

Chapter 9

Nikkiso Hemodiafiltration Equipment

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Abstract Observing the development of HDF patient numbers on a global scale between 2004 and 2010, the number of HDF patients increased by around 13 % per year. Online HDF was by far the predominant mode of HDF therapy, being applied to around 90 % of HDF patients in 2010. In this situation, NIKKISO has developed the “DBB-07” Dialysis System, which is focused on online-therapies. In this chapter the DBB-07 features will be explained.

Keywords Blood Volume Monitor (BVM) • Dialysis Dose Monitor (DDM) • Disinfection • Online hemodiafiltration • Predilution • Postdilution • Substitution fluid • Transmembrane pressure

Introduction

Observing the development of HDF patient numbers on a global scale between 2004 and 2010, the number of HDF patients increased by around 13 % per year [1]. Online HDF was by far the predominant mode of HDF therapy, being applied to around 90 % of HDF patients in 2010. In this situation, NIKKISO has developed the “DBB-07” Dialysis System, which is focused on online-therapies, see Fig. 9.1. In this chapter the DBB-07 features (see Fig. 9.1.) will be explained.

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Fig. 9.1 Dialysis machine

Water Treatment System Required

The water treatment system for hemodialysis and hemodiafiltration shall be designed on the knowledge of the feed water characteristics. This system should ensure a water quality at the dialysis machine inlet complying to applicable national standards, as well as the international ISO 13959 standard (Water for haemodialysis and related therapies). Concentrates must meet the requirements of ISO 13958 (Concentrates for haemodialysis and related therapies), and the produced dialysis fluid those of the ISO 11663 standard (Quality of dialysis fluid for haemodialysis and related therapies).

Short Description and Outline of the HDF Machine

Hydraulic prescription: In the DBB-05, a specific tubing line with single use dialysis fluid filter (EFL-015) is needed for online HDF, and the prepared dialysis fluid passes only one EF-02D filter before supplying fluids to the dialyser. The hydraulic system of the DBB-07 has been upgraded with an additional dialysis fluid filter (EF-02D) to ensure a quality of dialysis and substitution fluid complying with international standards [2].

Dialysis fluid and substitution fluid: In contrast to conventional HDF treatments (with bags), the substitution fluid used for the online HDF treatment is taken from the dialysis machine. The adjusted conductivity and temperature are continuously checked by independent monitoring systems to ensure safe operation. After passing two EF-02D filters, ultrapure substitution fluid is then supplied to the blood circuit using the substitution pump. The DBB-07 has a function called ‘Flow application’ whereby the flow rate of the dialysis fluid through the dialyser will not be influenced by the branched substitution fluid.

Technical aspects of fluid balance: The ultrafiltration rate in the dialyser is determined by the substitution fluid flow rate and the intradialytic weight loss of the patient.

To control the dialysis fluid flow and the removed ultrafiltration volume, the DBB-07 has a closed loop system consisting principally of a duplex pump, an ultrafiltration pump and solenoid valves. The duplex pump is a volumetric instead of a chamber system, supplying and draining the same amount of dialysate to and from the dialyser. Technical features of the DBB-07 dialysis machine are summarized in Table 9.1.

HDF Prescription Modality (Manual/Automatic)

The maximum substitution fluid rate is limited depending on the selection of pre- or post-dilution and blood flow rate, in order to limit the hemoconcentration in the blood compartment. It is possible to link the blood flow rate with substitution fluid rate by ratio setting. Dependent on whether pre- or post-dilution is performed, the substitution rate is governed by the blood pump speed.

HDF Modalities

The external scale offers at the moment the most flexible system for dialysis therapies. The DBB-07 with external scale can perform online treatments, see Fig. 9.2, but also HDF (predilution or postdilution), HF and Acetate-Free Biofiltration (AFB) treatments with solution bags. AFB is a special kind of treatment without acetate and bicarbonate in the dialysate.

