every 6 months.

Chart created from Schiff H. 2002 data

1. Shafi T., Jaar B., Plantinga L. Association of Residual Urine Output With Mortality, Quality of Life, and Inflammation in Incident Hemodialysis Patients: The Choices for Healthy Outcomes in Caring for End-Stage Renal Disease (CHOICE) Study. *Am J Kidney Dis* 2010; 56:348-358
2. Termorshuizen F., Dekker F., Van Manen J. Relative Contribution of Residual Renal Function and Different Measures of Adequacy to Survival in Hemodialysis Patients: An analysis of the Netherlands Cooperative Study on the Adequacy of Dialysis (NECOSAD)-2. *J Am Soc Nephrol* 2004; 15: 1061-1070

3. Obi Y., Rhee C., Mathew A. Residual Kidney Function Decline and Mortality in Incident Hemodialysis Patients. *J Am Soc Nephrol* 2016; 27: 3758-3768
4. Schiff H et al. Ultrapure dialysis fluid slows loss of residual renal function in new dialysis patients. *Nephrol Dial Transplant* 2002; 17: 1814-1818

Reduction of inflammation

Life changing medical benefits

Inflammation is an important risk factor for dialysis patients¹⁻³

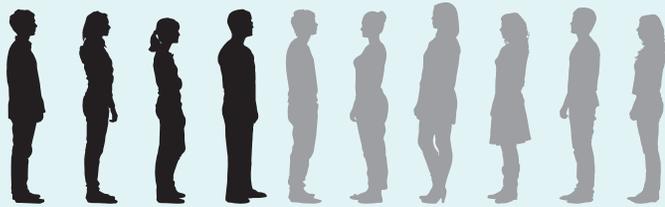
Residual Renal Function has been shown to influence quality of life and mortality of hemodialysis patients¹

- Elevated serum levels of inflammatory markers such as C-reactive protein pose a strong cardiovascular risk and contribute to EPO hyporesponsiveness
- Establishing ultrapure dialysis fluid as a standard could contribute to the reduction of inflammation in dialysis patients²
- In doing so it can contribute to lowering cardiovascular risk & morbidity, and improving response to EPO^{1,2}



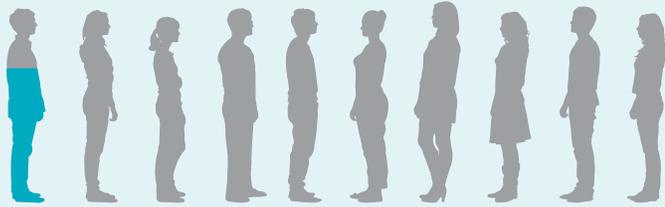


Ultrapure dialysis fluid produced with DIASAFE[®]plus is a significant contributing factor in reducing inflammation⁴



40 %

of patients with conventional (n = 15) dialysis fluid showed CRP levels above the normal range



7 %

of patients with ultrapure dialysis fluid (n = 15)

^a p < 0.05 vs corresponding value in patients treated with ultrapure dialysis fluid.

Study design:

30 patients starting hemodialysis were randomly assigned to ultrapure or conventional dialysis fluid. During the 24-month study period, creatinine clearance, CRP and IL-6 levels, hydration status, number of hypotensive episodes and blood pressure recordings were assessed every 6 months.

Chart created from Schiff H. 2002 data

1. Lederer SR, Schiff H. Ultrapure Dialysis Fluid Lowers the Cardiovascular Morbidity in Patients on Maintenance Hemodialysis by Reducing Continuous Microinflammation. *Nephron* 2002; 91: 452–455.
 2. Sitter Tet al. Dialysate related cytokine induction and response to recombinant human erythropoietin in haemodialysis patients. *Nephrol Dial Transplant* 2000; 15: 2107–2111.

3. Furuya R et al. Ultrapure Dialysate Reduces Plasma Levels of β_2 -Microglobulin and Pentosidine in Hemodialysis Patients. *Blood Purif* 2005; 23: 311–316.
 4. Schiff H et al. Ultrapure dialysis fluid slows loss of residual renal function in new dialysis patients. *Nephrol Dial Transplant* 2002; 17: 1814–1818.



