The 5008 Therapy System
A Vision turned into Reality

The 5008 Therapy System was developed to fulfil current challenges in haemodialysis: continually increasing patient numbers with a growing share of medically challenging patients, combined with often limited funding and staff.

The 5008 Therapy System therefore offers a combination of convincingly easy handling with a thoughtful use of the dialysis-relevant resources, coupled with the highest treatment quality and patient safety.

The serial configuration of the 5008 Therapy System offers unique therapeutic possibilities:

- ONLINE Haemodiafiltration – currently the most efficient renal replacement therapy
- OCM® – Online Clearance Monitoring and plasma sodium measurement
- Ultrapure dialysis fluid (DIASAFe®plus)
- Na- and UF-profiles
- Single-Needle treatment
- Integrated heparin pump, bibag®-connector and arterial clamp
- Highly automated procedures:
  - Online priming, bolus and reinfusion – completely without using saline rinse solutions in either bags or bottles
  - AutoFlow, EcoFlow – savings of water, energy and dialysate
  - AutoSub – adjustment of optimum HDF-substitution-rate
- Innovative user-guidance via a central, freely rotatable touchscreen monitor
- Sophisticated data management – easy data input and documentation; alternatively, with PatientCard (offline) or via network integration (online)

These fully integrated functions, together with the easy, intuitive operation of the 5008 Therapy System, allow the delivery of a superior therapy quality together with an optimal use of the human, medical and technical resources involved.

Additional innovative therapeutic tools and options (e.g. for an effective blood pressure management) are available fully integrated with convenient operation via the 5008 touchscreen:

- Blood Pressure Monitor (BPM)
- Blood Temperature Monitor (BTM)
- Blood Volume Monitor (BVM)
- Data management system Finesse® or TDMS/dXp (Therapy-Data-Management-System/Data exchange function)

5008 – A Touching Experience
Cardioprotective Haemodialysis with the 5008 Therapy System

Despite significant improvements in the quality and efficacy of haemodialysis therapy in recent years, cardiovascular disease still remains the leading cause of death for dialysis patients. The newly developed 5008 Therapy System allows to effectively minimise dialysis-related factors that may influence cardiovascular disease in the dialysis population.

The 5008 Therapy System enables, for the first time, a more general application of state-of-the-art ONLINE Haemodiafiltration as it perfectly balances best therapy with optimised practicability and an efficient use of resources. Additionally, because of its high flexibility, the 5008 Therapy System is best prepared to adapt the dialysis therapy according to the individual needs of the patient. At the same time, numerous integrated safety systems guarantee utmost patient security.
Best Therapy for your Patients

ONLINE Haemodiafiltration – The Therapy of Choice

ONLINE Haemodiafiltration, with its numerous positive effects on uraemia-related cardiovascular risk factors, is currently acknowledged as the most effective dialysis treatment modality that comes closest to the elimination profile of the natural kidney.

Haemodiafiltration Reduces Mortality and Morbidity

The results of two recent studies demonstrate that patients treated with ONLINE HDF had a significant 35 % reduction of mortality risk compared to patients treated with standard haemodialysis (Jirka et al.1 and Canaud et al.2)

Furthermore, convective therapies reduce dialysis-associated side-effects and intradialytic symptoms compared to standard haemodialysis (Altieri et al.3)

These clinical benefits of ONLINE HDF therapy are attributed to the more effective elimination of a broader spectrum of uraemic toxins, combined with minimal stimulation of inflammation and oxidative stress.

