Haemodialysis

4008S

Visually the best dialysis results

Fresenius Medical Care

Therapy

Through continuous optimisation of the treatment modalities Fresenius Medical Care always aims to offer patients the best renal replacement therapy to increase their well being and quality of life.

Our haemodialysis system 4008S ensures safety and efficiency of all important treatment modalities within the scope of renal replacement therapies, such as:

- Bicarbonate dialysis
- Single-Needle or SN Click-Clack
- Ultrafiltration and Sodium profiles
- ISO-UF programme
- ONLINE Haemo(dia)filtration

ONLINE*plus* System – ONLINE Haemo(dia)filtration

DIASAFE®*plus* – Dialysis fluid filter

bibag® – Dry bicarbonate concentrate

Ultrafiltration and Sodium Profiles

Monitoring

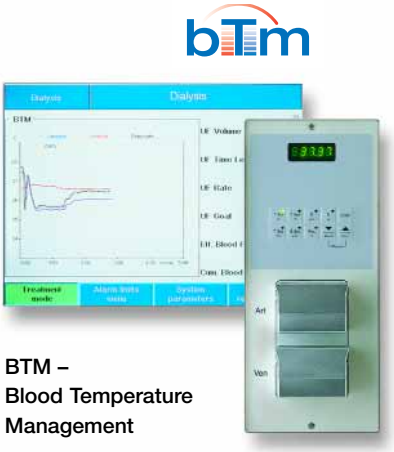
The 4008S can be customised by a modular combination of various monitoring and control functions.

The automated acquisition, monitoring and control of specific patient and machine parameters provide the operator with continuous and precise assessment of the current treatment situation.

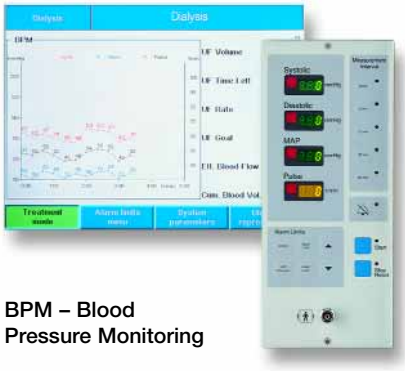
The 4008S is available with 5 functional slots for slide-in modules.

OCM® – ONLINE Clearance Monitoring

BVM – Blood Volume Management



BTM – Blood Temperature Management



BPM – Blood Pressure Monitoring

FINESSE® / TDMS Dialysis Data Acquisition and Management Systems

System

Operation

The ergonomical and logical operating structure with clear allocation of operating functions seen in only seven menu screens, permits the user easy programming of the treatment parameters on the high-resolution colour screen.

Additional information of the treatment is provided by the graphical representations of treatment parameters and measured values scaled to time. Warning messages give support and ease the operation. The automated setting of alarm limits and their intelligent monitoring ensures a straight forward treatment almost free from false alarms.