Table 9.1 Technical features of the DBB-07 dialysis machine

Technical features	DBB-07 (Nikkiso)
Blood pump flow range (ml/min)	40–600 ml/min
Dialysate flow (ml/min)	300–700 ml/min
Dialysate flow selection mode	Steps 1 mL/min
Emergency button	Bolus key and minimum UF key
Substitution mode: manual/automatic	Automatic (ratio of blood flow)
Settable parameter(s) in volume control mode	Substitution ratio (%), substitution rate (ml/min), target substitution volume (L)
Substitution fluid flow range	0.00; 0.10–18.00 L/h (OHDF) 0.00; 0.10–30.00 L/h (OHF)
Electrolyte concentration adjustment	Yes
Substitution fluid delivery options	Pre, post
Online priming, rinsing, IV bolus	Yes
Stationary ultrafilters	Yes, 2 EF-02D filters
Additional ultrafilter	No
Integrity pressure test ultrafilter	Filter test for leakage and clogging of filters
Blood access monitoring	Pressure and Kt/V measurement
Online clearance monitoring	Yes, optional
Blood volume monitoring (BVM)	Yes (Haemo-Master), optional
Blood temperature monitoring	No
Other monitoring options	Blood pressure monitor, optional
Alarm and information signals	4 lights external status display; alarm and information display with help message; outlet for alarm output
IT connectivity	Yes, optional
Data transfer via patient card	No
Standard safety features	Complying to international standards
Advanced safety features	Dialyser inlet pressure measurement, as an indication of hemoconcentration in the dialyser; Clean Coupling® for better hygiene; continuous monitoring system of a closed loop system (valves check function for safety); disinfectable concentrate suction nozzles
Touchscreen operation and ergonomic design	Yes
Special features	Flow application: the dialysis fluid flow is not influenced by the branched substitution fluid; external scale for H(D)F or AFB with bags, eco-friendly concentrate-, water- and energy- saving mode; optimized energy use as standard via integrated heat-exchangers; customizable operating screen

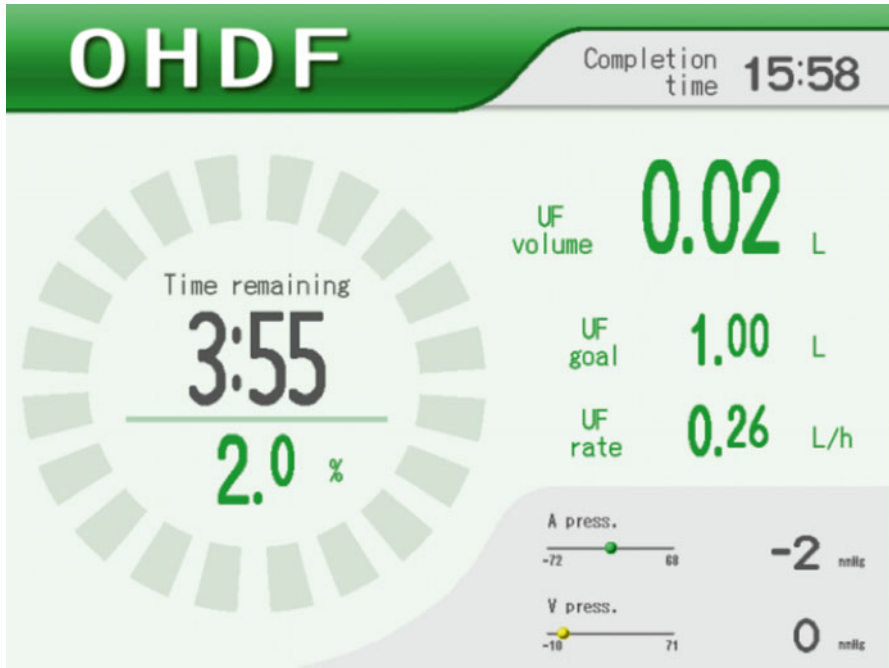


Fig. 9.2 Snapshot screen I

Specificities of Disposables Required

- Hemodiafilters

The DBB-07 is compatible with commercially available dialysers that are equipped with standard dialysis fluid and blood connection (ISO8637).

- Blood tubing sets

The steam sterilized blood tubing lines (AV-06 series) and Online HDF line (C07J-P) can be used on DBB-07 with OHDF. The shunt lock connector cap (for A/V line) is equipped with an integrated discharge hook. The capless hydrophobic filters and the perfectly fitting blood tubing lines facilitate the set-up of the DBB-07.

- Ultrafilters

The membrane used for the EF-02D is Polyester Polymer Alloy (PEPA®), which is a unique membrane with a specially developed three-layer structure, providing excellent protection against endotoxins and their fragments. Using a fluorescent endotoxin marker in laboratory tests, it has been shown that endotoxins are safely retained [3, 4].

Additional Therapeutic Options

- Blood Volume Monitor (BVM, Haemo-Master)

The BVM continuously measures the relative blood-volume during the treatment. This is the basis for the automatic regulation system Haemo-Master, which controls the conductivity and ultrafiltration rate (UF rate). The intelligent interplay of the regulation of the conductivity and UF rate adapts the blood volume changes to the ideal curve for the specific patient, in order to prevent hypotensive episodes during the treatment. This option can be combined with all treatments; see Fig. 9.3 for a snapshot of the screen.