Patient Safety and Minimisation

- Self-evident programme settings minimise operational errors
- Breakthrough technology safety systems – e.g. various leakage sensors (at the extracorporeal blood circuit, the DIASAFE®plus-filters and the hydraulics)

Patient Surveillance Systems

Blood Temperature Monitor BTM:
Effective haemodynamic stabilisation and recirculation measurement

5008 – Achieving Cardioprotective Haemodialysis

---

• “Emergency-button” for quick response in case of emergencies

• Consistent pre-setting of patient-specific treatment parameters: offline with PatientCard or online via LAN network connection (Finesse® or TDMS/dXp)

• Non-invasive, air-free arterial pressure monitoring

• Clearly-structured, door-secured extracorporeal blood module

Blood Volume Monitor BVM:
Controlled ultrafiltration for effective fluid removal with less incidence of hypotensive episodes

Blood Pressure Monitor BPM:
Fully automated and non-invasive blood pressure monitoring (systolic & diastolic blood pressure, MAP, pulse)

Online Clearance Monitor OCM®:
Reliable measurement and analysis of dialysis efficiency and dialysis dose (Kt/V) plus continuous monitoring of plasma sodium concentration
Best Handling

Tailor-made to Meet the Needs of all Operators

The 5008 Therapy System is the first haemodialysis system created out of the practice for the practice – that is, created by users for users! The complete 5008 operation procedure was designed in an easy and ergonomic way in order to give the nursing personnel much-needed time for patient care.

Well-designed User Interface Navigation System

- Large (15” TFT), individually adjustable and freely rotatable touchscreen monitor
- 3-D buttons with feedback
- “Intuitively correct” user-guidance philosophy: designed for quick, error-free data entry

Easy, Rapid and Safe Data Management

- Patient and therapy data of current and previous three treatments is always available
- Individualised therapy prescription and documentation: “Offline” with PatientCard “Online” via an integrated LAN network connector (Data management system Finesse® or Therapy-Data-Management-System TDMS/Data Exchange function dXp)
Optimised Ergonomics

- Optimised 5008 bibag®: rapid and hygienic one-hand connection
- Optimised 5008 bloodline system: easy, machine-assisted set-up & dismantling
- Workflow optimisation by highly automated user assistance:
  - Multiple automated tests during preparation
  - ONLINE priming, bolus and blood reinfusion
  - Self-initiating functions (e.g. UF, OCM®, ONLINE HDF and heparinisation)
  - Numerous auto-regulating mechanisms (e.g. AutoFlow, EcoFlow, AutoSub, AutoSN)
  - Automated disinfection program

Unmatched Service-Friendliness

- Comprehensive service program and technical error memory (access with “ServiceCard”)
- Long-living components with innovative fixation (“Snap-lock” technology)
- Real-time hydraulic flow charts (accessible also during the therapy)
- Convenient accessibility to all parts and components

Efficient and Sustainable

With the 5008 Therapy System, Fresenius Medical Care offers a system to perform premium dialysis therapy that at the same time supports the sensible and sustainable use of the limited resources available.

Optimised Workflows

- **AutoFlow** – Automatic adjustment and optimal adaptation of dialysate flow to effective blood flow. Allows substantial savings of water, concentrates and energy while maintaining a constant dialysis quality.
- **EcoFlow** – Automatic adjustment and optimal adaptation of dialysate flow to the effective blood flow. Allows substantial savings of water, concentrate and energy during machine stand-by mode up to the point when the patient is connected.
- **AutoSub** – Automatic patient-individual adjustment of HDF substitution rate to the effective blood flow rate.
- **AutoSN** – Automatic adjustment of single-needle pump rate to blood-pump rate.

ONLINEplus-System – Ultrapure and Physiologic Rinse- and Substitution-Solutions

- ONLINE HDF, ONLINE Priming, ONLINE Bolus and ONLINE Reinfusion:
  - Complete substitution of all conventional saline rinse-solutions and substitution-solutions (bags or bottles) with ONLINE prepared solutions.
  - Bicarbonate-buffered electrolyte solutions – highly physiological having patient-individual compositions
- Optimised workflow for all operators and users

Prepared for Future Therapy-, Monitoring- and Safety-Modules – thanks to the well-proven modular design, roomy installation space plus free processor- and memory capacities.