Advanced Dialysis Fluid Circuit

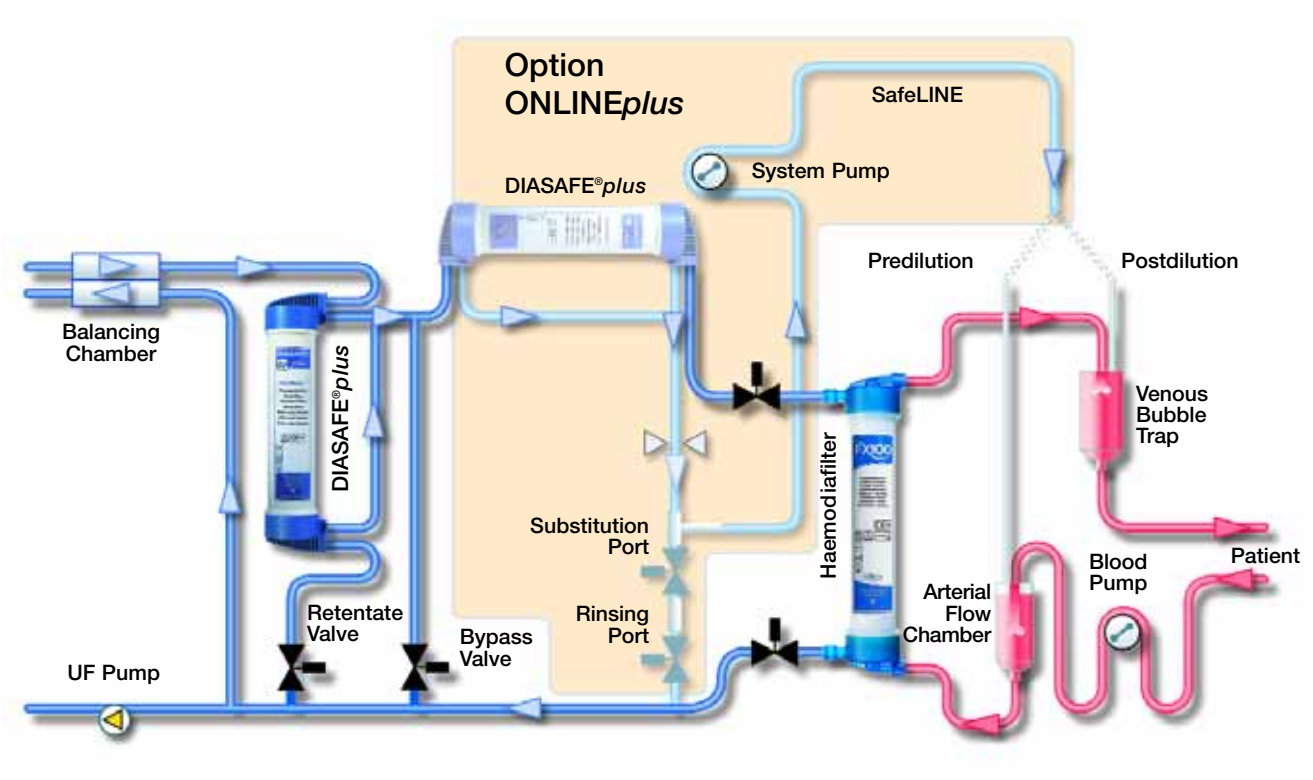
The preparation of the dialysis fluid occurs in a closed, media-separated and volumetric balancing system with volumetrically controlled ultrafiltration. The Advanced Dialysis Fluid Circuit is the basis to perform the highly effective ONLINE H(D)F therapy (ONLINE*plus* System) and the precise ONLINE Clearance Monitoring (OCM®).

Adjustable dialysate parameters include:

- Sodium and Bicarbonate content
- flow: 0 – 300 – 500 – 800 mL/min

The concentrate can be supplied in various mixing ratios using:

- canisters
- central concentrate delivery systems (CDS)
- dry bicarbonate concentrate bibag®.



Monitoring

OCM® – Impulses to improve quality of life!

The „**online Clearance monitoring**“ enables the continuous monitoring of:

- the effective *in-vivo* urea clearance (K)
- the accumulated cleared plasma (Kt) or
- the current dialysis dose administered (Kt/V)
- and the plasma sodium concentration, during treatment.

OCM® can also be combined with ONLINE*plus* Haemodiafiltration in pre- or postdilution. The user can specify the prescribed therapy goal and detect immediately possible deviations during the course of the treatment and perform the necessary corrections.

The measuring technique is:

- non-invasive
- runs completely automated
- causes no additional treatment costs and
- requires no additional disposable, laboratory or staff effort.