Additional Monitoring Options

- Blood Pressure Measurement (BPM)

Continuous blood pressure measurement can be carried out during treatment, and monitored as a course chronologically on the screen. An automatic deactivation of the UF rate also occurs when the pre-selected pressure limits are reached.

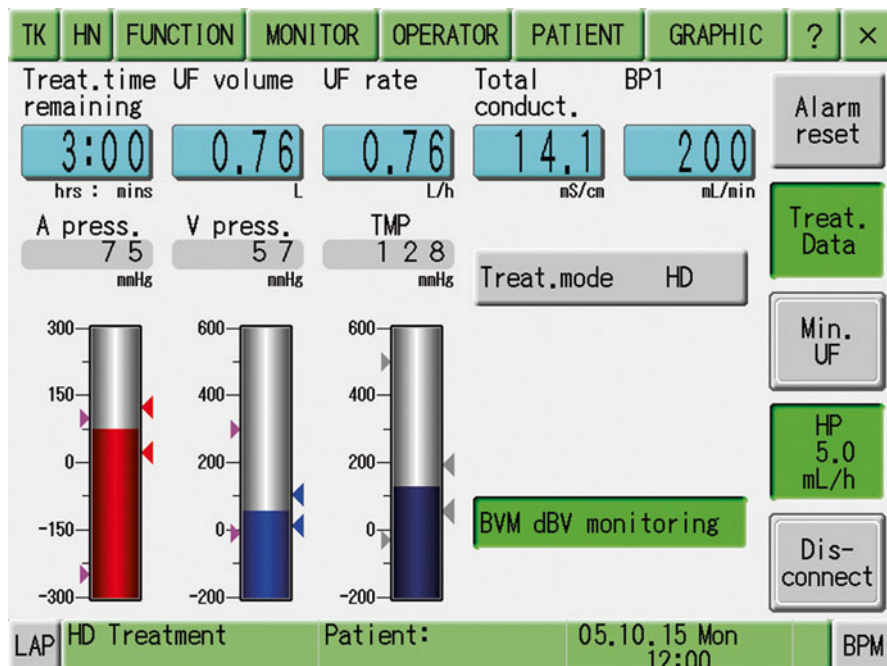


Fig. 9.3 Snapshot screen II

- Dialysis Dose Monitor (DDM)

DDM can monitor Kt/V continuously without interruption of the treatment and is easy to handle. It is activated automatically after entering the parameters. It is not necessary to enter the distribution volume, which is normally estimated using approximation formula to display expected accurate results.

Cleaning and Disinfection

The DBB-07 must have a disinfection with citric acid (50 %), or a chemical disinfection with peracetic acid or sodium hypochlorite before each on-line HDF/HF treatment. To optimize the hygiene of the dialysis fluid circuit NIKKISO has integrated the concentrate suction nozzles and patented Clean Couplings® into the disinfection cycle.

Risk Management System

- Continuous monitoring system of a closed loop system (see Short description and outline of the machine)

To ensure the accuracy of the closed system and ensuring no leakage during the treatment, the DBB-07 monitors hydraulic pressure as well as conductivity across the solenoids, duplex pump and ultrafiltration pump valves.

- Dialyser inlet blood pressure (DIP)

The extracorporeal circuit of the DBB-07 incorporates dialyser inlet blood pressure measurement. This enables an accurate TMP measurement and an indication of hemoconcentration in the dialyser, which is especially useful whilst carrying out high volume online HDF.

Display of Settings and Connection to the Hospital Information System

Data and information from the treatment procedure are sent simply and conveniently to the hospital information system via the hospital network. The DBB-07 offers various interfaces for main software solutions with an experienced partner in the market.

Cost Assessment

Please see below comparison table.

Consumables	DBB-05		DBB-07	
	HD	Online HDF	HD	Online HDF
Blood tubing lines and dialyser	X	X	X	X
Single dialysis fluid filter (EF-02D)	X	X	–	–
Double dialysis fluid filters (two EF-02Ds)	–	–	X	X
Substitution line with single use filter (EFL-015)	–	X	–	–
Substitution line without single use filter (C07J-P)	–	–	X	X
Saline bag	X	–	–	–
Cost assessment	100 %	300 %	100 %	100 %

Conclusion

The DBB-07 provides HD, HF, HDF, OHF and OHDF with a safe system, reducing any risk to the patient, along with helpful monitoring functions of the patients condition. This enables the operator to closely customize the treatment to the patients needs. When HDF is selected for a patient, an operator has to prepare the disposables and the device for HDF. The operators workload could increase in the future as the number of HDF patients is increasing. To make HDF therapies economical, easy to set up and assessable to all, NIKKISO are continuously developing their systems to meet todays needs.

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