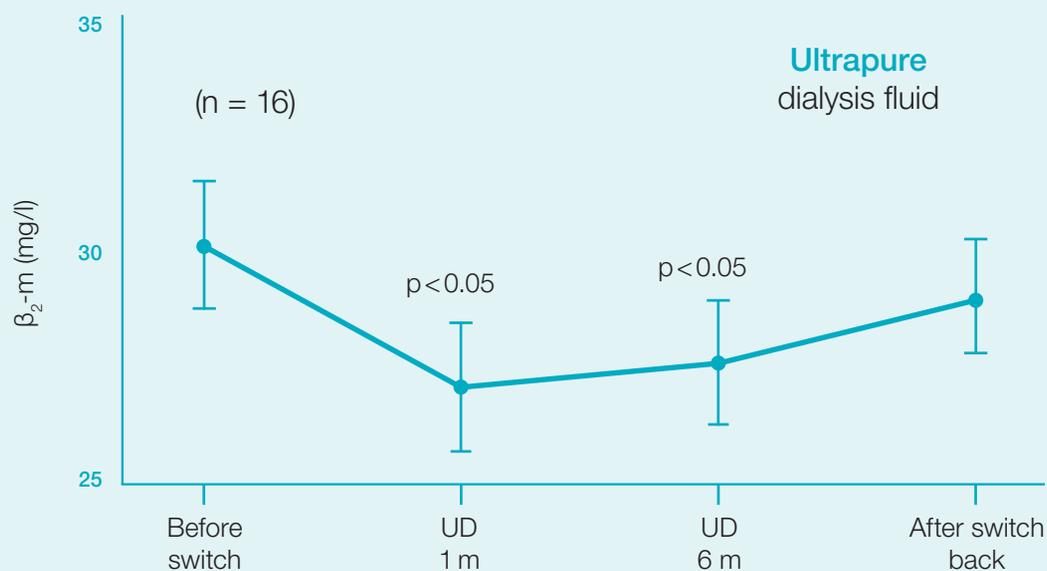
Reduced risk of dialysis-related amyloidosis

Life changing medical benefits

In long-term HD patients, dialysis-related amyloidosis can be a serious complication

- Dialysis-related amyloidosis results from the build up of β_2 -microglobulin (β_2 -m) and can lead to carpal tunnel syndrome, chronic pain and decreased joint mobility
- Reduced plasma levels for β_2 -m may delay the onset of dialysis-related amyloidosis^{2,3,4}
- The use of ultrapure dialysis fluid has been shown to contribute to the reduction of plasma levels of β_2 -m¹
- Therefore, setting ultrapure dialysis fluid as standard for all treatments could contribute to delaying the onset and reducing the risk of dialysis related amyloidosis

Ultrapure dialysis fluid produced with DIASAFE[®]plus has been shown to contribute to reducing plasma levels of β_2 -m which could contribute to delaying the onset and reducing the risk of dialysis-related amyloidosis^{1,5,6}



UD = Ultrapure dialysis fluid

Study design:

16 patients undergoing hemodialysis had their dialysis fluid switched from a conventional to an ultrapure dialysis fluid. Patients were followed for 6 months on ultrapure dialysis fluid, and then switched back to conventional dialysate. Among others, the plasma level of β_2 -m was measured.

Chart created from Furuya R. 2005 data



1. Furuya R et al. *Ultrapure Dialysate Reduces Plasma Levels of β_2 -Microglobulin and Pentosidine in Hemodialysis Patients.* *Blood Purif* 2005; 23: 311–316.

2. Gejyo F, Yamada T, Odani S. *A new form of amyloid protein associated with chronic hemodialysis was identified as β_2 -microglobulin.* *Biochem Biophys Res Commun* 1985; 129:701–706.

3. Miyata T, Oda O, Inagi R. *β_2 -Microglobulin modified with advanced glycation end products is a major component of hemodialysis-associated amyloidosis.* *J Clin Invest* 1993; 92: 1243–1252.

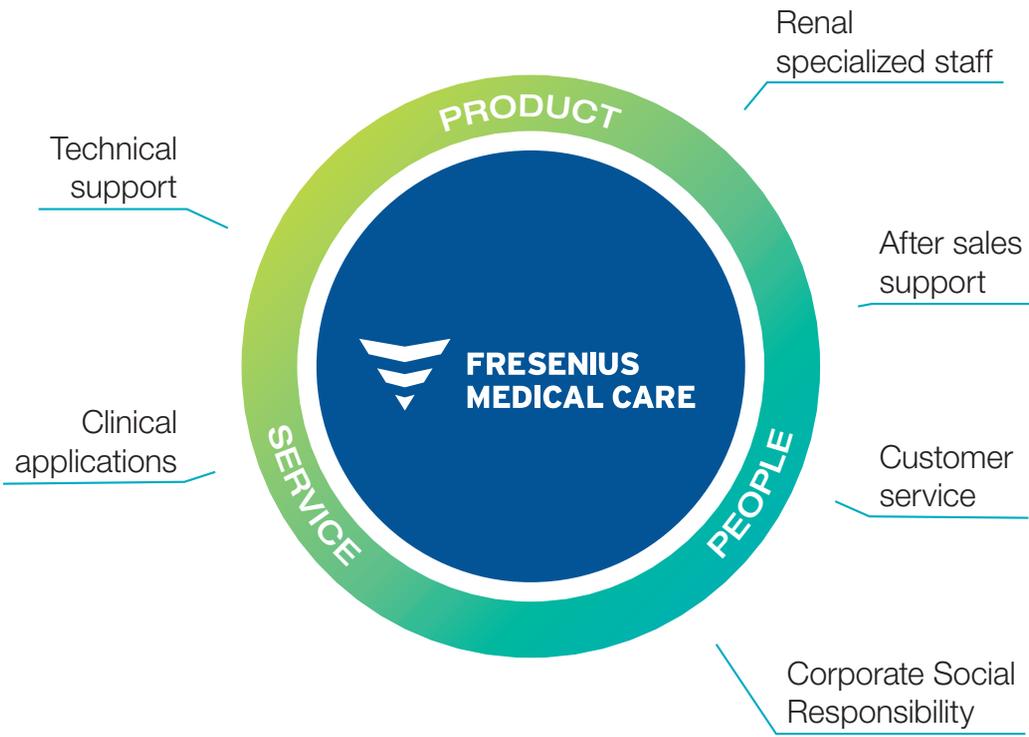
4. Miyata T, Inagi R, Iida Y. *Involvement of β_2 -microglobulin modified with advanced glycation end products in the pathogenesis of hemodialysis-associated amyloidosis.* *J Clin Invest* 1994; 93: 521–528.