BVM – Blood Volume Management

Based on the precise ultrasound measuring technology the Blood Volume Monitor BVM permits the exact and continuous acquisition of the:

- relative changes in the blood volume (RBV)
- Haematocrit value (Hct)
- Haemoglobin value (Hb)

as well as an:

- individualised, blood volume dependent control of the ultrafiltration rate during the haemodialysis treatment

With the clinically evaluated algorithms of this option, symptomatic hypotension due to excessive fluid removal can now be prevented, without the need of an additional sodium load for the patient.

BTM – Blood Temperature Management

An effective modality to reduce intradialytic complications and to stabilise haemodynamic parameters is the monitoring and control of the blood temperature using the BTM:

- stabilisation of the intradialytic body temperature
- control of thermal energy balance

Additionally, the BTM facilitates:

- the assessment of the fistula function by measuring the recirculation during the treatment using a thermodilution technique

Thanks to the automated measuring procedure, the information on the total recirculation is obtained within a few minutes.

Monitoring

BPM – Blood Pressure Monitoring

The BPM is a fully automated and non-invasive blood pressure monitor, operating on the principles of oscillometry.

In addition to the manual procedure for blood pressure measurement, it is also possible to perform measurements in preselected intervals:

- interval modes of 5 - 15 - 30 - 60 minutes
- quick mode for individual measurements approx. every 30 seconds over a period of 5 minutes

The following obtained values will be recorded:

- Systolic blood pressure
- Diastolic blood pressure
- Mean Arterial Pressure (MAP)
- Pulse

FINESSE® / TDMS – Dialysis Data Acquisition and Management Systems

FINESSE® / TDMS are Dialysis Data Acquisition and Management Systems for continuous quality improvement and process analysis providing the basis for an effective and efficient organisation of the dialysis practice:

- providing valuable clinical and therapy information in an easy-to-use format
- support in planning and organisation of day to day activities in a dialysis unit
- supporting the increase in efficiency in a modern dialysis unit by automating work-intensive and time-consuming activities (e.g. manual pre-setting of dialysis machines, filling in dialysis protocols etc.)
- easy, fast and targeted online access for all users to all relevant treatment data e.g. for further data processing
- automated pre-setting of our dialysis machines via the download
- easy and safe performance of patient individualised dialysis treatments
- online data acquisition from our dialysis machines as well as from connected scales and/or online lab analysers via a computer network offers valuable treatment documentation, which is automatically stored in the connected clinical management system
- data is accessible at any time providing a comprehensive overview of relevant data for analytical and organisational purposes
- modular designed and flexible system for easy and unlimited growth

Finesse®

TDMS
Therapy Data Management System

Ultrafiltration and Sodium Profiles

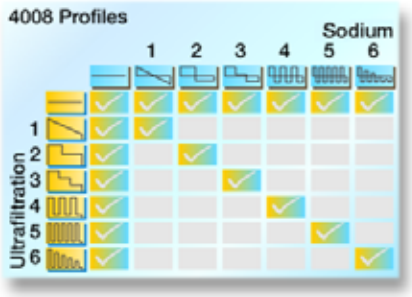
Profiles counteract actively against intra and post-dialytic complications by targeted influence on the fluid and electrolyte balance.

Sodium profiles can achieve:

- a temporary increase of the plasma sodium concentration
- a support of the intradialytic refilling
- stabilisation of the circulation

The increase in the plasma sodium concentration is phased out completely at the end of the treatment (neutral balancing) and does not cause a problematic increase in the post-dialytic plasma sodium.

The UF profiles adapt the fluid removal to the intradialytic change in the UF tolerance of the patients and are designed in such a way that an adequate refilling can take place in the intravascular space. Sodium and UF profiles can be combined, but can also be used individually.



DIASAFE®*plus* – Dialysis Fluid Filter

Due to its high retention properties for microbiological contaminants the Fresenius Polysulfone® dialysis fluid filter DIASAFE®*plus* prevents the passage of microbial substances and assures ultrapure dialysis fluid, independent from the type of dialyser and treatment modality selected:

- maximum safety due to an automated filter integrity test prior to each treatment
- automatic control of the filter life time
- automated programme for exchanging the filter
- aseptic connection technology developed for the hygienic, easy and fast installation of the DIASAFE®*plus*.