5008 – The Sustainable Haemodialysis Therapy System
Technical Data 5008

General data

Dimensions 5008 1620 x 480 x 720 mm (H x W x D) (depth with extended concentrate rack approx. 86 cm)
Weight approx. 135 kg

Water supply
Water inlet pressure 1.5 – 6.0 bar
Water inlet temperature 5 – 30 °C; for “integrated hot rinse” 85 to 95 °C
Max. drain height 1 m
Flush Rinse of water supply area

Concentrate supply
Supply pressure 0 to 100 mbar; 1 m suction height with Central Delivery System: 0.05 to 2.0 bar
Central supply 2 central acid concentrates (option) 1 central bicarbonate (option)

Electrical data
Power supply 100 to 240 V AC ± 10 %, 47–63 Hz
Current consumption Approx. 6 A (at 230 V) at a water inlet temperature of 17 °C, Dialysate temperature 37 °C Dialysate flow: 500 ml/min

External connections
Alarm output: potential free alarm outlet (alternating contact max. 24 V/24 W).
LAN (RJ 45) port for data exchange with Therapy Data Management System/Finesse®

Extracorporeal circuit

Arterial pressure monitoring
Display range - 300 mmHg to + 300 mmHg
Accuracy ± 7 mmHg
Resolution 5 mmHg

Venous pressure monitoring
Display range - 100 mmHg to + 500 mmHg
Accuracy ± 7 mmHg
Resolution 5 mmHg

Arterial blood pump
Blood flow range (effective) 30 to 600 ml/min
Accuracy ± 10 %

Single-Needle system
with 2 blood pumps. Internal pressure/pressure control with variable stroke volume (max. 50 ml)

Air bubble detector ultrasound transmission measurement on blood line, additional capacitive level and optical monitoring

Heparin pump
Delivery range: 0.5 to 10 ml/h
Bolus function: 1.0 up to 20.0 ml
Syringe size: 20 ml, 30 ml

Dialysis fluid circuit

Dialysis fluid flow range Selectable
AutoFlow (selectable) Automatic adaptation of the dialysate flow to the effective blood flow (factors adjustable)
EcoFlow Stand-by flow during preparation and reinfusion

Dialysis fluid temperature
Range 34 – 39 °C

Dialysate 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

Dialysate fluid bicarbonate component
Default mixing ratio 1 + 27.6 (others possible)
Adjustment range 20.0 – 40.0 mmol/l (depending on concentrate used; steps of 0.5 mmol/l)

OCM® Accuracy Clearance K ± 6 %

Bicarbonate dry concentrate biog®

Dialysis fluid filter system DIASAFE®plus

ONLINEplus
Substitution rate 25 – 600 ml/min
Accuracy ± 10 %
AutoSub Substitution ideally matched to effective bloodflow

Balancing accuracy ± 0.1 % related to the total dialysate volume
Pressure holding test Event controlled

Ultrafiltration
UF rate 0 – 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 – 1000 ml/min

BTM (Option)
Temperature measurement Accuracy ± 0.2 °C
Body temperature control Allowed change rate ± 0.5 °C/h
Recirculation measurement Accuracy ± 2 %

BVM (Option)
Relative Blood Volume (RBV) 1.7 % (absolute)
Haematocrit (Hct) ± 2.9 Hct % (if plasma protein concentration range is 60 – 85 g/l)
Haemoglobin (Hb) ± 0.8 g/dl
Temperature 0.1 °C (33.5 – 40 °C)

BPM (Option)
Display range Systole: 30 mmHg – 280 mmHg
Diastole: 10 mmHg – 240 mmHg
MAP: 20 mmHg – 255 mmHg
Accuracy ± 3 mmHg

Disinfection and cleaning programmes*

Rinse Temperature/flow 37 °C/600 – 800 ml/min (adjustable)

Hot rinse (recirculation) Temperature/flow 85 °C/600 – 800 ml/min (adjustable)

Cleaning Sporotal® 100 (recirculation) Temperature/flow 37 °C/600 – 800 ml/min (adjustable)

Heat disinfection Diasteril®/Citrosteril® (recirculation) Temperature/flow 85 °C/600 – 800 ml/min (adjustable)

Disinfection Puristeril® 340/plus (recirculation) Temperature/flow 37 °C/600 – 800 ml/min (adjustable)

*Varios programmes: combinations selectable