5. Baz M, Durand C, Ragon A, Jaber K, Andrieu D, Merzouk T, Purgus R, Olmer M, Reynier JP, Berland Y. *Using ultrapure water in hemodialysis delays carpal tunnel syndrome.* *Int J Artif Organs* 1991; 14: 681–685.

6. Schiffli H. *Nephrol Dial Transplant.* 2000; 15(6):840-5. *Clinical manifestations of AB-amyloidosis: Effects of biocompatibility and flux*

The new 4008A

Life changing customer services



Technical Data Haemodialysis Machine 4008A

General Data

Dimensions 4008A	Height: approx. 134 cm (approx. 149 cm with infusion hook) Width: approx. 50 cm (approx. 57 cm with dialyser holder and approx. 63 cm with degreasing agent container) Depth: approx. 65 cm (approx. 71 cm with DIASAFE [®] plus, approx. 80 cm with disinfectant container)
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Weight	Empty weight including all options: approx. 61 kg Safe working load: approx. 39 kg Maximum total weight: approx. 100 kg
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Water supply

Water inlet pressure	1.5 to 6.0 bar
Water inlet temperature	5 °C to 30 °C
Max. drain height	1 m

Electrical data

Power supply	110 to 240 V AC, 50 to 60 Hz, 10 to 15 A
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Current consumption	<p>The consumption and energy data are comprised of examples of average values during typical operation:</p> <p>Blood pump rate: 300 ml/min Dialysate flow: 500 ml/min Ultrafiltration: 0.5 l/h Dialysate temperature: 36.5 °C Mixing ratio: 1+44 Ambient conditions: Water inlet temperature 15 °C, ambient temperature 22 °C.</p> <p>Mean energy consumption Dialysis: approx. 0.59 kWh per hour Rinsing: approx. 0.26 kWh (program length of 16 minutes) Heat disinfection: approx. 0.62 kWh (program length of 41 minutes) Degreasing: approx. 0.45 kWh (program length of 41 minutes)</p>
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Extracorporeal circuit

Arterial pressure monitoring

Display range	-300 to +280 mmHg
Accuracy	±10 mmHg
Resolution	5 mmHg

Venous pressure monitoring

Display range	-60 to +520 mmHg
Accuracy	±10 mmHg
Resolution	5 mmHg

Arterial blood pump

Blood flow range	0.30 to 500 mL/min
Accuracy	±10 %
Resolution	10 mL/min

Heparin pump

Delivery range: 0.5 to 10 mL/h
Bolus function: 1.0 to 9.9 mL
Syringe size: 20 mL

Dialysis fluid circuit

Dialysis fluid flow range

Dialysate flow	300, 500 ml/min
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Dialysis fluid temperature

Selectable	35.0 °C to 39.0 °C (adjustable in increments of 0.5 °C) target temperature 35.0 °C to 39.0 °C adjustable in increments of 0.5 °C Measurement accuracy: ±0.5 °C Alarm limits: 33.5 °C and 40.0 °C
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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 150 mmol/L

Dialysis fluid bicarbonate component

Mixing ratio	1 + 27.6 (others possible)
Adjustment range	-8 to +8 mmol/L

Endotoxin retention filter

Dialysis fluid filter system	DIASAFE [®] plus
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Balancing accuracy

Pressure holding tests	±0.1 % relative to the total dialysate volume Event controlled
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Ultrafiltration

UF rate	Selectable UF time: 0:01 h to 9:59 h (in 1 min increments) Selectable UF goal: 10 ml to 9,990 ml (in 10 ml increments)
Pump volume accuracy	±1 %
Parameters displayed	UF goal, UF time, UF rate

Blood leak detector

Sensitivity	Response threshold less than or equal to 0.35 ml blood loss per minute into the dialysate for a haematocrit of 0.32
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Disinfection and cleaning programmes

Rinse

Temperature/flow	37 °C/700 mL/min
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Heat disinfection

Temperature/flow	84 °C/700 ml/min
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Degreasing

Temperature/flow	37 °C/700 mL/min
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Technical changes reserved.

Article Number: M202201

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Life changing dialysis

- Life changing safety and handling standards
- Life changing medical benefits
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TRUST IN US, BECAUSE YOUR PATIENTS TRUST IN YOU



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