The ONLINE*plus* System

Recent studies show that ONLINE Haemodiafiltration procedures improves the patient's quality of life and outcome.

The high microbiological quality requirements stipulated for dialysis fluid and substitution solution are met by the filtration of dialysate through two DIASAFE®*plus* filters.

- Haemodiafiltration in pre or post-dilution, also in combination with Single-Needle procedure
- Haemofiltration in pre or post-dilution, also in combination with Single-Needle procedure
- Haemodialysis with ultrapure dialysis fluid
- bolus programme / also in HD
- priming and infinite rinsing of the extracorporeal circuit / also in HD
- reinfusion without additional saline solution / also in HD.

Therapy

bibag® – Bicarbonate Dry Concentrate

The supply of the bicarbonate buffer as a dry substance avoids the risk of a potential, microbiological contamination of the liquid bicarbonate concentrate. Further advantages of the bibag® are:

- high hygienic safety
- easy handling
- minimum storage/space required
- ecologically beneficial, reduced waste volume

The bibag® is available in three sizes:

- 650 g
- 700 g
- 950 g

Hygiene/Service

Disinfection Procedures

The disinfection and cleaning procedures used in the 4008S are:

- validated, user-friendly
- environmental friendly and economical.

Thanks to their:

- disinfecting
- decalcifying and
- cleaning effect

we recommend the use of the heat disinfectant Diasteril® based on hydroxyacetic acid or the cold disinfectant Puristeril® 340 based on peracetic acid:

- wide range of action: sporocidal, bactericidal, virucidal, Hepatitis B/C and HIV inactivating
- non-offensive odour and non-volatile
- biodegradable

Controlled volumes of the disinfectant are aspirated from a firmly connected canister. Depending on the disinfection regime the contents of the canister will last for several weeks.

Flush – Complete Rinsing of the Treated Water Supply Line

The quality of the dialysis fluid and its contamination with organisms is taking an important role in haemodialysis. A critical point under the aspects of hygiene is the risk of fluid within the treated water supply line deteriorating during the interdialytic interval.

A potential microbiological contamination of the disinfected dialysis fluid circuit of the machine is prevented by:

- flushing the treated water supply line using the optional flush valve every time the machine is switched on
- bypassing the dialysis machine and discarding the entire contents of the supply line directly into the drain, via the hygienic flush adapter.

AquaUNO

The single patient reverse osmosis device AquaUNO is especially designed for the operation of our haemodialysis machines in home dialysis and intensive care units. The AquaUNO is intended for mobile stand-alone use, together with the 4008S dialysis machines.

The system features:

- automated circulating rinse with pre-selected rinse cycles
- optimised cleaning and disinfection programmes including the permeate supply lines
- Initial self-test of essential components
- improved safety feature
- recovery of excess permeate and concentrate
- monitoring of cleaning cycles to protect the membrane.

Service Programme 4008S

The technical servicing of the 4008S haemodialysis machines is optimised by an innovative, computer-supported service tool.

This system features:

- an automated test for the dialysis fluid circuit
- real time flow chart
- display, printing and memory of device specific data
- individual configuration of the set-up menu

4008S – The ideal partner for home haemodialysis

The haemodialysis system 4008S ensures safety and ease-of-use for the patient when dialysing at home with or without the assistance of a family member or spouse / partner.

Important operation and safety features

- The compact size of the dialysis machine, the offer of a remote control unit with all main functions and the integrated blood pressure module (BPM) make it easy for the patient to operate the dialysis machine and monitor the treatment process from chair or bed.
- Easy, step-by-step user-guidance on a clear and colour-coded display.
- Pre-setting of all the therapy parameters facilitates the preparation process and ensures that the parameters are maintained by the patient as prescribed.
- Adjustable settings of blood flow rate and dialysate flow rate allow a variety of treatment modalities, from conventional dialysis to short daily dialysis or nocturnal dialysis – depending on patient's life style and the doctor's prescription.
- Additional assistance in alarm handling gives the patient the confidence needed to dialyse at home.

Patient monitoring:

The FINESSE® / TDMS Dialysis Data Acquisition and Management Systems allows a remote patient monitoring with an immediate alarm reporting.

Excellent "Home" Services

- A special training manual tailored to the needs of the home haemodialysis patient supports the training and education.
- Our experienced and dedicated technical service installs and maintains the dialysis equipment.
- The reliable and punctual delivery and disposal service is part and parcel of our customer service.

Technical Data Sheet Haemodialysis Machine 4008S

General Data

Dimensions	1330 x 495 x 340 mm (H x W x D) (depth of pedestal 630 mm)
Weight	approx. 80 kg

Water supply

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

Concentrate supply

Supply pressure	1 m suction height

Electrical data

Power supply	230 V – 10 % to + 6 %, 50 Hz, 16 A
Current consumption	max. 9 A

External connections

"Alarm in": zero potential alarm inlet
"Alarm out": zero potential alarm outlet
Serial Port RS 232 for data transmission to TDMS (optional)

Extracorporeal circuit

Arterial pressure monitoring

Display range	– 300 mmHg to + 280 mmHg
Accuracy	± 10 mmHg
Resolution	20 mmHg

Venous pressure monitoring

Display range	– 60 mmHg to + 520 mmHg
Accuracy	± 10 mmHg
Resolution	20 mmHg

Transmembrane pressure monitoring

Display range	– 60 mmHg to + 520 mmHg
Resolution	20 mmHg

Arterial blood pump

Blood flow range	10 to 600 mL/min
Accuracy	± 10 %

Single-Needle system

with 2 blood pumps. Internal pressure/ pressure control with variable stroke volume

Air bubble detector

by ultrasound transmission, additional optical monitoring in venous clamp

Heparin pump

Delivery range	0 to 10 mL/h
Bolus function	max. 5 mL per bolus
Syringe size	20 mL, 30 mL

Dialysis fluid circuit

Dialysis fluid flow range

Selectable	0 – 300 – 500 – 800 mL/min

Dialysis fluid temperature

Selectable	35 °C to 39 °C

Dialysis fluid conductivity

Range	12.8 to 15.7 mS/cm (25 °C)
Accuracy	± 0.1 mS/cm

Sodium concentration dialysis fluid

Default mixing ratio	1 + 34 (others possible)
Range	–13 to +13 mmol/l sodium

Bicarbonate concentration dialysis fluid

Default mixing ratio	1 + 27.6 (others possible)
Range	– 8 to + 8 mmol/l bicarbonate

Bicarbonate dry concentrate

bi*b*ag®

Dialysis fluid filter system DIASAFE®*plus*

Balancing accuracy

± 0.1 % of dialysate flow

Ultrafiltration

UF rate	0 to 4.00 l/h
Accuracy	± 0.5 %
Allowed dialyser UF factor	unlimited
Parameters displayed	UF goal, UF time, UF rate, UF volume

Blood leak detector

Sensitivity	≤ 0.5 mL blood/min (Hct = 25) at max. flow 800 mL/min

Disinfection and cleaning programmes*

Rinse

Temperature/flow	37 °C / 600 mL/min

Hot rinse (recirculation)

Temperature/flow	85 °C / 450 mL/min

Cleaning Sporotal® (recirculation)

Temperature/flow	37 °C / 600 mL/min

Hot disinfection Diasteril® (recirculation)

Temperature/flow	85 °C / 450 mL/min

Disinfection Puristeril® 340 (recirculation)

Temperature/flow	37 °C / 600 mL/min

***Various programme combinations selectable**

CE 0123

Technical changes reserved

Fresenius Medical Care

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